UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

ELI LILLY AND COMPANY,

Plaintiff,

v.

AGV SASON INC. D/B/A LUCY'S LASER & MEDSPA,

Defendant.

Case No. 1:24-cv-1036

JURY TRIAL DEMANDED

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

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant AGV Sason Inc. d/b/a Lucy's Laser & Medspa ("Defendant") has designed its website 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

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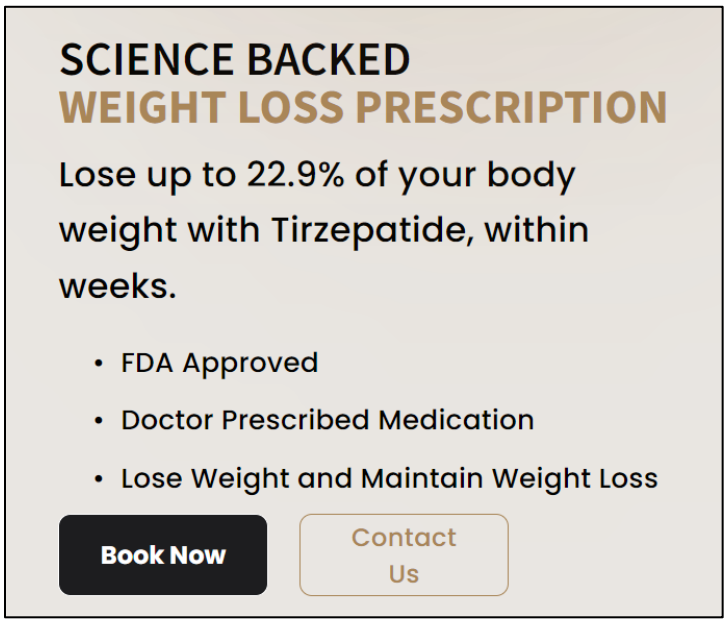
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

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 begins with its eye-catching product description, wherein Defendant claims to offer a "Science Backed Weight Loss Prescription" that is "FDA Approved," as shown below.



7. Despite this impossible-to-miss advertisement, Defendant's product is neither "science backed" nor "FDA approved." Rather, it is untested, unapproved, and unsafe.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Ohio statutory and common law regarding deceptive and unfair trade practices. Lilly's claims arise out of Defendant's infringement of Lilly's rights in the MOUNJARO® and ZEPBOUND® trademarks and Defendant's acts of false designation of origin, false advertising, deceptive trade practices, and unfair methods of 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 an Ohio corporation d/b/a Lucy's Laser & Medspa, with a principal place of business in Concord, Ohio, in this District. Defendant additionally does business at

8806 Mentor Avenue, Suite G, Mentor, Ohio 44060, also in this District. Its registered agent is Lucille Zappitelli Sason with a registered agent address 6726 Rosemarie Court, Concord, Ohio 44077.

11. Defendant also does business using the domain name "https://lucyslasermedspa.com."

JURISDICTION AND VENUE

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

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

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

14. Lilly's MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's MOUNJARO® was clinically proven to improve blood sugar control "more

effective[ly] than the other diabetes therapies with which it was compared in clinical studies." *Id.*

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

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

17. As with MOUNJARO®, the safety, quality, and effectiveness of ZEPBOUND® was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND® and indicated it for adults with obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 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.

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

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-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.*

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

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

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

24. Lilly is the owner of two federal trademark registrations for MOUNJARO®, U.S. Reg. Nos. 6,809,369 (issued August 2, 2022) and 7,068,463 (issued May 30, 2023). True and correct copies of Plaintiff Lilly's registrations for the MOUNJARO® mark are attached hereto as part of **Exhibit A.** Lilly additionally has several pending applications to register its MOUNJARO® mark in connection with more classes, services, and goods, including U.S. Trademark Ser. Nos. 97/596,856, 97/668,206, and 98/253,743. As a result of its use of the MOUNJARO® mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO® mark.

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

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

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

28. Lilly promotes, advertises, and markets MOUNJARO® and ZEPBOUND® both to healthcare professionals and to patients, among others, through various channels, including on the websites mounjaro.com, mounjaro.lilly.com, zepbound.com, and zepbound.lilly.com, in social media, in online advertisements, and on television.

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

THE RISKS OF COMPOUNDING

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

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters

ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/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.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

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

https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed

physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to []GMP requirements, are provided to a patient only based on individual patient need." *Id.* (emphasis in original).

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

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

Id. (emphasis added).

35. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients." The FDA has warned that: "Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of

compounded drugs unnecessarily exposes patients to potentially serious health risks. Because compounded drugs are not FDA-approved, FDA does not verify their safety, effectiveness, or quality before they are marketed." https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/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.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/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).

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

39. Consequences from compounded drugs may be deadly. In 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

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

41. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically. https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective. https://www.fda.gov/inspections-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).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-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).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/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.*

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

Alternative-Statement_Final_Logos-1.pdf (joint statement from leading obesity expert organizations).

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

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

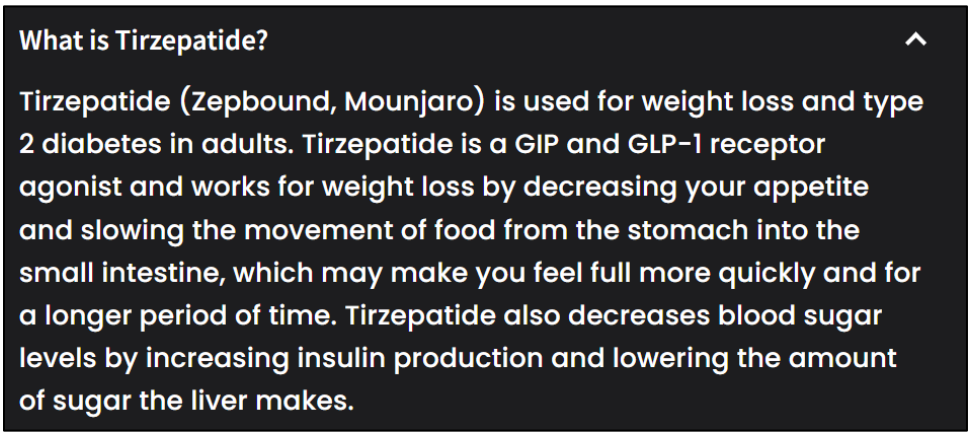
47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO®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

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

49. Defendant also passes off as "Mounjaro" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

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 its Tirzepatide webpage (https://lucyslasermedspa.com/tirzepatide), is shown below.



52. As the image shows, Defendant promotes its Unapproved Compounded Drugs with the explanation that they are "Zepbound, Mounjaro."

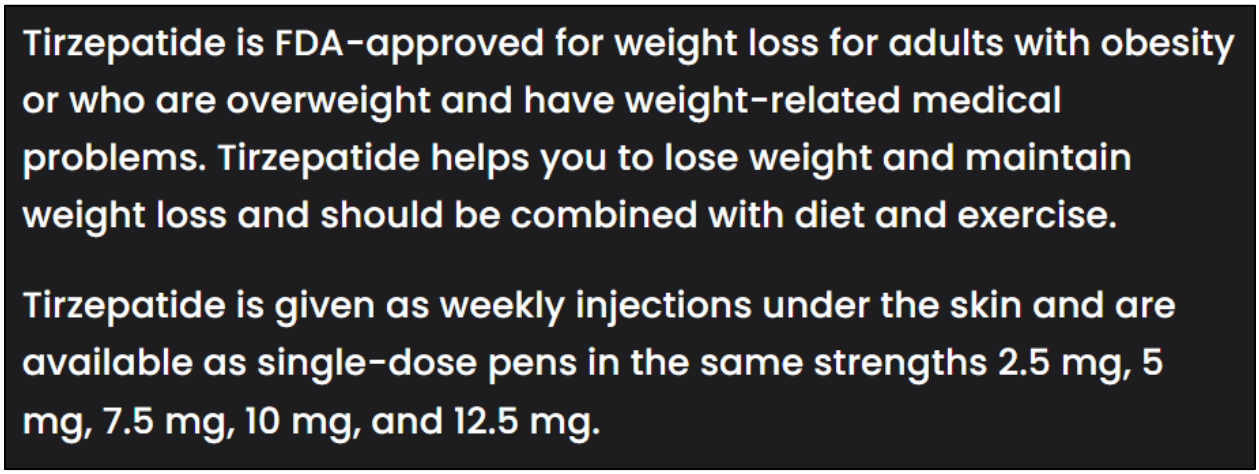
53. Defendant's website conveys the unmistakable impression that Defendant is offering for sale a product that either is, has the same source as, or is the same as, Lilly's MOUNJARO® and ZEPBOUND®. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution.

54. 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.

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

56. For example, as shown below, Defendant's "Tirzepatide" webpage advertises that: "Tirzepatide is FDA-approved for weight loss." "Tirzepatide," however, is ***not*** approved for weight loss or any other condition; Lilly's MOUNJARO® and ZEPBOUND®, medicines ***containing*** tirzepatide, are FDA approved for the indications described above.



57. Additionally, as shown above, Defendant claims to offer its Unapproved Compounded Drugs in "single-dose pens" in doses corresponding to FDA-approved dosages of MOUNJARO® and ZEPBOUND®, which can only be construed as a reference to Lilly's MOUNJARO® and ZEPBOUND® autoinjector pens. Defendant does not, however, offer Lilly's MOUNJARO® and ZEPBOUND®, in autoinjector pen or any other form.

58. In fact, Defendant stated in an October 26, 2023 Instagram post that Defendant gets its "tirzepatide from trusted United states Compounding pharmacies ***only***." https://www.instagram.com/p/Cy3On4mLgC7/ (emphasis added).

59. In another Instagram post, from December 13, 2023, Defendant referred to "studies" that allegedly proved the safety, quality, or effectiveness of Defendant's Unapproved Compounded Drugs. These "studies," however, were conducted on ***Lilly's*** medicines and do not prove anything about Defendant's Unapproved Compounded Drugs.

60. 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*** subjected to clinical trials, and therefore are ***not*** "clinically proven" to achieve any results.

61. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, 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.

62. 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.

63. 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.

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

65. 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.

66. 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 OHIO AND LILLY

67. 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.

68. 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.

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

70. Not only does this deceitful content expose the people of Ohio 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

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

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

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

78. 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

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

80. 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.

81. 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.

82. 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).

83. 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.

84. 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.

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

86. 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)

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

88. 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).

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

90. 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.

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

92. 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.

93. 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.

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

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

FOURTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of Ohio Rev. Code § 4165.01 *et seq*.

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

97. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio Rev. Code § 4165.01 et seq.

98. Among other things, Ohio Rev. Code § 4165.02 defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (1) Passes off goods or services as those of another;
> (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) Causes likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another;
> * * *
> (7) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
> * * *
> (9) Represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> * * *
> (11) Advertises goods or services with intent not to sell them as advertised;

99. As set forth herein, Defendant's actions fit within the scope of Ohio Rev. Code § 4165.02.

100. 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.

101. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of Ohio Rev. Code § 4165.01 *et seq*.

102. 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 with the intent to deceive.

103. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

104. 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.

105. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

106. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief. In addition, Lilly is entitled to attorneys' fees and costs.

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

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

108. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Ohio common law.

109. 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®.

110. 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.

111. 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.

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

113. As a direct and proximate result of Defendant's trademark infringement and unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

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

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 deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Ohio Rev. Code § 4165.01 *et seq.* and Ohio common law;

   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 deceptive trade practices.

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 Ohio state law in amounts as of yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Ohio 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/ Matthew J. Cavanagh

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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/ Matthew J. Cavanagh

Matthew J. Cavanagh (OH 0079522)
Attorney for Plaintiff
ELI LILLY AND COMPANY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ELI LILLY AND COMPANY,

Plaintiff,

v.

ALDERWOOD SURGICAL CENTER LLC D/B/A ALLURE ESTHETIC, D/B/A GALLERY OF COSMETIC SURGERY, D/B/A SEATTLE PLASTIC SURGERY, ET AL.

Defendant.

Case No. 2:24-cv-00878

COMPLAINT FOR:

1. **TRADEMARK INFRINGEMENT**
2. **FALSE ADVERTISING**
3. **FALSE DESIGNATION OF ORIGIN**
4. **UNFAIR AND DECEPTIVE TRADE PRACTICES**

JURY TRIAL DEMANDED

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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. Defendants Alderwood Surgical Center LLC d/b/a Allure Esthetic, d/b/a Gallery of Cosmetic Surgery, and d/b/a Seattle Plastic Surgery ("Defendant Alderwood"); and Northwest Nasal Sinus Center P.S., d/b/a Northwest Face & Body ("Defendant Northwest"); Javad A. Sajan, M.D.; and Craig R. Jonov, M.D. (collectively, "Defendants") have designed their websites, social media, and advertising materials to deceive patients into thinking Defendants offer a way to obtain Lilly's clinically studied medicines, when in reality Defendants offer no such thing.[1] Lilly brings this action under federal and state law to protect patients from Defendants' 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 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-

[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.

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

6. Defendants' intentional deception of patients is pervasive. For example, on several of their websites, Defendants include a supposed "Seattle Zepbound Weight Loss Program," sometimes called simply "ZEPBOUND, SEATTLE," as shown below:

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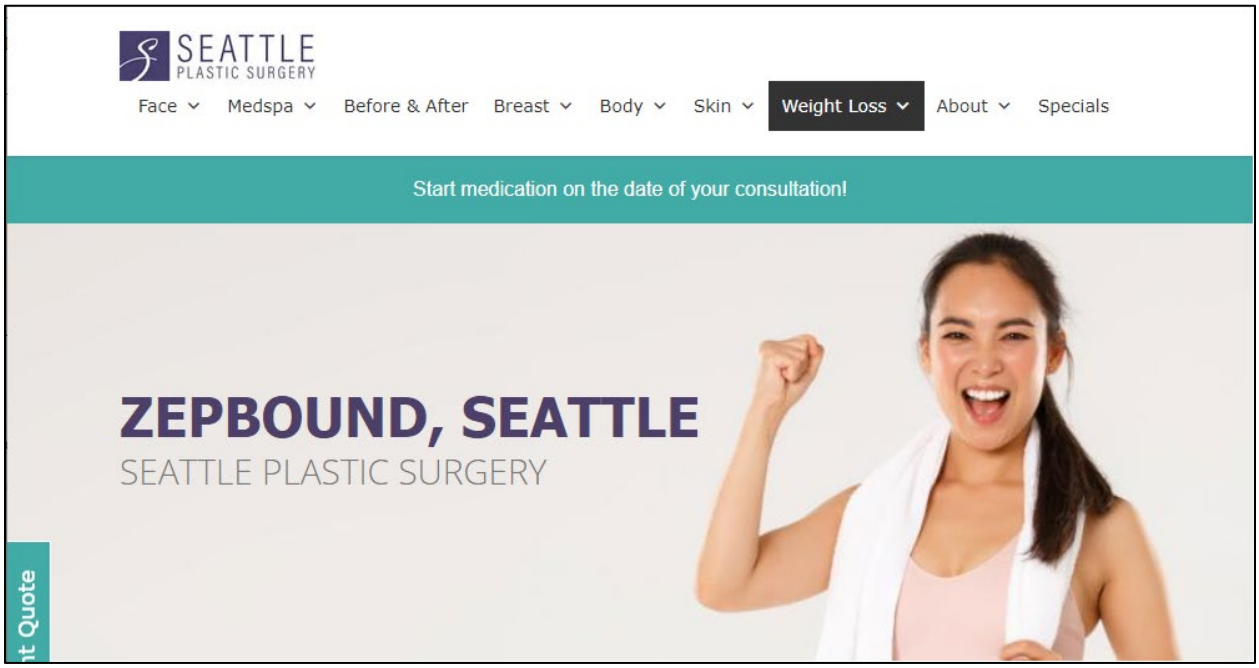

7. Despite this impossible-to-miss headline, Defendants do not offer ZEPBOUND®, nor any generic version of it. Rather, Defendants' "Zepbound Consultations" lead to patients being injected with "Compounded Tirzepatide," as shown below:

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8. In fact, there is ***no such thing*** as generic or compounded ZEPBOUND®. And ZEPBOUND® is not the same thing as the active pharmaceutical ingredient tirzepatide or compounded versions thereof.

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

THE PARTIES

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

11. Defendant Alderwood is a Washington limited liability company with a principal place of business at 3500 188th Street SW, Suite 670, Lynnwood, Washington 98037, in this District. Its registered agent is MPBA Service Company LLC, with registered agent address 701 5th Avenue, Suite 5500, Seattle, Washington 98104. Defendant Alderwood's governor is Defendant Javad A. Sajan, M.D. Defendant Alderwood conducts business under several trade names, each with its own website:

a. Allure Esthetic (https://www.allureesthetic.com/).

b. Gallery of Cosmetic Surgery (https://www.cosmeticsurgeryforyou.com/)

c. Seattle Plastic Surgery (https://www.seattleplasticsurgery.com/).

12. Defendant Northwest Nasal Sinus Center P.S., d/b/a Northwest Face & Body is a Washington professional service corporation with a principal place of business located at 3100 Carillon Point, Kirkland, Washington 98033, in this District. Its registered agent is MPBA Service Company LLC, with registered agent address 701 5th Avenue, Suite 5500, Seattle, Washington 98104. Defendant Northwest's governor is Defendant Javad A. Sajan, M.D. Defendant Northwest also conducts business on its website (https://www.nwface.com/).

13. Defendant Javad A. Sajan, M.D. is an individual residing in King County, Washington, in this District. Defendant Sajan is the owner of both Defendant Alderwood

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Surgical Center, LLC, which he acquired in 2016, and Defendant Northwest Nasal Sinus Center P.S., which he acquired in 2020.

14. Defendant Craig R. Jonov, M.D. is an individual residing in Snohomish County, Washington, in this District. Defendant Jonov holds himself out as an owner of Seattle Plastic Surgery. https://www.americanboardcosmeticsurgery.org/doctors/craig-r-jonov/.

JURISDICTION AND VENUE

15. 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).

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendants operate and conduct business in this District. Defendants are subject to personal jurisdiction in this District.

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

17. 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.*

18. 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

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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.

19. 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).

20. 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.

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

22. 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-

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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.*

23. 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.

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

25. 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.

26. 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.

27. 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

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MOUNJARO® mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO® mark.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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

33. 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").

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34. 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.

35. 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).

36. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed

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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).

37. 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).

38. 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

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quality before they are marketed." https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

39. 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.*

40. 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).

41. 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

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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.

42. 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

43. 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.

44. 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.

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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).

45. 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).

46. 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.*

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47. 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).

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

DEFENDANTS' FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

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

50. On information and belief, Defendants do not sell Lilly's MOUNJARO® and ZEPBOUND® and have no association with Lilly. Yet Defendants boldly and falsely appropriate the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendants pass 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.

51. Because Defendants are not offering genuine MOUNJARO® or ZEPBOUND®, Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendants.

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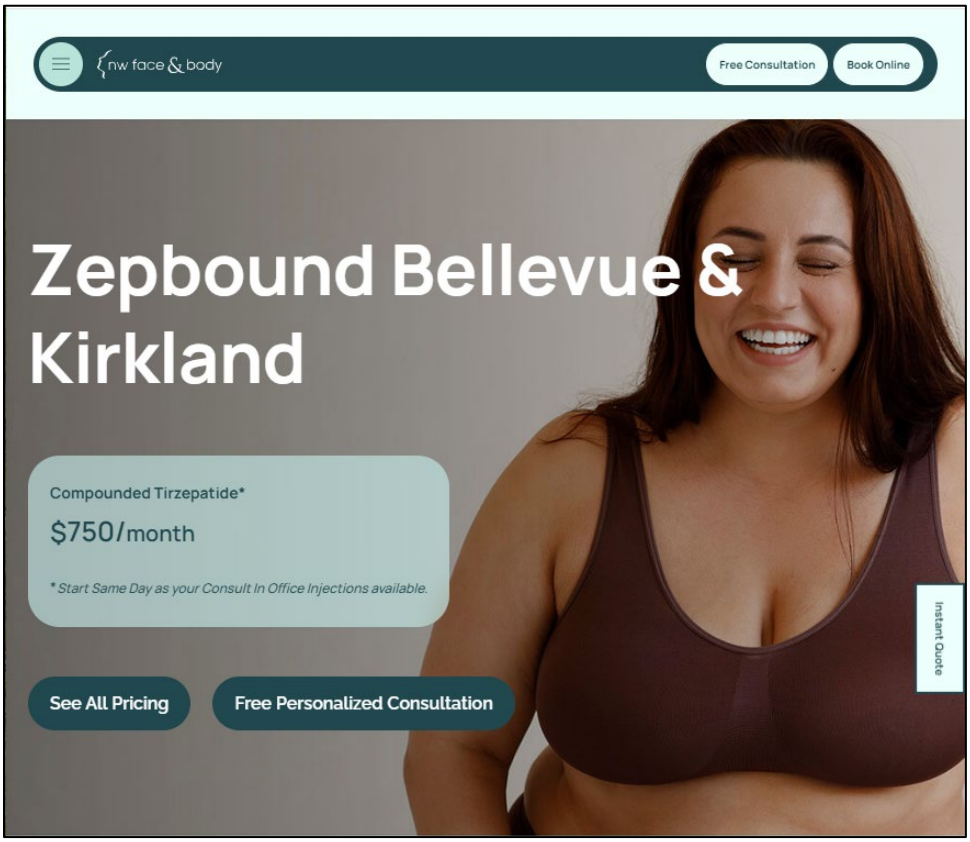
52. This is all the more concerning given that, on April 12, 2024, this Court found Defendants' Alderwood, Northwest, and Sajan had illegally prevented patients from posting negative reviews of their businesses online, in violation of Washington State's Consumer Review Fairness Act. *See Washington v. Alderwood Surgical Center, LLC*, No. 22 Civ. 1835, 2024 WL 1606143 (W.D. Wash. Apr. 12, 2024). Because Defendants prevented patients from posting accurate reviews of their businesses online, prospective patients may have insufficient notice as to the nature or quality of Defendants' services.

53. Examples of Defendants' trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

54. An example of Defendants' unauthorized use of the Lilly Marks, from Defendant Northwest's website, is shown below.



55. As the image shows, Defendant Northwest promotes its Unapproved Compounded Drugs with the header "Zepbound Bellevue & Kirkland," and only in smaller font

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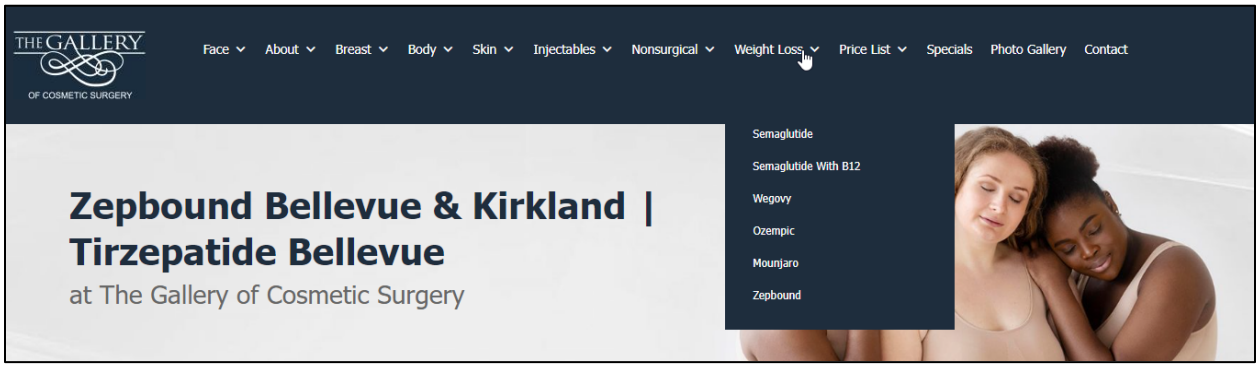
clarifying that what is actually for sale is "Compounded Tirzepatide*". A similar page to this one appears on the website associated with each of Defendants' trade names.

56. These webpages are even labeled "Zepbound" in Defendants' directories, as shown below in a screengrab from the Gallery of Cosmetic Surgery's website.



57. On Defendant Northwest's version of this "Zepbound" webpage, Defendant Northwest uses the word "Zepbound" ***28 times*** as part of selling its Unapproved Compounded Drugs. Defendant Alderwood similarly uses the word "Zepbound" ***24 times***, ***33 times***, and an astonishing ***36 times*** on the "Zepbound" webpages on the websites of Seattle Plastic Surgery, Gallery of Cosmetic Surgery, and Allure Esthetic respectively—all while ***not selling ZEPBOUND®***.

58. Defendants' websites convey the unmistakable impression that Defendants are offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved generic version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendants for resale or redistribution. Moreover, there are ***no*** generic versions of either MOUNJARO® and ZEPBOUND®.

59. Defendants first started using the Lilly Marks to advertise their Unapproved Compounded Drugs long after Lilly had adopted them. Defendants' use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

60. Defendants also falsely advertise their Unapproved Compounded Drugs on their websites by making statements that claim or imply that their Unapproved Compounded Drugs

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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, Defendants' Unapproved Compounded Drugs, which upon information and belief are sold without having undergone any clinical trials on safety and effectiveness.

61. For example, as shown below, Defendants' "Seattle Zepbound Weight Loss Program" webpage on the Allure Esthetic' website (https://www.allureesthetic.com/body/zepbound-seattle/)—which, again, is used to sell Unapproved Compounded Drugs rather than genuine ZEPBOUND®—includes an entire section devoted explaining that "Zepbound Seattle" (a non-existent product) "is an FDA-approved medication."

> Zepbound Seattle is an FDA-approved medication that promotes weight loss and helps patients achieve their fitness goals. Zepbound is an FDA-approved, tirzepatide-based medication that interacts with the body's hormones that respond to food. By replicating the same response, Zepbound works to curb the appetite and prevent patients from overeating.

62. Defendants' statements that ZEPBOUND® is FDA-approved can only be intended to deceive Defendants' patients, who Defendants provide with non-FDA-approved non-ZEPBOUND® Unapproved Compounded Drugs.

63. Upon information and belief, these statements are false and/or misleading as to Defendants' Unapproved Compounded Drugs, which are ***not*** FDA approved, were ***not*** the subject of any clinical trials, and are ***not*** clinically proven to achieve any results.

64. Defendants continue to use the Lilly Marks, including in advertising and promotion on their websites, to deceive patients who, upon information and belief, are seeking to buy genuine FDA-approved MOUNJARO® and/or and ZEPBOUND® to treat their serious health conditions.

65. Defendants' 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

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Defendants are a source for Lilly's FDA-approved treatment options MOUNJARO® and/or ZEPBOUND®, that Defendants' Unapproved Compound Drugs are as safe and effective as Lilly's FDA-approved treatment options MOUNJARO® and ZEPBOUND®, and/or that Defendants' services are provided, licensed, sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

66. Defendants' use of the Lilly Marks is without the permission, consent, or authorization of Lilly. Defendants have no right to use, and Defendants know that they have no right to use, the Lilly Marks in connection with Defendants' Unapproved Compounded Drugs or otherwise. Defendants' 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 Defendants to use the Lilly Marks to advertise or promote their Unapproved Compounded Drugs purporting to contain tirzepatide, other than to trade upon Lilly's reputation and to create confusion in the marketplace and/or mislead patients with serious health conditions regarding the origin, identity, or source of Defendants' Unapproved Compounded Drugs.

68. Defendants' 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, Defendants will continue to use the Lilly Marks and/or otherwise falsely advertise their Unapproved Compounded Drugs as associated with or being MOUNJARO® and ZEPBOUND®, all in violation of Lilly's rights.

HARM TO THE PEOPLE OF WASHINGTON 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,

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quality, or effectiveness of Defendant's Unapproved Compounded Drugs.

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

72. Defendants advertise themselves as providing MOUNJARO® and ZEPBOUND® (or their supposed "generic" equivalents), when, in reality, Defendants provide untested Unapproved Compounded Drugs. Defendants' 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 Defendants' Unapproved Compounded Drugs and suffer harm will have had no forewarning.

73. Not only does this deceitful content expose the people of Washington to serious health risks, but Defendants' unlawful tactics undermine the name, goodwill, and reputation that Lilly has invested heavily in developing. Moreover, Defendants' unfair methods allow them and their 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, Defendants have used and continue to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of their Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendants'

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

79. As a direct and proximate result of the actions of Defendants alleged above, Lilly has been damaged and will continue to be damaged. Defendants' 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 Defendants' 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, Defendants have used and continue to use in commerce the Lilly Marks in connection with the offering, sale, and advertising of their Unapproved Compounded Drugs purporting to contain tirzepatide. Consumers who encounter Defendants'

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

87. As a direct and proximate result of the actions of Defendants alleged above, Lilly has been damaged and will continue to be damaged. Defendants' 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. Defendants' 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. Defendants have knowingly and willfully made material false and misleading statements in their commercial advertisements for their Unapproved Compounded Drugs, and these statements regarding Unapproved Compounded Drugs' safety, quality, effectiveness, and

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regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

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

94. Defendants have caused their false statements to enter interstate trade or commerce.

95. As a direct and proximate result of Defendants' 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 Defendants' 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 Defendants and Defendants' 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 Defendants' profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

FOURTH CAUSE OF ACTION
Unfair and Deceptive Trade Practices in Violation of RCW 19.86.010 *et seq.*

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

100. Defendants' acts constitute unfair and deceptive trade practices, in violation of the laws of the State of Washington, including RCW 19.86.010 *et seq.*

101. RCW 19.86.010 states that "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

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102. Plaintiff is a "person" within the meaning of RCW 19.86.090 and has standing to bring an action based on unfair and deceptive trade practices.

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

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

105. The public interest is harmed by Defendants' conduct because such conduct has the capacity to injure any of Defendants' patients or prospective patients. Members of the public are likely to suffer injury from Defendants' acts by purchasing Defendants' Unapproved Compounded Drugs that they believe to be Lilly's MOUNJARO® or ZEPBOUND®.

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

107. Upon information and belief, Defendants' deceptive, unfair, and fraudulent business practices were willfully undertaken, as described in the allegations above.

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

109. By reason of Defendants' acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendants. Accordingly, Lilly is entitled to entry of

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preliminary and permanent injunctive relief, in addition to treble damages, attorneys' fees, and costs.

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 Defendants:

   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 and deceptive trade practices in violation of RCW 19.86.010 *et seq.*;

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

2. An injunction preliminarily and then permanently enjoining and restraining Defendants and their 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;

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b. Falsely stating or suggesting that Defendants' Unapproved Compounded Drugs are genuine or generic versions of MOUNJARO® or ZEPBOUND®, that Defendants are associated or connected in any way with Plaintiff or its products, or that Defendants' 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 Defendants and their 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 Defendants are not and never have been authorized by, affiliated with, sponsored by, approved by, or related to Plaintiff Lilly or MOUNJARO® and ZEPBOUND®, that Defendants' Unapproved Compounded Drugs are not MOUNJARO® or ZEPBOUND®, that Defendants' Unapproved Compounded Drugs are not generic MOUNJARO® or generic ZEPBOUND®, that Defendants' Unapproved Compounded Drugs have never been genuine or generic versions of MOUNJARO® and ZEPBOUND®, and that Defendants' 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 Defendants to file with this Court and serve on Lilly's attorneys, thirty 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 Defendants 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 and deceptive trade practices;

6. An Order requiring Defendants to pay Lilly compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, false designation of origin,

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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 Defendants to pay Lilly all types of monetary remedies available under Washington state law in amounts as of yet undetermined caused by the foregoing acts of unfair and deceptive trade practices;

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

10. Other relief as the Court may deem appropriate.

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Dated: June 20, 2024

Respectfully submitted,

/s/ Jason Sykes

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JURY DEMAND

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

/s/ Jason Sykes

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ELI LILLY AND COMPANY

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

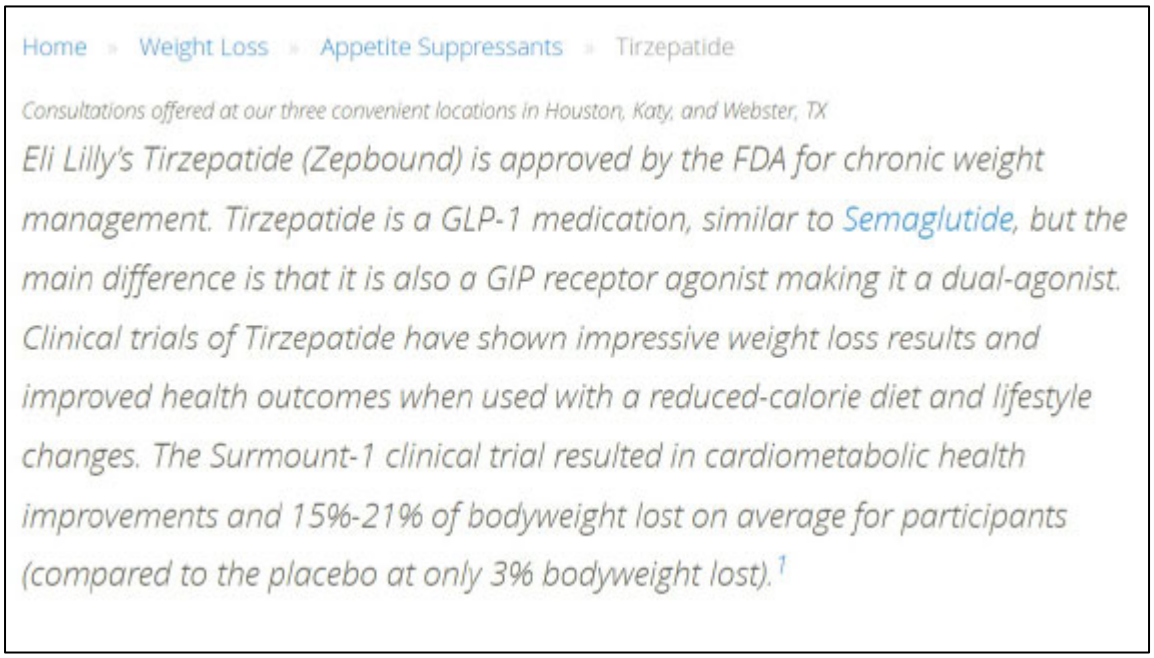
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

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.

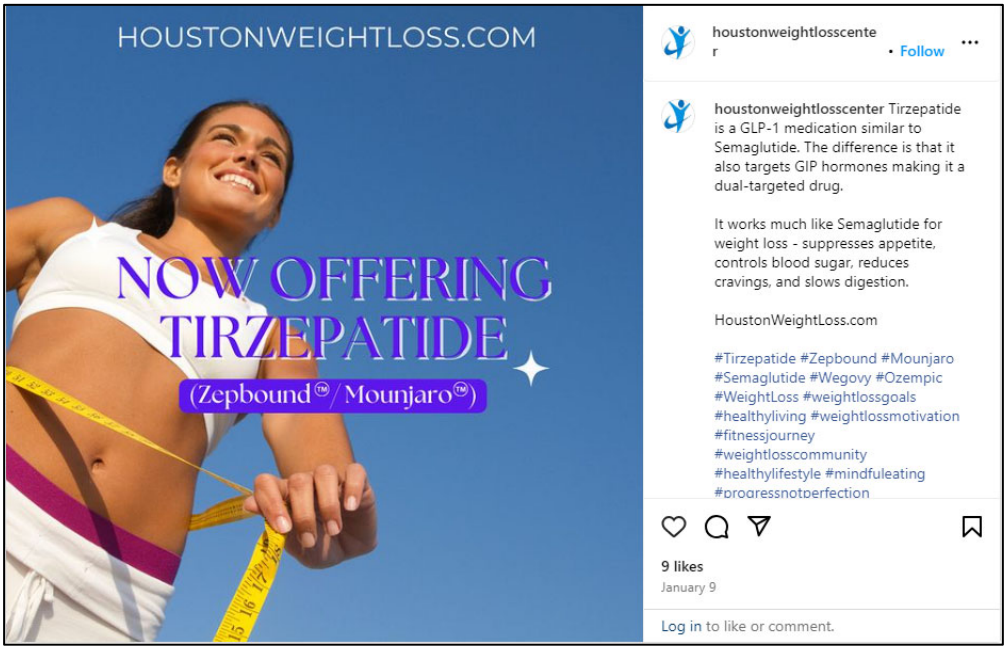
50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

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.

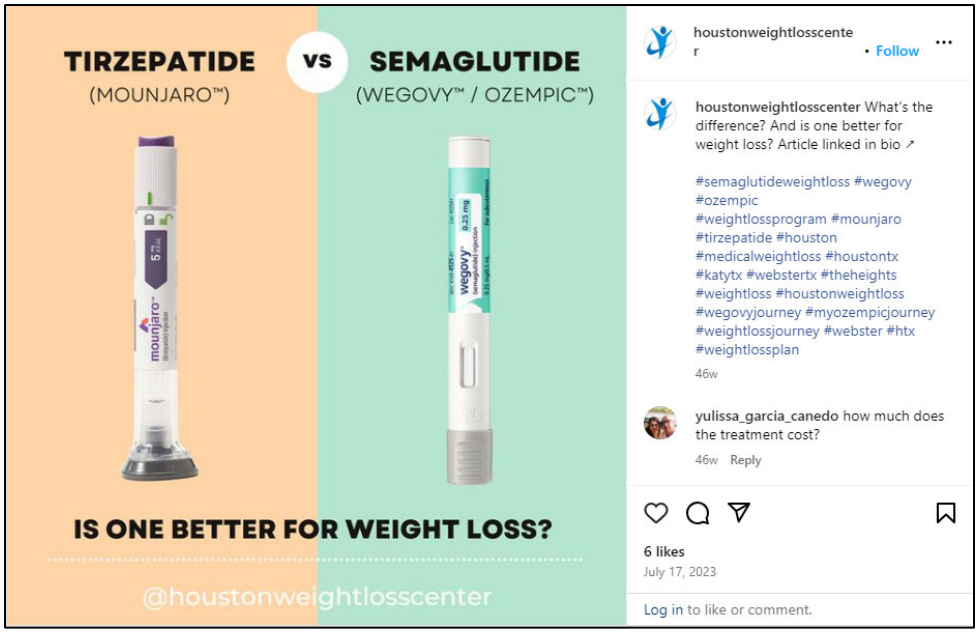
52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "approved for weight loss under the brand name Zepbound. It is also approved for Type 2 diabetes under the brand name, Mounjaro." Defendant's Unapproved Compounded Drugs are ***not*** sold under the brand name "Zepbound" or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

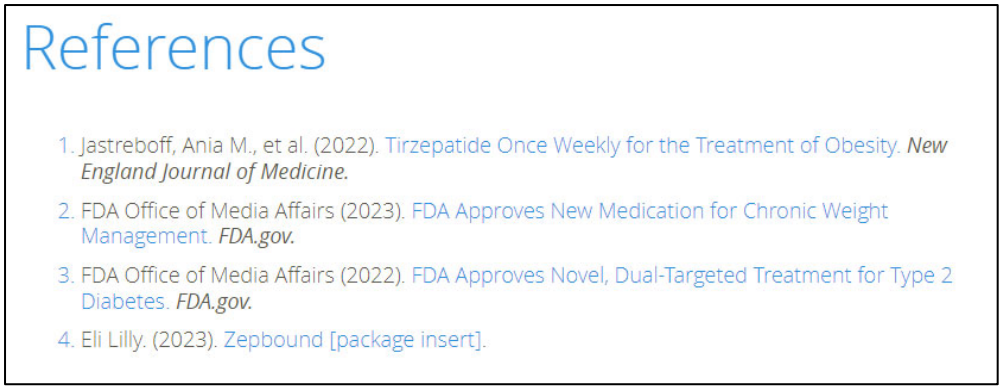
- Tirzepatide 5-mg doses – Average change in weight was -15%
- Tirzepatide 10-mg dose – Average change is weight was -19.5%
- Tirzepatide 15-mg dose – Average change in weight was -20.59%

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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Fed. I.D. No. 3511238
Attorney for Plaintiff
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UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

ELI LILLY AND COMPANY, an Indiana corporation located at Lilly Corporate Center Indianapolis, Indiana 46285,

Plaintiff,

v.

CAPITOL CONTOURS LLC, a Virginia limited liability company located at 3335 Duke Street, Alexandria, Virginia 22314,

Defendant.

Case No. 24-1781

COMPLAINT

JURY TRIAL DEMANDED

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 Capitol Contours LLC ("Defendant") has designed its website 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

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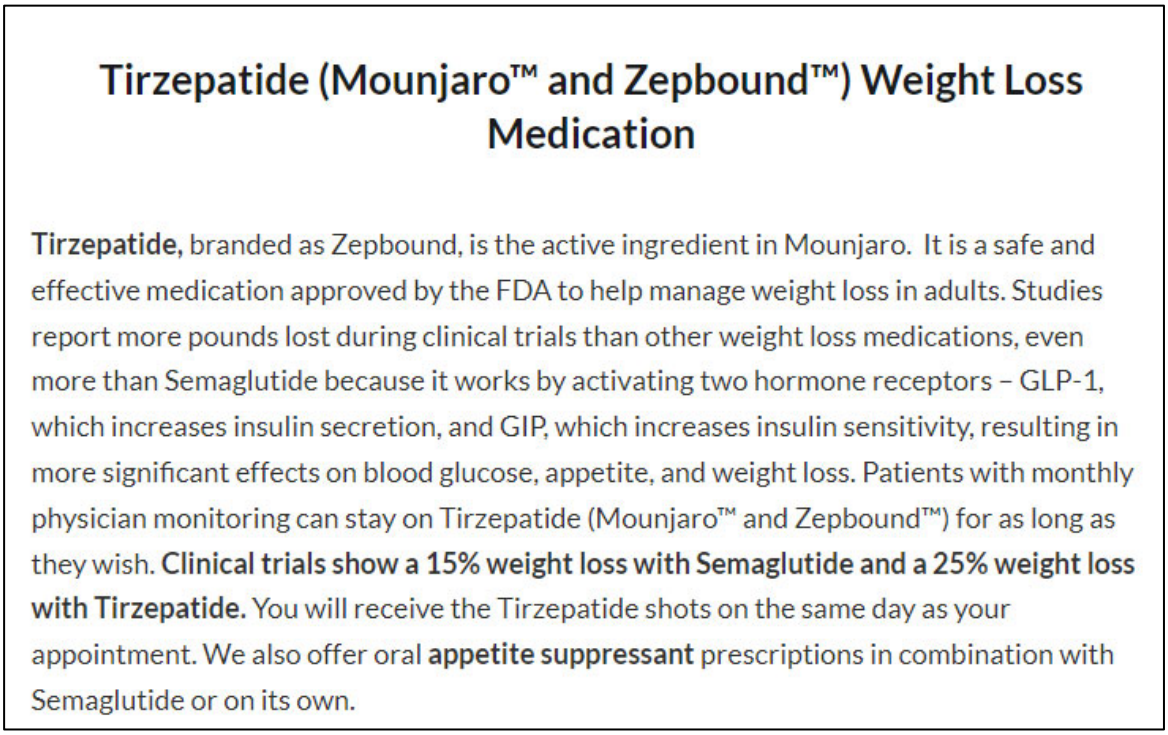
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

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. When patients arrive at Defendant's website, they can navigate to a webpage labeled "Tirzepatide." There, patients are greeted by a large banner proclaiming to describe "Tirzepatide (Mounjaro™ and Zepbound™) Weight Loss Medication." The page further reads that "**Tirzepatide**, branded as Zepbound, is the active ingredient in Mounjaro" before reporting Tirzepatide to be "approved by the FDA" and having had results demonstrated in "clinical trials," as shown below:



7. Tirzepatide, however, is not simply "branded as Zepbound." Tirzepatide is the active ingredient—but not the only ingredient—in Lilly's FDA-approved medicine. On its own, tirzepatide is not "approved by the FDA" to treat any condition, much less weight loss. Genuine MOUNJARO® and ZEPBOUND® are not the same as the compounded forms of tirzepatide offered by Defendant, but rather were tested in clinical trials and approved by the FDA.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of the 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 and false advertising.

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 Capitol Contours LLC is a Virginia limited liability company with a principal place of business at 3335 Duke Street, Alexandria, Virginia 22314. Its registered agent is United States Corporation Agents, Inc., with registered agent address 4445 Corporation Lane Suite 259, Virginia Beach, Virginia 23462.

11. Defendant also conducts business in this District at 1430 K Street, NW, Unit 102, Washington D.C., 20005.

12. Defendant also does business using the domain name "capitolcontours.com," on which it advertises its Washington, DC location.

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

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

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 the District of Columbia 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

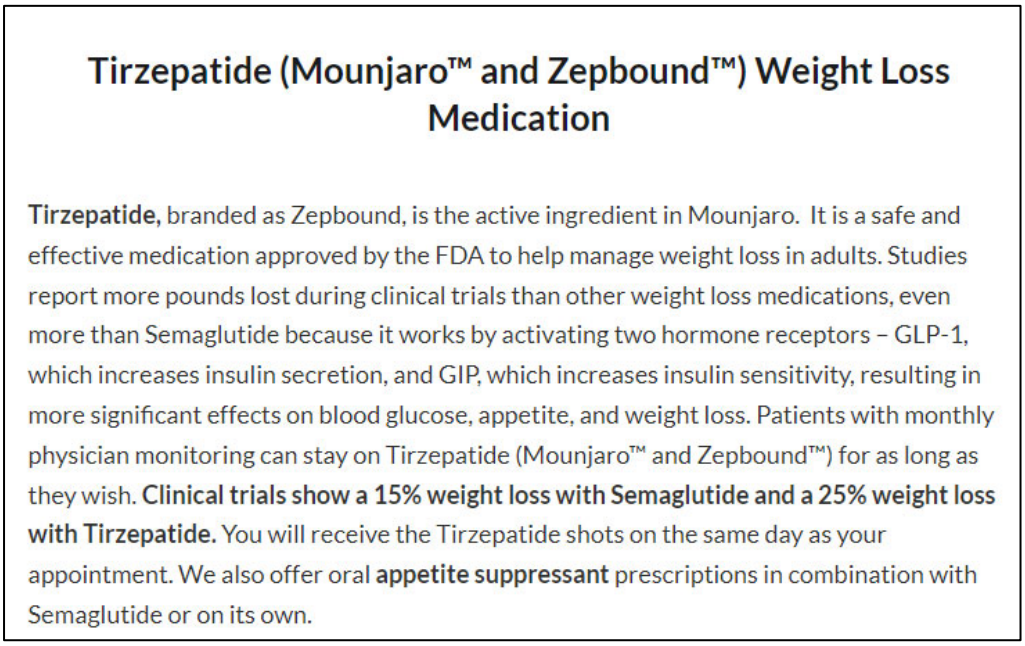
tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendant passes off Unapproved Compounded Drugs as "Mounjaro" and/or "Zepbound." Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

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. Defendant also passes off as "Mounjaro™ and Zepbound™" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely weight loss.

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

52. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (capitolcontours.com/tirzepatide), is shown below.



Tirzepatide (Mounjaro™ and Zepbound™) Weight Loss Medication

Tirzepatide, branded as Zepbound, is the active ingredient in Mounjaro. It is a safe and effective medication approved by the FDA to help manage weight loss in adults. Studies report more pounds lost during clinical trials than other weight loss medications, even more than Semaglutide because it works by activating two hormone receptors – GLP-1, which increases insulin secretion, and GIP, which increases insulin sensitivity, resulting in more significant effects on blood glucose, appetite, and weight loss. Patients with monthly physician monitoring can stay on Tirzepatide (Mounjaro™ and Zepbound™) for as long as they wish. **Clinical trials show a 15% weight loss with Semaglutide and a 25% weight loss with Tirzepatide.** You will receive the Tirzepatide shots on the same day as your appointment. We also offer oral **appetite suppressant** prescriptions in combination with Semaglutide or on its own.

53. As the image shows, Defendant equates its Unapproved Compounded Drugs with "Mounjaro™ and Zepbound™."

54. When referring to Defendant's Unapproved Compounded Drugs, this paragraph is also false and/or misleading. For example, Defendant's Unapproved Compounded Drugs are not "approved by the FDA" for any purpose. Likewise, Defendant's Unapproved Compounded Drugs were not "report[ed]" in any "studies," and there were no "clinical trials show[ing]" any effects of Defendant's Unapproved Compounded Drugs.

55. On social media, Defendant's deceptive practices continue. For example, Defendant posted a video on Instagram on January 29, 2024 that declared Tirzepatide is "also known as Mounjaro™ and Zepbound™." A screenshot from this Instagram post is shown below:

56. Defendant's Instagram post also refers to "studies" that were conducted on ***Lilly's*** medicines; the studies do not bear on the safety, quality, or efficacy of Defendant's Unapproved Compounded Drugs, which the studies did not test.

57. As shown in this Instagram post, Defendant offers its Unapproved Compounded Drug in a barely-labeled vial that says only "Tirzepatide" and "Rx Only." Genuine Lilly MOUNJARO® and ZEPBOUND® are sold in pre-filled, branded autoinjector pens along with FDA-approved labels. A ZEPBOUND® pen is shown below:

58. Defendant's website conveys the unmistakable impression that Defendant is offering for sale 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.

59. 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.

60. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** MOUNJARO® or ZEPBOUND®, are ***not*** "approved by the FDA," and were ***not*** subjected to clinical trials, and therefore lack any data from "studies."

61. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website and social media channels, 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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 THE DISTRICT OF COLUMBIA AND LILLY

67. 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.

68. 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.

69. 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.

70. Not only does this deceitful content expose the people of the District of Columbia 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

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

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

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

78. 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

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

80. 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.

81. 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.

82. 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).

83. 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.

84. 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.

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

86. 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)

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

88. 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).

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

90. 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.

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

92. 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.

93. 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.

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

95. 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
Trademark Infringement and Unfair Competition in Violation of the Common Law

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

97. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of the District of Columbia's common law.

98. 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®.

99. 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.

100. 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.

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

102. As a direct and proximate result of Defendant's trademark infringement and 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. Defendant therefore has unfairly profited from the actions alleged.

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

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 trademark infringement in violation of the common law;

   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 the common law in amounts as of yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition;

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117 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.

Dated: June 20, 2024

Respectfully submitted,

/s/ James John Lomeo

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Attorneys for Plaintiff
ELI LILLY AND COMPANY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

ELI LILLY AND COMPANY,

Plaintiff,

v.

ED PARTNERS, LLC D/B/A CLEVELAND HEALTH GROUP,

Defendant.

Case No. 1:24-cv-1035

JURY TRIAL DEMANDED

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

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant Ed Partners LLC d/b/a Cleveland Health Group ("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

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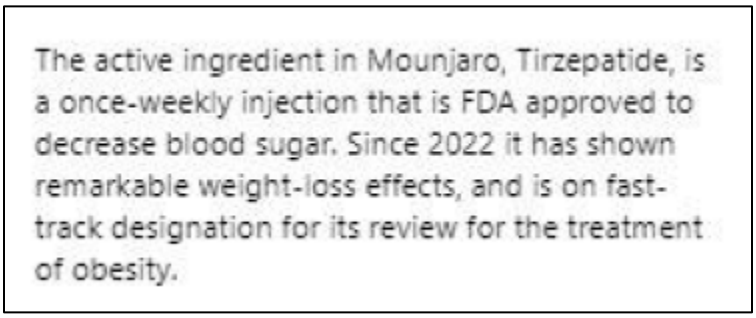
[1] In support of this Complaint, Lilly's allegations are upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

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 or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

6. Defendant's intentional deception is evident from its social media accounts, where in dozens of posts Defendant advertises by unnecessarily invoking the MOUNJARO® Mark and falsely claiming that its tirzepatide product is "FDA approved" or backed by research, as shown below.



7. Defendant also uses its website to falsely advertise its products. For example, in a video posted to Defendant's tirzepatide webpage, Defendant refers to its product at timestamp 0:09 as "generic MOUNJARO®."

8. Despite these repeated and impossible-to-miss advertisements, Defendant's products are not "FDA approved," are not the same tirzepatide as is used in MOUNJARO®, and are not "shown" to have any effects. Nor can it be "generic MOUNJARO®," because there is ***no such thing*** as "generic MOUNJARO.®" Rather, Defendant's products are unstudied, unapproved, and unsafe.

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

THE PARTIES

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

11. Defendant is an Ohio limited liability company d/b/a Cleveland Health Group, with a principal place of business at 6571 Brecksville Road, Independence, Ohio 44131 in this District. Its registered agent is Registered Agents Inc. with a registered agent address 6545 Market Avenue N, Suite 100, North Canton, Ohio, 44721.

12. Defendant also does business using the domain name "https://clevelandhealthgroup.com/."

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

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

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 Ohio 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 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.

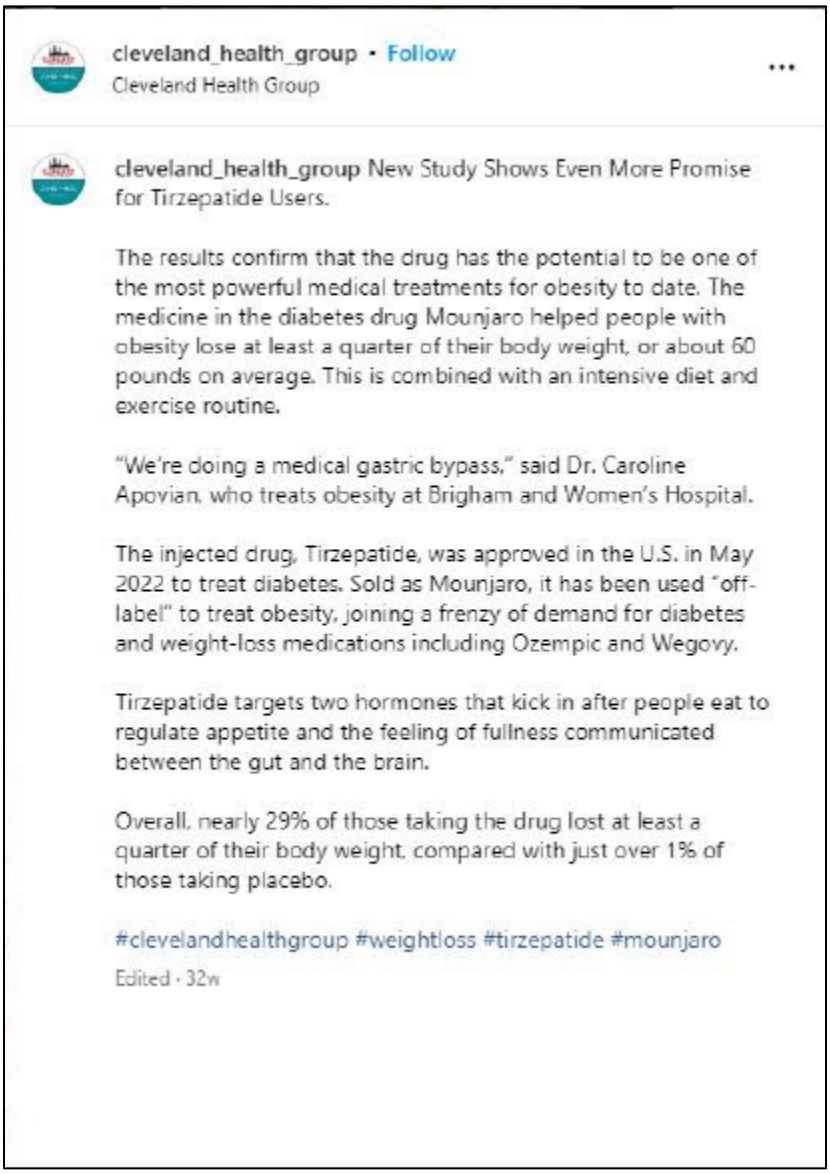
48. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendant passes off Unapproved Compounded Drugs as the same as "Mounjaro" or as "generic Mounjaro." 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. Defendant also passes off as "Mounjaro" or "generic Mounjaro" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

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

52. An example of Defendant's unauthorized use of the Lilly Marks, from an October 17, 2023 post to Defendant's Instagram page, is shown below.



53. As the image shows, Defendant promotes its Unapproved Compounded Drugs by first noting that its Unapproved Compounded Drugs contain the same active ingredient as in

MOUNJARO® and then switching to describing its product as "Sold as Mounjaro" and tagging the post #mounjaro as well.

54. Defendant interchanges "Tirzepatide" (the name for its Unapproved Compounded Drug) and "MOUNJARO®" (Lilly's trademarked name for its FDA-approved medicine) on its website, too.

55. For example, as shown below, Defendant's characterization of its products side effects (none of which have been scientifically proven) notes that "These are not all the possible side effects of Mounjaro."

> The most common side effects of Tirzepatide include nausea, diarrhea, decreased appetite, vomiting, constipation, indigestion, and stomach (abdominal) pain. These are not all the possible side effects of Mounjaro. Talk to your healthcare provider about any side effects you might experience.

56. Defendant's social media and website convey the unmistakable impression that Defendant is offering for sale a product that either is, has the same source as, or is the same 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.

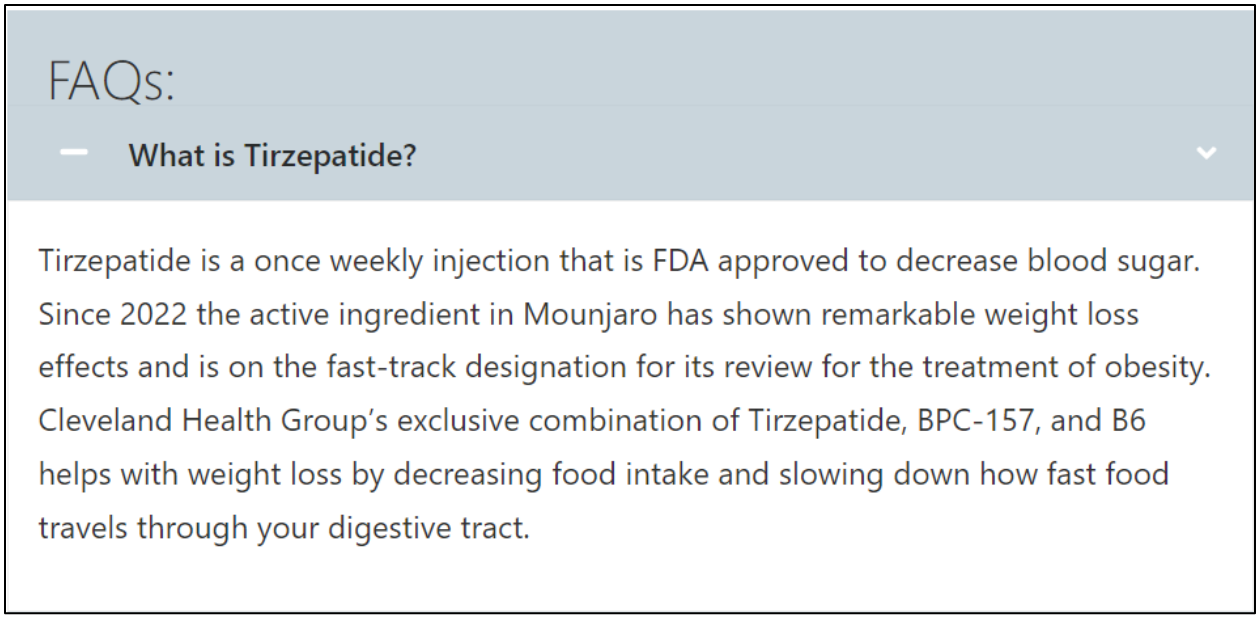
58. Defendant also falsely advertises its Unapproved Compounded Drugs on its website and social media by making statements that claim or imply that its Unapproved Compounded Drugs are FDA-approved and have been proven to achieve certain therapeutic outcomes. These statements rely on the FDA's approval 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, in the Instagram post shown above, Defendant cited to a "New Study Show[ing] Even More Promise for Tirzepatide Users." This study, however, was of ***Lilly's*** medicine and has no bearing on Defendant's Unapproved Compounded Drugs.

60. Additionally, in a video posted to Defendant's tirzepatide webpage, Defendant refers to its product at timestamp 0:09 as "generic MOUNJARO®." There is, however, ***no such thing*** as "generic MOUNJARO®."

61. In another section of Defendant's tirzepatide webpage, as shown below, Defendant advertises that: (1) "Tirzepatide is [] FDA approved to decrease blood sugar" and that "the active ingredient in Mounjaro has shown remarkable weight loss effects." "Tirzepatide," however, is ***not*** approved for weight loss or any other condition; Lilly's MOUNJARO® and ZEPBOUND®, medicines ***containing*** tirzepatide, are FDA approved for the indications described above. Additionally, Defendant notes that it offers an "exclusive combination of Tirzepatide, BPC-157, and B6"—a combination that has ***never*** been studied in clinical trials, is ***not*** FDA approved, and is ***not*** the non-existent "generic MOUNJARO®" that Defendant claims it to be. Rather, Defendant offers Unapproved Compounded Drugs.



62. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** "generic MOUNJARO®," are ***not*** "FDA approved," were ***not*** subjected to clinical trials, and therefore are ***not*** "clinically proven" to achieve any results.

63. 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.

64. 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.

65. 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.

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

67. 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.

68. 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 OHIO AND LILLY

69. 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.

70. 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.

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

72. Not only does this deceitful content expose the people of Ohio 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

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

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

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

80. 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

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

82. 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.

83. 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.

84. 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).

85. 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.

86. 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.

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

88. 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)

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

90. 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).

91. 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.

92. 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.

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

94. 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.

95. 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.

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

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

FOURTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of Ohio Rev. Code § 4165.01 *et seq*.

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

99. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio Rev. Code § 4165.01 *et seq.*

100. Among other things, Ohio Rev. Code § 4165.02 defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (1) Passes off goods or services as those of another;
> (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) Causes likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another;
> * * *
> (7) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
> * * *
> (9) Represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> * * *
> (11) Advertises goods or services with intent not to sell them as advertised;

101. As set forth herein, Defendant's actions fit within the scope of Ohio Rev. Code § 4165.02.

102. 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.

103. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of Ohio Rev. Code § 4165.01 et seq.

104. 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 with the intent to deceive.

105. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for Mounjaro® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

106. 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.

107. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine Mounjaro® and ZEPBOUND®, not an Unapproved Compounded Drug.

108. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief. In addition, Lilly is entitled to attorneys' fees and costs.

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

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

110. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Ohio common law.

111. 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®.

112. 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.

113. 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.

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

115. As a direct and proximate result of Defendant's trademark infringement and unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

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

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 deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Ohio Rev. Code § 4165.01 *et seq.* and Ohio common law;

   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 deceptive trade practices.

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 Ohio state law in amounts as of yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Ohio 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/ Matthew J. Cavanagh

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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/ Matthew J. Cavanagh

Matthew J. Cavanagh (OH 0079522)
Attorney for Plaintiff
ELI LILLY AND COMPANY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-001715

ELI LILLY AND COMPANY,

Plaintiff,

v.

HYDRAMED IV LLC,

Defendant.

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

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant HydraMed IV, LLC ("Defendant") has designed its website 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.

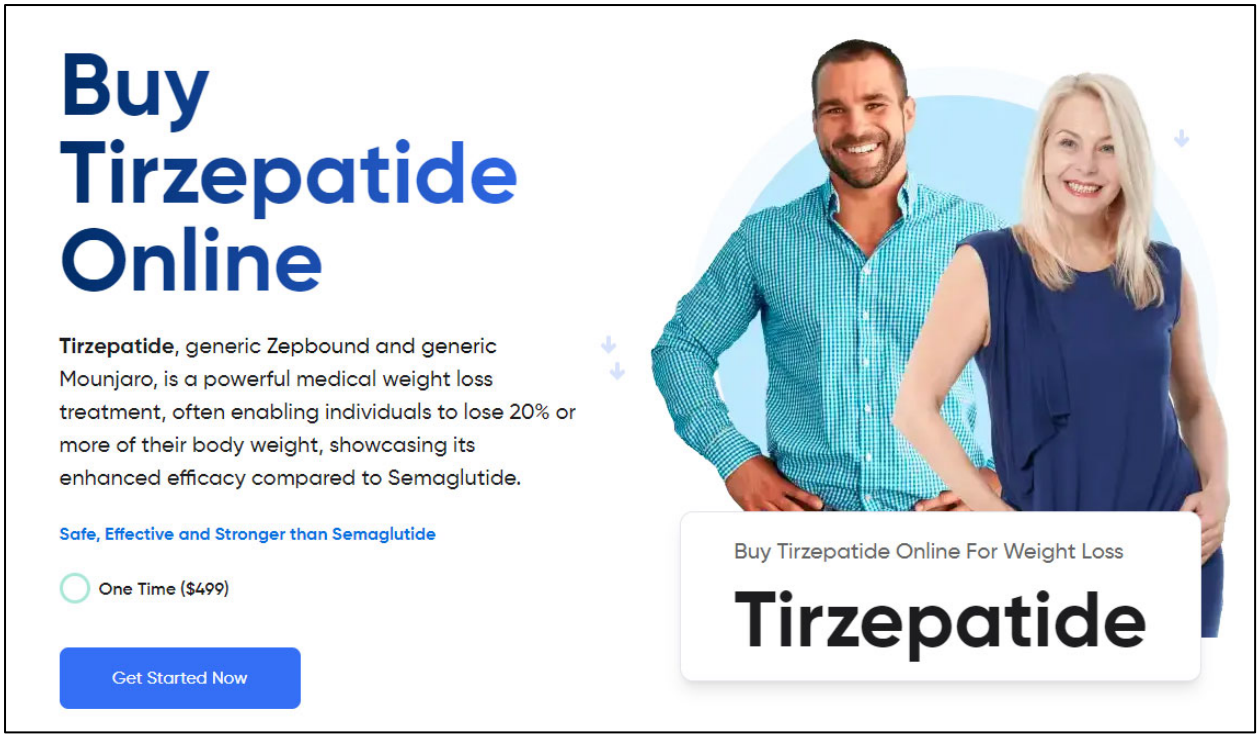
advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-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 or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes

that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

6. Defendant's intentional deception of patients starts from the top of its "Buy Tirzepatide Online" webpage, where it boldly and false defines "Tirzepatide" as "generic Zepbound and generic Mounjaro," as shown below:



7. Despite this impossible-to-miss headline, Defendant offers neither MOUNJARO® nor ZEPBOUND®, nor any "generic" version of them. In fact, there is ***no such thing*** as generic MOUNJARO® or generic ZEPBOUND®.

8. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of Colorado statutory and common law regarding deceptive trade practices. Lilly's claims arise out of Defendant's infringement of Lilly's rights in the

MOUNJARO® and ZEPBOUND® trademarks and Defendant's acts of false designation of origin, false advertising, and deceptive trade practices.

THE PARTIES

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

10. Defendant is a Colorado limited liability company with a principal place of business at 11990 Grant Street, Suite 550, Northglenn, Colorado 80233, in this District. Its sole member and registered agent is Bear Harper, with registered agent address 11990 Grant Street, Suite 550, Northglenn, Colorado 80233.

11. Defendant also conducts business at its website "https://hydramed.com." According to Defendant's website, Defendant offers services "throughout the greater Denver and Front Range areas." https://hydramed.com/areas-served/Colorado. Defendant additionally offers its services, including its "Tirzepatide" product "Shipped To You."

JURISDICTION AND VENUE

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

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

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

14. Lilly's MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's MOUNJARO® was clinically proven to improve blood sugar control "more effective[ly] than the other diabetes therapies with which it was compared in clinical studies." *Id.*

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

16. In addition to MOUNJARO®, Lilly markets and sells ZEPBOUND®, another proprietary, FDA-approved treatment option containing the active pharmaceutical ingredient tirzepatide. With ZEPBOUND®, Lilly aims to help the many dozens of millions of American adults with obesity or with excess weight and weight-related medical problems lower their risks of cardiovascular disease and other leading causes of death. As the FDA has noted,

ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

17. As with MOUNJARO®, the safety, quality, and effectiveness of ZEPBOUND® was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND® and indicated it for adults with obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 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.

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

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-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.*

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

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

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

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

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

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

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

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

28. Lilly promotes, advertises, and markets MOUNJARO® and ZEPBOUND® both to healthcare professionals and to patients, among others, through various channels, including on

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

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

THE RISKS OF COMPOUNDING

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

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/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.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not

required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

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

https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to []GMP requirements, are provided to a patient only based on individual patient need." *Id.* (emphasis in original).

34. Compounders are also limited in their ability to engage in a practice called anticipatory compounding, which is when, "based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician

will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received." *Id.* As the FDA further explained:

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

Id. (emphasis added).

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

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated

compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/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.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/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).

38. Lilly has seen problems first-hand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly's FDA-approved medicines. In at least one instance, Lilly saw nothing more than sugar alcohol. Lilly also has

received reports of patients experiencing significant adverse events after being injected with non-Lilly tirzepatide, including a patient who experienced a seizure and was admitted to the Intensive Care Unit and other patients who experienced severe allergic reactions. According to the FDA's Adverse Events Reporting System (FAERS), to date, over 150 adverse events associated with compounded or so-called (but not actually) "generic" tirzepatide have been reported, including over 100 "serious cases" and at least 5 deaths.

39. Consequences from compounded drugs may be deadly. In 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

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

41. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically. https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective. https://www.fda.gov/inspections-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).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-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).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/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.*

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

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

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

47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and 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 "generic Zepbound and generic Mounjaro." Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

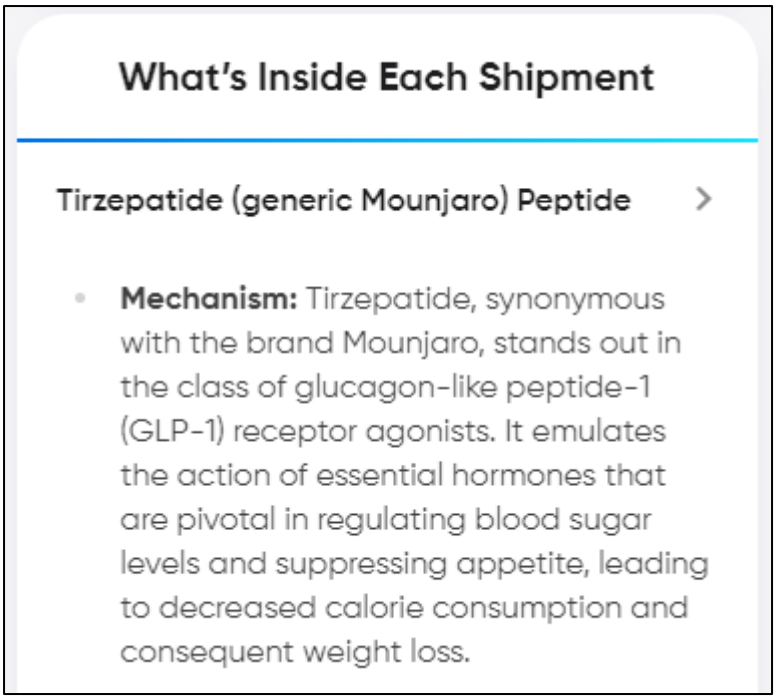
48. Because Defendant is not offering genuine MOUNJARO® or ZEPBOUND®, Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendant.

49. Defendant also passes off as "generic Mounjaro" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

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

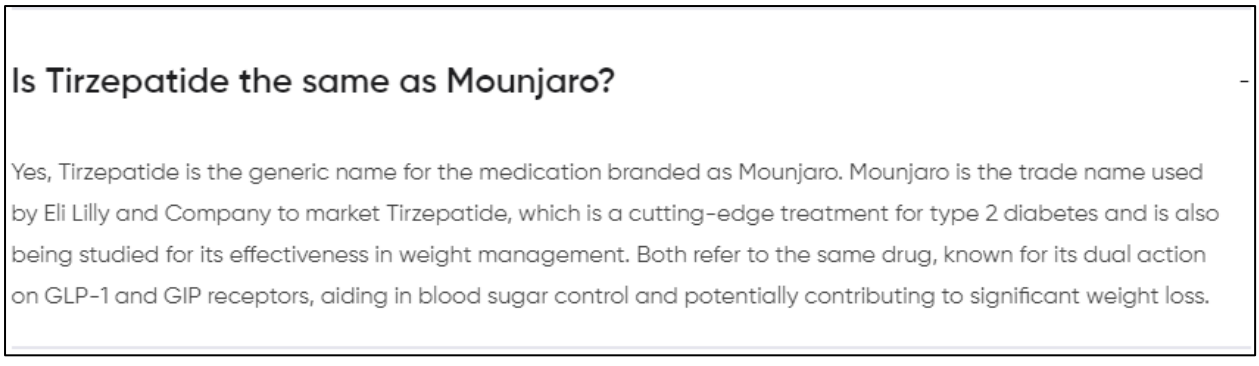
51. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (hydramed.com/rx/tirzepatide), is shown below.

52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "Generic Zepbound & Mounjaro." Just below that, and as shown below, Defendant goes further, describing Tirzepatide as "synonymous with the brand Mounjaro."



53. Tirzepatide is not "synonymous with the brand Mounjaro;" tirzepatide is one among several ingredients in Lilly's MOUNJARO® and ZEPBOUND®.

54. Elsewhere on the same page, Defendant describes its Unapproved Compounded Drug as "known under the brand name Mounjaro." Defendant also provides a question-and-answer section that proclaims "Yes" "Tirzepatide [is] the same as Mounjaro," as shown below:



55. In this same paragraph, Defendant asserts that "Mounjaro is the trade name used by Eli Lilly and Company to market Tirzepatide"—rather than a federally registered trademark

used in connection with a medicine *containing* the active pharmaceutical ingredient tirzepatide—and that Defendant's capital-T "Tirzepatide" and MOUNJARO® "refer to the same drug."

56. On this "tirzepatide" webpage, which Defendant uses to sell its Unapproved Compounded Drugs, Defendant uses Lilly's coined terms MOUNJARO® and ZEPBOUND® at least 16 times, despite the fact that Defendant does not offer either of these Lilly medicines.

57. Defendant's website conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved "generic" version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution. Moreover, there are ***no*** "generic" versions of either MOUNJARO® and ZEPBOUND®.

58. 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.

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

60. For example, Defendant's same Tirzepatide webpage advertises that its Unapproved Compounded Drug is "an FDA-approved injectable medication utilized for weight management."

61. Defendant also cites to the results of clinical trials, including referring by name to Lilly's SURMOUNT® trials and stating that "individuals using Tirzepatide experienced notable weight reductions, some achieving weight loss that surpasses traditional benchmarks."

62. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** "FDA approved," are not "generic" forms of MOUNJARO® and/or ZEPBOUND®, were ***not*** subjected to clinical trials including Lilly's SURMOUNT® trials, and therefore are ***not*** clinically proven to achieve any results.

63. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, 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.

64. 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.

65. 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.

66. 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.

67. Defendant's unauthorized use of the Lilly Marks is not only intended to but likely to cause confusion, to cause mistake, or to deceive, and infringes Lilly's established exclusive rights in the Lilly Marks.

68. 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 COLORADO AND LILLY

69. 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.

70. 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.

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

72. Not only does this deceitful content expose the people of Colorado 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

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

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

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

80. 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

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

82. 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.

83. 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.

84. 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).

85. 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.

86. 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.

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

88. 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)

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

90. 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).

91. Defendant has knowingly and willfully made material false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs, and these statements regarding Unapproved Compounded Drugs' safety, quality, effectiveness, and

regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

92. 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.

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

94. 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.

95. 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.

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

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

FOURTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of C.R.S. § 6-1-101 *et seq*.

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

99. The above-described acts of Defendant constitute deceptive trade practices in violation C.R.S. § 6-1-101 *et seq.*

100. Among other things, C.R.S. § 6-1-105 defines actions that constitute a "deceptive trade practice" as including, but not limited to, when a person, in the course of the person's business, vocation, or occupation, does the following:

(a) Either knowingly or recklessly passes off goods, services, or property as those of another;

(b) Either knowingly or recklessly makes a false representation as to the source, sponsorship, approval, or certification of goods, services, or property;

(c) Either knowingly or recklessly makes a false representation as to affiliation, connection, or association with or certification by another;

* * *

(e) Either knowingly or recklessly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations, or quantities of goods, food, services, or property or a false representation as to the sponsorship, approval, status, affiliation, or connection of a person therewith;

* * *

(g) Represents that goods, food, services, or property are of a particular standard, quality, or grade, or that goods are of a particular style or model, if he knows or should know that they are of another;

* * *

(i) Advertises goods, services, or property with intent not to sell them as advertised;

* * *

(u) Fails to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction.

101. As set forth herein, Defendant's actions fit within the scope of C.R.S. § 6-1-105.

102. Evidence that Defendant has engaged in these deceptive trade practices is prima facie evidence of Defendant's intent to injure competitors and to destroy or substantially lessen competition under C.R.S. § 6-1-105(2).

103. 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.

104. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of C.R.S. § 6-1-101 *et seq.*

105. 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 with the intent to deceive.

106. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be

important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

107. Because Defendant conducts sales online, a significant number of Defendant's consumers will encounter Defendant's services via Defendant's website, on which Defendant engages in trademark infringement and false advertising.

108. Because Defendant's misrepresentations are advertised directly to the public as potential or actual consumers, a significant public impact is presumed.

109. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been injured and damaged and will continue to be injured and damaged, making Defendant liable to Lilly under C.R.S. § 6-1-113.

110. Under C.R.S. § 6-1-113, Defendant is liable to Lilly for damages, including treble damages, as a result of Defendant's bad faith conduct. In addition, Lilly is entitled to attorneys' fees and costs.

111. 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.

112. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

113. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief.

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

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

115. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Colorado common law.

116. 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®.

117. 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.

118. 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.

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

120. As a direct and proximate result of Defendant's trademark infringement and 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. Defendant therefore has unfairly profited from the actions alleged.

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

JURY DEMAND

Plaintiff Lilly hereby demands a trial by jury on all issues so triable.

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 deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of C.R.S. §§ 6-1-101 *et seq*. and in violation of the common law of Colorado; and

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 Colorado state law in amounts as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition.

9. An Order requiring Defendant to pay Lilly's costs and attorney's fees in this action pursuant to 15 U.S.C. § 1117, Colorado 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/ Daniel N. Guisbond

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 20, 2024, I electronically filed the foregoing **COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, AND DECEPTIVE TRADE PRACTICES** with the Clerk of the Court using the CM/ECF system.

/s/ Daniel N. Guisbond

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

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

Defendant.

Case No. _____

JURY TRIAL DEMANDED

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

INTRODUCTION

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

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

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

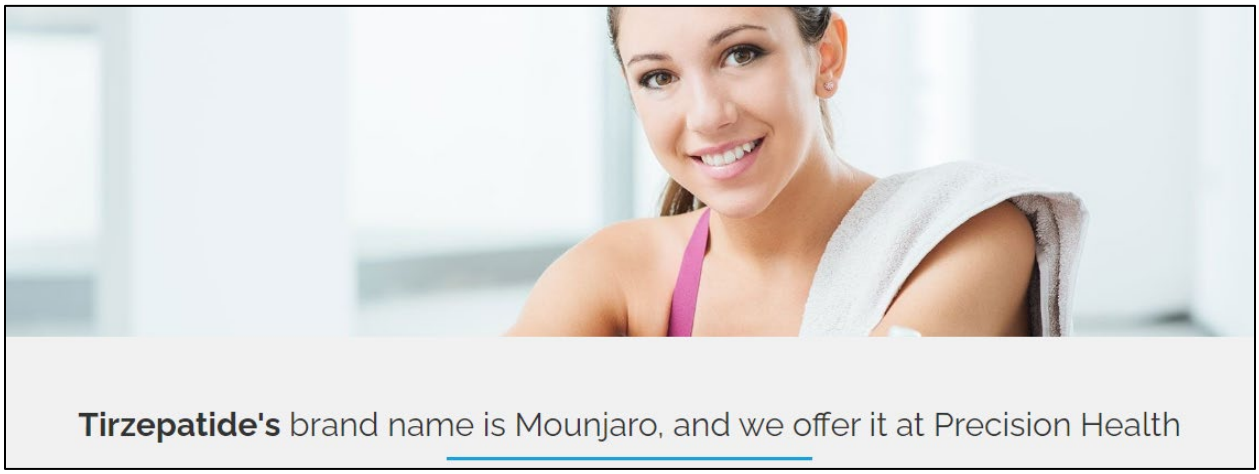
3. Before obtaining FDA approval, Lilly's new medicines underwent years-long clinical trials, which tested them for safety, quality, and effectiveness on thousands of patients. When approving these medicines, the FDA called Lilly's "novel" MOUNJARO® an "important advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/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 or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

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



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

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

THE PARTIES

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

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

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

JURISDICTION AND VENUE

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

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

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

14. Lilly's MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's

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

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

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

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

obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 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.

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

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-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.*

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

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

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

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

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

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

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

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

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

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

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

THE RISKS OF COMPOUNDING

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

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/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.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

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

https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved,

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

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

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

Id. (emphasis added).

35. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety,

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

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/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.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/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).

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

39. Consequences from compounded drugs may be deadly. In 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

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

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

because they are not safe or effective. https://www.fda.gov/inspections-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).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-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).

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

and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/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.*

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

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

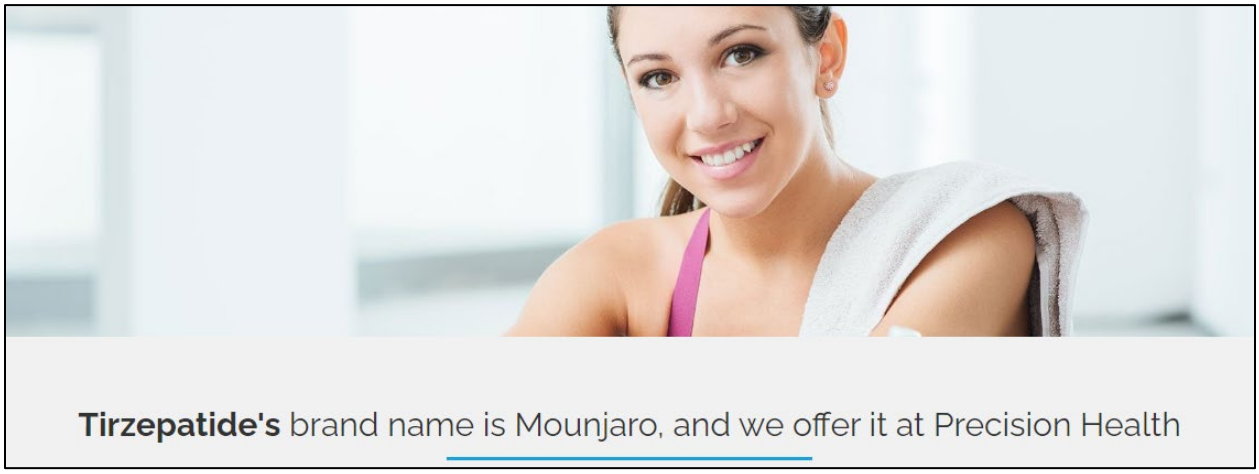
46. Lilly does not sell MOUNJARO® or ZEPBOUND® to Defendant for resale or redistribution. Nor has Lilly authorized Defendant to use the Lilly Marks in connection with any of Defendant's offered goods or services. On information and belief, therefore, the Unapproved Compounded Drugs sold by Defendant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

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

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

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

50. An example of Defendant's unauthorized use of the Lilly Marks, on the "Tirzepatide" page of Defendant's website (precisionhealthandweightloss.com/tirzepatide/), is shown below.

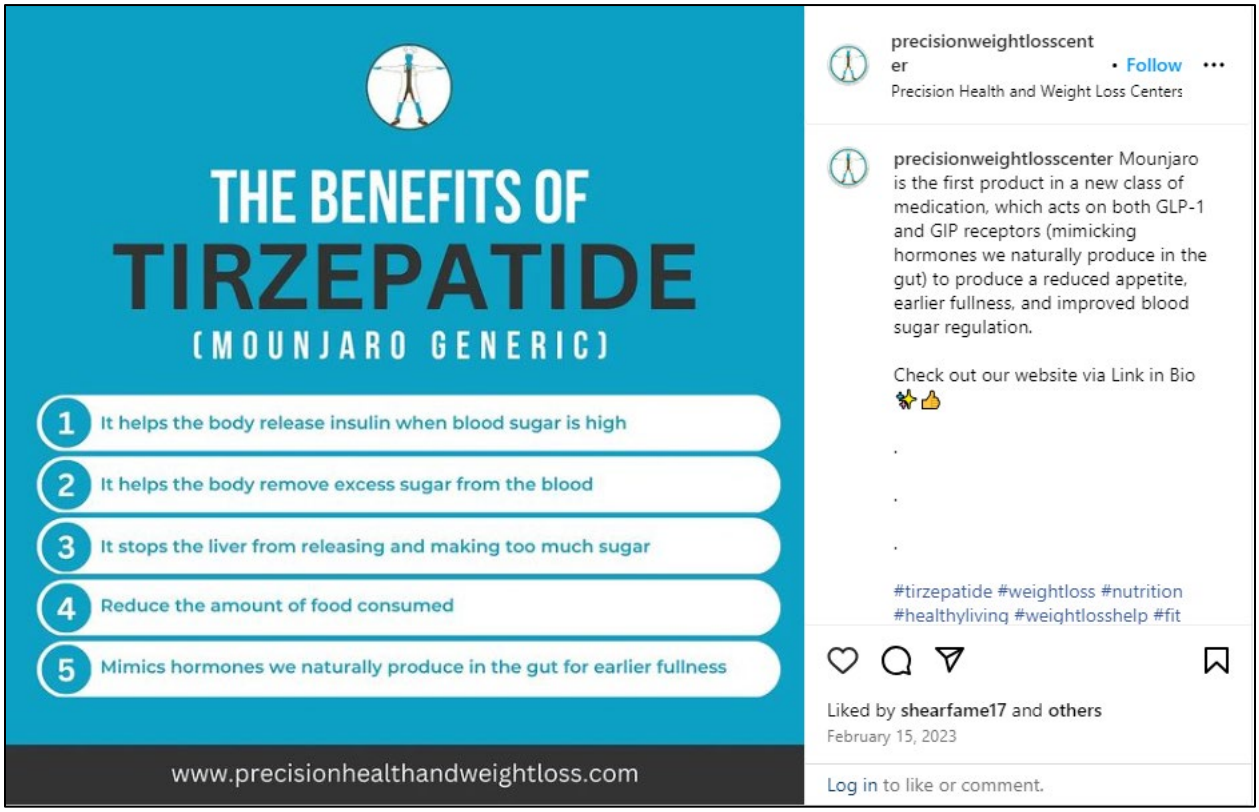


51. As the image shows, Defendant promotes its Unapproved Compounded Drugs by noting the "brand name is Mounjaro, and we offer it at Precision Health." Defendant's Unapproved Compounded Drugs are ***not*** sold under the brand name "Mounjaro," because they are not MOUNJARO®. Nor does Defendant offer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

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

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

OF TIRZEPATIDE (MOUNJARO GENERIC),” as shown below. This post is also “tagged” #mounjaro.



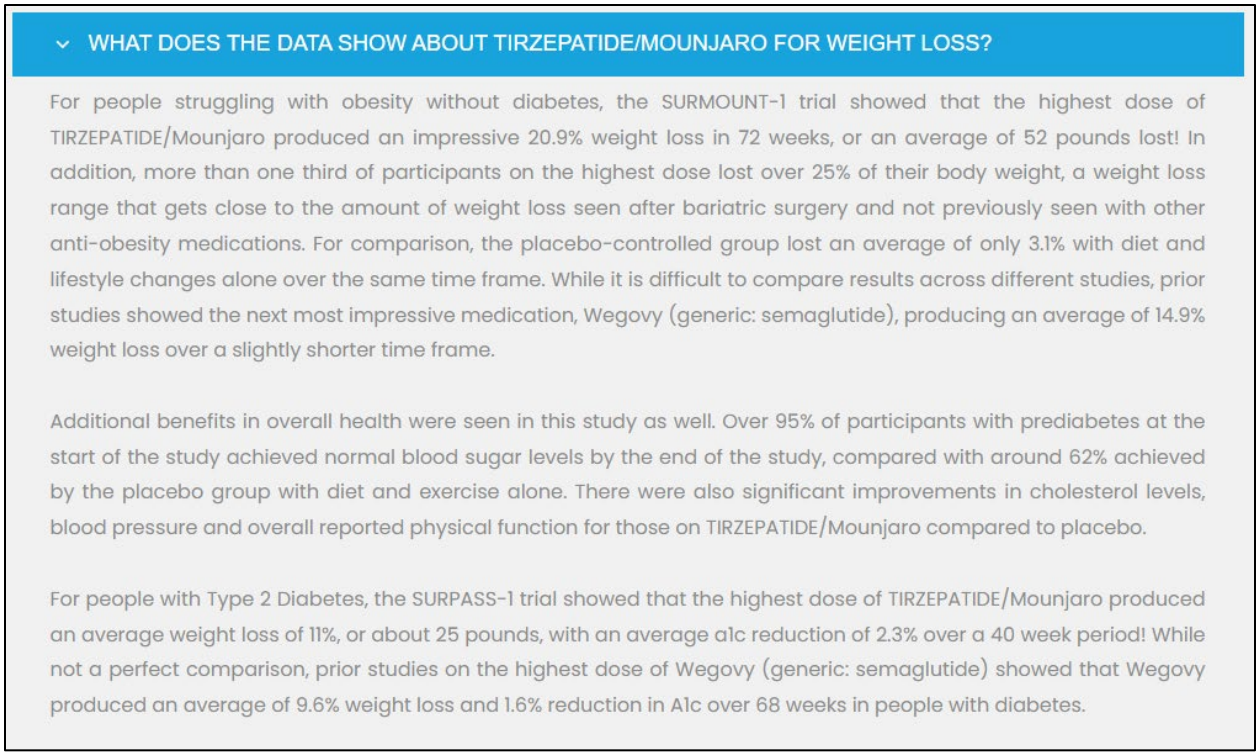
54. The caption on this post, however, does not refer to any so-called “MOUNJARO GENERIC” but instead refers simply to “Mounjaro”—a product Defendant does not offer for sale.

55. Defendant’s website and social media convey the unmistakable impression that Defendant is offering for sale Lilly’s MOUNJARO® and ZEPBOUND®, and/or an FDA-approved “generic” version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution. Moreover, there are ***no*** generic versions of either MOUNJARO® and ZEPBOUND®.

56. Defendant first started using the Lilly Marks to advertise its Unapproved Compounded Drugs long after Lilly had adopted them. Defendant's use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

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

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



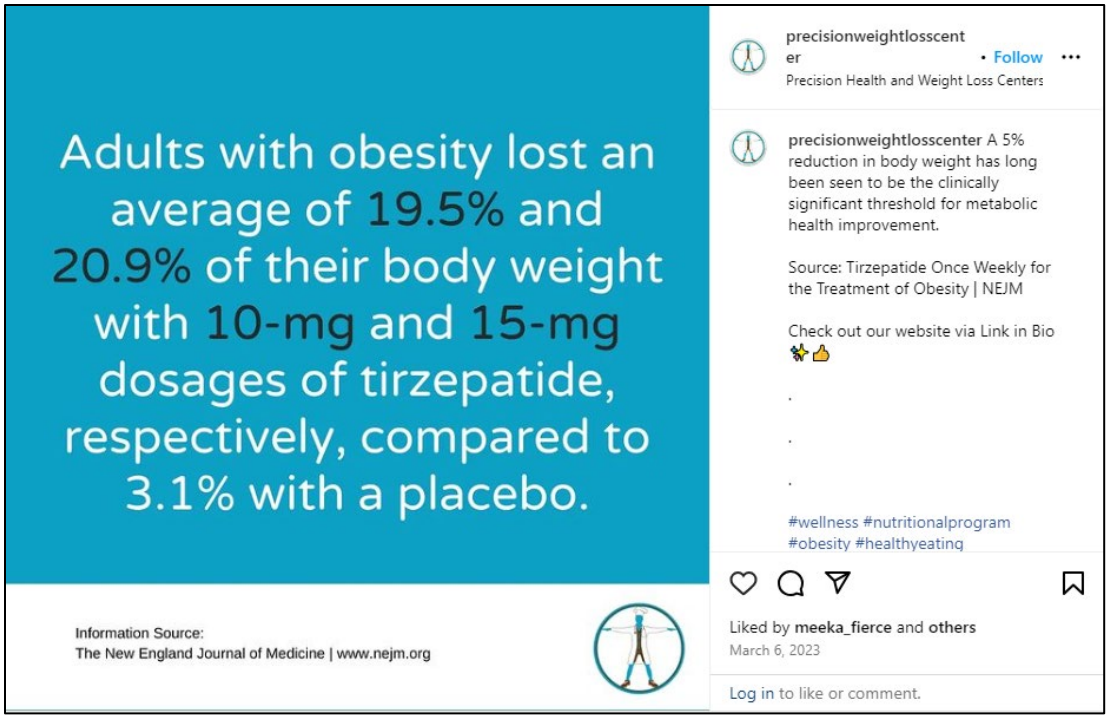
WHAT DOES THE DATA SHOW ABOUT TIRZEPATIDE/MOUNJARO FOR WEIGHT LOSS?

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

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

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

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



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

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

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

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

64. Defendant continues to use the Lilly Marks, including in advertising and promotion on its websites and social media, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine 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 Lilly's reputation and to create confusion in the marketplace and/or mislead patients with serious health conditions regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

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

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

HARM TO THE PEOPLE OF FLORIDA AND LILLY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

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

1. An Order declaring that Defendant:

   a. Infringed the federally registered Lilly Marks, in violation of 15 U.S.C. § 1114(1);

   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 deceptive and unfair practices in violation of the statutory and common law of Florida;

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

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

a. Using the Lilly Marks or any mark confusingly similar to them, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake, or deceive or otherwise infringe any rights of Plaintiff Lilly in the Lilly Marks or any similar mark;

b. Falsely stating or suggesting that Defendant's Unapproved Compounded Drugs are genuine or generic versions of MOUNJARO® or ZEPBOUND®, that Defendant is associated or connected in any way with Plaintiff or its products, or that Defendant's Unapproved Compounded Drugs are approved by the FDA, have been the subject of clinical studies, or achieve certain therapeutic outcomes;

c. Engaging in any unfair competition with Plaintiff Lilly; and

d. Engaging in any deceptive or unfair acts.

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

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

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

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

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

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

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

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

10. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,

/s/ Gavin C. Gaukroger

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JURY DEMAND

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

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[Additional counsel listed in signature block]

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ELI LILLY AND COMPANY,

Plaintiff,

v.

SDBODYCONTOURING, A MEDICAL CORPORATION D/B/A ZEPBOUND PRESCRIPTION CLINIC D/B/A ZEPBOUND RX CLINIC D/B/A SAN DIEGO BODY CONTOURING,

Defendant.

Case No. '24CV1061 RSH SBC

COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, AND CYBERSQUATTING

DEMAND FOR A JURY TRIAL

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 SDBodyContouring, A Medical Corporation d/b/a Zepbound Prescription Clinic d/b/a Zepbound Rx Clinic d/b/a San Diego Body Contouring ("Defendant") has designed its websites, social media, and advertising materials to deceive patients into thinking Defendant offers a way to obtain Lilly's clinically studied medicines, when in reality Defendant offers no such thing.[1] Lilly therefore brings this action under federal and state law to protect patients from Defendant's dangerous, deceptive, and unlawful practices.

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

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[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.

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).

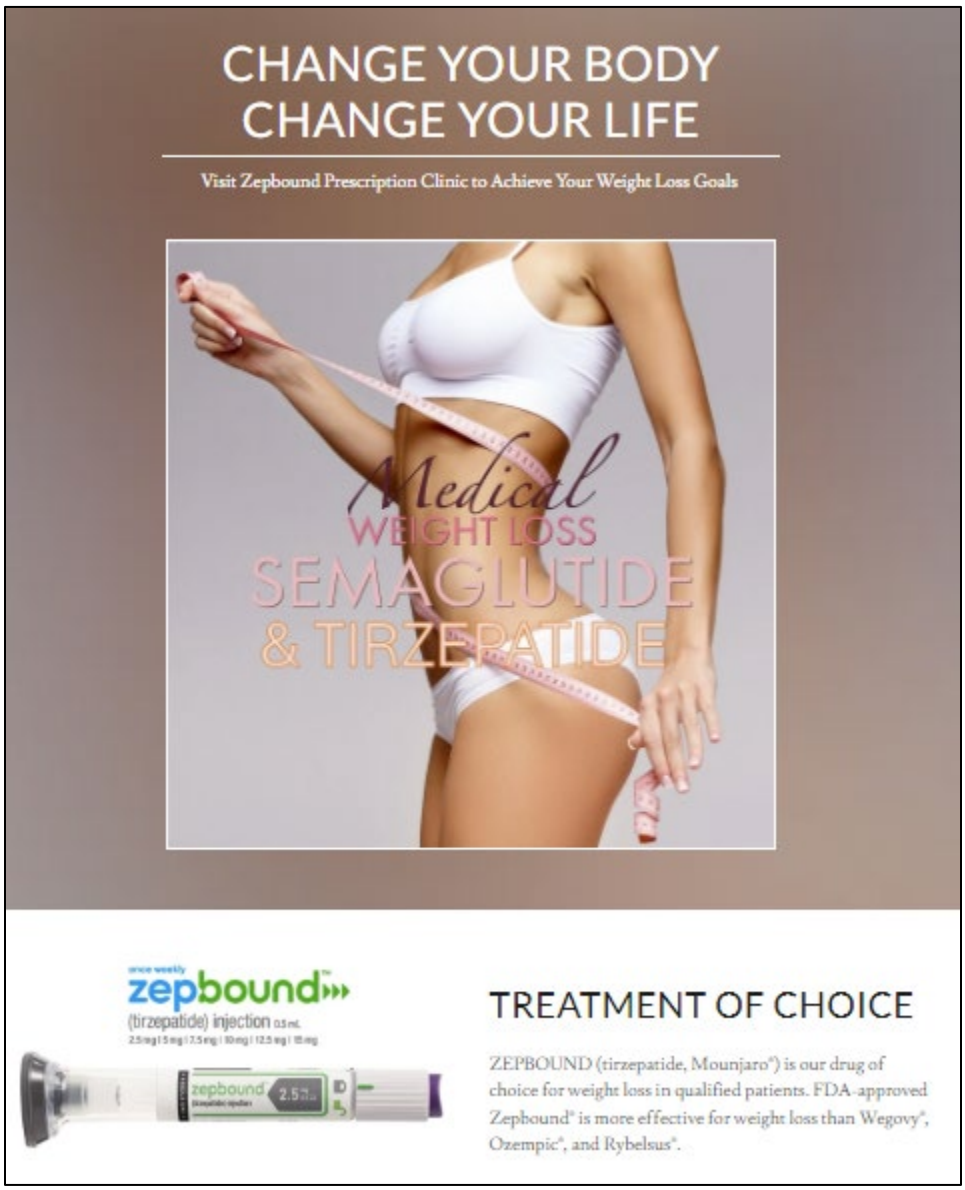
4. Compounded products sold as "tirzepatide," meanwhile, are not approved or even reviewed by the FDA. Pharmacies currently offering compounded versions of tirzepatide are not required to follow the FDA's "good manufacturing practices," nor to comply with the same controls on sterility and safe storage 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 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 with one of its website domain names—"zepboundclinic.com"—which it uses to lure patients

looking for ZEPBOUND® to Defendant's business. Defendant further holds itself out to the public as "Zepbound Rx Clinic" or "Zepbound Prescription Clinic."

7. When patients arrive at the Zepbound Rx Clinic website, the deception continues. Defendant's website describes "ZEPBOUND (tirzepatide, Mounjaro®)" as a "treatment of choice," and includes a picture of Lilly's ZEPBOUND® autoinjector pen, as shown below.



8. But in another section of this homepage titled "TIRZEPATIDE COMPOUNDED EXCLUSIVELY FOR OUR PATIENTS," Defendant displays the following image:

9. The vial depicted, which purports to be a compounded product containing tirzepatide, is labeled "(MOUNJARO) FOR WEIGHT LOSS" in a blatant attempt to associate Defendant's unapproved compounded drug with genuine Lilly MOUNJARO®. But genuine MOUNJARO® is not a compounded drug, nor is it indicated "for weight loss."

10. Lilly therefore brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and for violation of California's statutory and common law regarding unfair and deceptive competition. Lilly's claims arise out of Defendant's infringement of Lilly's rights in the MOUNJARO® and ZEPBOUND® trademarks and

Defendant's acts of cybersquatting, false designation of origin, false advertising, and unfair competition.

THE PARTIES

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

12. Defendant is a California corporation with a principal place of business at 8690 Center Drive, La Mesa, California 91942 in this District. Its sole registered agent and owner is Charles J. Sarosy, with registered agent address 8690 Center Drive, La Mesa, California 91942. Defendant additionally does business as Zepbound Prescription Clinic, Zepbound Rx Clinic, and San Diego Body Contouring.

13. Defendant also does business using the domain names "zepboundclinic.com" and "sdbodycontouring.com."

JURISDICTION AND VENUE

14. 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).

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

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

16. 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.*

17. 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.

18. 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).

19. 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.

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

21. 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.*

22. 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.

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

25. 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.

26. 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.

27. 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.

28. 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 **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.

29. 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.

30. 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.

31. 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

32. 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").

33. 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.

34. 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).

35. 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).

36. 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).

37. 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).

38. 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. *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries. 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. *See* hhttps://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.*

39. 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).

40. 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.

41. 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

42. 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.

43. 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).

44. 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).

45. 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.*

46. 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).

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

48. 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.

49. 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" and/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.

50. 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.

51. Defendant also passes off as "Mounjaro" its own Unapproved Compounded Drugs for a use for which is not approved or indicated, namely weight loss.

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

53. An example of Defendant's unauthorized use of the Lilly Marks, on the homepage of one of Defendant's websites (https://zepboundclinic.com/), is shown below. This same banner appears on ***every page*** on this website.

54. As the image shows, Defendant equates its Unapproved Compounded Drugs with "Zepbound." Defendant further holds itself out to the public as

"Zepbound Rx Clinic" and "Zepbound Prescription Clinic" despite having no affiliation with or license from Lilly, the owner of the exclusive right to use the ZEPBOUND® mark.

55. At the top of the homepage of Defendant's zepboundclinic.com website, just below the "Zepbound Rx Clinic" banner, Defendant invites users to "Visit Zepbound Prescription Clinic to Achieve Your Weight Loss Goals," again unauthorizedly associating itself with Lilly's ZEPBOUND® mark. Defendant even includes a picture of Lilly's patented Zepbound autoinjector pen.

56. Further down the homepage, in a section entitled "TIRZEPATIDE COMPOUNDED EXCLUSIVELY FOR OUR PATIENTS," Defendant displays an image of a vial produced by Thrive Health Solutions, as shown below:

57. Thrive Health Solutions describes this product as a "Generic form of Mounjaro and ZepBound." https://thrivecolorado.com/services/weight-loss-clinic-in-denver/tirzepatide-in-denver/. But there are ***no*** FDA-approved "generic" versions of

either MOUNJARO® and ZEPBOUND® available in the United States. Rather, this is an Unapproved Compounded Drug.

58. Moreover, the bottle in the image is labeled "TIRZEPATIDE (MOUNJARO) FOR WEIGHT LOSS." Not only does this label convey to consumers that the product being sold is the same as Lilly's MOUNJARO® when it is not, but also the bottle conveys that MOUNJARO® has been approved for weight loss when it has not.

59. From the homepage of zepboundclinic.com website, if a user clicks on the button labeled "Contact Us California," the user is directed to a page titled "About Us." https://zepboundclinic.com/contact-us-california. This page provides contact information for ZEPBOUND Rx CLINIC (San Diego Body Contouring). The address listed is Defendant's principal place of business.

60. The webpage further identifies Dr. Charles J. Sarosy, M.D. as the owner of "Zepbound Rx Clinic in San Diego, California." If a user clicks on the button labeled "About Dr. Sarosy," the user is directed to "sdbodycountouring.com/contact/dr-charles-sarosy." The phone number listed at the top right corner of this webpage matches the one provided on the "Contact Us California" page of "zepboundclinic.com."

61. On the San Diego Body Contouring website (sdbodycontouring.com), if a user then hovers over the heading labelled "MED SPA" and selects "Tirzepatide" from the drop-down menu, they will arrive at a page titled "Tirzepatide Injections in La Mesa." This page advertises "Tirzepatide injections in La Mesa for men and women who are looking to achieve a slimmer and healthier physique." On information and belief, the "tirzepatide injections" being offered are not genuine Lilly MOUNJARO® or ZEPBOUND® but are Unapproved Compounded Drugs made by compounding pharmacies, including Thrive Health Solutions.

62. Defendant also falsely advertises its Unapproved Compounded Drugs 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.

63. For example, Defendant's sdbodycountouring.com website states that "When looking at the data from research studies, it was found that Tirzepatide was much more potent and could result in greater fat loss compared to" another GLP-1 agonist. The following sentence links to an article that analyzed results from Lilly's SURMOUNT-1 clinical trial. The SURMOUNT® clinical trials studied ***Lilly's*** tirzepatide formulation and have no bearing on the Unapproved Compounded Drugs sold by Defendant.

64. Defendant's false advertising extends to social media as well. For example, Defendant's website has embedded in it a YouTube video titled "Instructional Video on Semaglutide & Tirzepatide Injections." https://www.youtube.com/watch?v=TMviq9606Eg. In the video, Dr. Sarosy, Defendant's agent and identified owner, shows the product that Defendant offers, which is obviously not the ZEPBOUND® autoinjector pen advertised on the Zepbound Prescription Clinic website and produced by Lilly, as shown below:

65. Moreover, in a Facebook post on May 1, 2024 shown below, Defendant advertises "tirzepatide" "Starting @ $119 a week." Immediately below this, Defendant claims to offer the "Newest FDA approved weightloss [*sic*] injections." On information and belief, these statements are false and misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** "FDA approved."

66. Defendant's online presence conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or otherwise FDA-approved weight loss injections containing tirzepatide that are the same as, or have 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. Moreover, there are ***no*** "generic" versions of either MOUNJARO® and ZEPBOUND®.

67. 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 good will Lilly generated around the Lilly Marks.

68. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** MOUNJARO® or ZEPBOUND®, are ***not*** "FDA approved," and were ***not*** subjected to clinical trials, and therefore lack any "data from research studies."

69. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website and social media channels, 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.

70. 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.

71. 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.

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

73. 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.

74. 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.

DEFENDANT'S CYBERSQUATTING

75. Upon information and belief, on November 8, 2023—the very day that the FDA approved Lilly's ZEPBOUND® medicine—Defendant registered the domain name "zepboundclinic.com." This was long after Lilly first applied to register the ZEPBOUND® mark (on April 14, 2022) on an intent-to-use basis.

76. Because Lilly filed its application to register the ZEPBOUND® mark before Defendant registered the domain name "zepboundclinic.com," Lilly has priority.

77. Upon information and belief, when Defendant registered the domain name "zepboundclinic.com," Defendant took steps to conceal Defendant's ownership of the domain name. For example, Defendant used a proxy server to register the domain name, as seen in publicly available WHOIS data. https://whois.domaintools.com/zepboundclinic.com (WHOIS data for "zepboundclinic.com"). A true and correct copy of WHOIS data for "zepboundclinic.com" is attached hereto as **Exhibit C**.

78. The domain name used by Defendant includes Lilly's ZEPBOUND® mark in its entirety and is intended to falsely suggest that Defendant's business is associated with Lilly and/or Lilly's ZEPBOUND® medicine.

79. Despite Defendant's use of the domain name "zepboundclinic.com," and the use of the Lilly Marks on Defendant's website, Defendant is not affiliated with Lilly in any way. Indeed, Lilly has not authorized Defendant to use the ZEPBOUND® trademark in any way.

80. Defendant's registration of the domain name "zepboundclinic.com" was a bad faith attempt by Defendant to trade on Lilly's reputation and goodwill and profit from Lilly's rights in the ZEPBOUND® trademark.

HARM TO THE PEOPLE OF CALIFORNIA AND LILLY

81. 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.

82. 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.

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

84. Not only does this deceitful content expose the people of California 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

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

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

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

92. 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

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

94. 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.

95. 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.

96. 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).

97. 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.

98. 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.

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

100. 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)

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

102. 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).

103. 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.

104. 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.

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

106. 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.

107. 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.

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

109. 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
Cybersquatting
in Violation of 15 U.S.C. § 1125(d)

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

111. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks as well as a federal trademark registration for the ZEPBOUND® mark.

112. Lilly has not authorized Defendant to use the Lilly Marks as a portion of an Internet domain name.

113. Defendant is the domain name registrant for the domain name "zepboundclinic.com," which Defendant uses to redirect consumers to Defendant's website.

114. Defendant's domain name "zepboundclinic.com" includes the ZEPBOUND® mark in its entirety, coupled with a word indicating a facility where patients receive medical care and treatment.

115. The domain name "zepboundclinic.com" used by Defendant is confusingly similar to Lilly's ZEPBOUND® mark.

116. Defendant's registration and use of the domain name "zepboundclinic.com" commenced long after Lilly first filed an application to register the ZEPBOUND® mark, indicating Lilly's intent to use the ZEPBOUND® mark in commerce. When the FDA approved ZEPBOUND® on November 8, 2023, the U.S. PTO records already reflected the ZEPBOUND® mark's affiliation with Lilly. Defendant therefore had actual and/or constructive knowledge of Lilly's rights prior to its registration and use of the domain name "zepboundclinic.com," which

demonstrates Defendant's bad faith intent to profit from Lilly's ZEPBOUND® mark, goodwill, and reputation.

117. Defendant's acts are willful and malicious.

118. Defendant's registration and use of the "zepboundclinic.com" domain name constitutes cybersquatting in violation of 15 U.S.C. § 1125(d), entitling Lilly to relief.

119. Unless the "zepboundclinic.com" domain name registration is forfeited, canceled, or transferred to Lilly, Defendant will in fact profit, as described above. Lilly's remedy at law is not adequate to compensate it for the injuries inflicted by Defendant by its acts of cybersquatting. Lilly is therefore entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

120. By reason of Defendant's acts of cybersquatting alleged herein, Lilly is entitled to recover Defendant's profits and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "zepboundclinic.com" domain name to Lilly.

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

122. Lilly is entitled to injunctive relief and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "zepboundclinic.com" domain name to Lilly, as well as other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, reasonable attorneys' fees, costs, and prejudgment interest.

FIFTH CAUSE OF ACTION
False and Misleading Advertising in Violation of Cal. Bus. & Prof. Code § 17500

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

124. Defendant's commercial advertising claims described herein are false and misleading in violation of Cal. Bus. & Prof. Code § 17500.

125. Defendant has knowingly made false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs and related goods and services addressed to the public and a substantial number of consumers. These statements regarding Unapproved Compounded Drugs' safety, quality, effectiveness, and regulatory status have influenced and are likely to continue to influence consumers' purchasing decisions.

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

127. As a direct and proximate result of Defendant's false and misleading advertising 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 by a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks.

128. By reason of Defendant's acts, Lilly has been injured and is thereby entitled to the recovery of damages.

129. Because Defendant has violated and continues to violate § 17500, Lilly is entitled to entry of preliminary and permanent injunctive relief, including disgorgement of Defendant's unjustly obtained profits from the sale of its Unapproved Compounded Drugs and related goods and services.

SIXTH CAUSE OF ACTION
Unlawful, Unfair, and Fraudulent Business Practices in Violation of Cal. Bus. & Prof. Code § 17200 *et seq.*

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

131. The above-described acts of Defendant constitute unlawful, unfair, and fraudulent business practices in violation of Cal. Bus. & Prof. Code § 17200 *et seq*. ("UCL").

132. 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.

133. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute unlawful, unfair, and deceptive trade practices with respect to the Lilly Marks, in violation of the UCL.

134. 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.

135. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs.

136. Defendant's business practices are unlawful because independently actionable under the Lanham Act and California's false advertising law.

137. Defendant's business practices are unfair because they are immoral, unethical, oppressive, unscrupulous and substantially injurious to consumers.

138. Defendant's business practices are fraudulent because members of the public are likely to be deceived.

139. 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.

140. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

141. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief as provided in Cal. Bus. & Prof. Code §§ 17203 and 17535, and other appropriate relief, including attorneys' fees pursuant to CCP § 1021.5.

SEVENTH CAUSE OF ACTION
Trademark Infringement and Unfair Competition in Violation of California Common Law

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

143. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of California common law.

144. 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®.

145. 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.

146. 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.

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

148. As a direct and proximate result of Defendant's trademark infringement and 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. Defendant therefore has unfairly profited from the actions alleged.

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

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 cybersquatting in violation of 15 U.S.C. § 1125(d);

e. Engaged in deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Cal. Bus. & Prof. Code §§ 17200 *et seq.* and § 17500 and in violation of the common law of California;

f. 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, cybersquatting, and unlawful, unfair, and fraudulent business practices.

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 requiring the forfeiture or cancellation of the "zepboundclinic.com" domain name and/or the transfer of the domain name to Plaintiff Lilly, together with any other domain names containing "mounjaro" or "zepbound" in Defendant's ownership, possession, or control.

8. An Order requiring that Defendant pay statutory damages under 15 U.S.C. § 1117(d), on election by Plaintiff Lilly.

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

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

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

12. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,
/s/ Sharre Lotfollahi

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DEMAND FOR A JURY TRIAL

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

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ELI LILLY AND COMPANY

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

ELI LILLY AND COMPANY, Plaintiff, vs. STUART LERNER M.D., LLC D/B/A “STUART LERNER, MD” AND UNREGISTERED TRADE NAME “MOUNJARO HAWAII”, Defendant.	CASE NO. _____ **COMPLAINT FOR TRADEMARK INFRINGEMENT, FALSE ADVERTISING, FALSE DESIGNATION OF ORIGIN, CYBERSQUATTING, AND DECEPTIVE TRADE PRACTICES; EXHIBITS A, B, AND C; DEMAND FOR JURY TRIAL**

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

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company’s (“Lilly”) FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant Stuart Lerner M.D., LLC d/b/a “Stuart Lerner, MD” and unregistered trade name “Mounjaro Hawaii” (“Defendant”) has designed its website 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

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[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.

"novel" MOUNJARO® an "important advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/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 or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

6. Defendant's intentional deception of patients starts with one of its website domain names—"mounjarohawaii.com"—which it uses to lure patients looking for MOUNJARO® to Defendant's website.

7. When patients arrive at Defendant's website, the deception continues. Defendant's website greets visitors at the top of its homepage with the bright red, highly conspicuous message below:

8. Despite this impossible-to-miss banner, Defendant offers neither MOUNJARO® nor ZEPBOUND®, nor any "generic" version of them. In fact, there is ***no such thing*** as "generic MOUNJARO®" or "generic ZEPBOUND®."

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

THE PARTIES

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

11. Defendant is a Hawai‘i limited liability company d/b/a Stuart Lerner, MD, with a principal place of business at 970 N Kalaheo Avenue, Suite C316, Kailua, Hawai‘i 96734, in this District. Its sole member and registered agent is Dr. Stuart D. Lerner, with registered agent address 2428 Burbank St., Honolulu, Hawai‘i 96817. Defendant also does business using the unregistered trade name "Mounjaro Hawaii" and the domain names "dr-lerner.com" and "mounjarohawaii.com."

JURISDICTION AND VENUE

12. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and

1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

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

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

14. Lilly's MOUNJARO® is a novel treatment for type 2 diabetes, a chronic and progressive condition facing more than 30 million Americans. As the FDA has noted, "Despite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement). MOUNJARO® targets this problem head-on using an innovative active pharmaceutical ingredient, tirzepatide. Before it received FDA approval, Lilly's MOUNJARO® was clinically proven to improve blood sugar control "more effective[ly] than the other diabetes therapies with which it was compared in clinical studies." *Id.*

15. The FDA approved MOUNJARO® and indicated it in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

As part of the approval process, Lilly submitted data on safety, quality, and effectiveness collected through clinical trials involving thousands of patients. Lilly's MOUNJARO® is thus proven safe and effective when used as directed.

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

17. As with MOUNJARO®, the safety, quality, and effectiveness of ZEPBOUND® was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND® and indicated it for adults with obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 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.

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

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-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.*

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

21. Lilly now promotes, offers, and sells MOUNJARO® and ZEPBOUND® medicines in Hawai'i and throughout the United States.

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

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

24. Lilly is the owner of two federal trademark registrations for MOUNJARO®, U.S. Reg. Nos. 6,809,369 (issued August 2, 2022) and 7,068,463

(issued May 30, 2023). True and correct copies of Plaintiff Lilly's registrations for the MOUNJARO® mark are attached hereto as part of **Exhibit A.** Lilly additionally has several pending applications to register its MOUNJARO® mark in connection with more classes, services, and goods, including U.S. Trademark Ser. Nos. 97/596,856, 97/668,206, and 98/253,743. As a result of its use of the MOUNJARO® mark, Lilly also owns valuable common law and other rights in and to the MOUNJARO® mark.

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

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

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

28. Lilly promotes, advertises, and markets MOUNJARO® and ZEPBOUND® both to healthcare professionals and to patients, among others, through various channels, including on the websites mounjaro.com, mounjaro.lilly.com, zepbound.com, and zepbound.lilly.com, in social media, in online advertisements, and on television.

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

THE RISKS OF COMPOUNDING

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

31. Typically, prescription medicines must undergo a rigorous premarket approval process. Federal law creates a narrow exception for compounding, which the FDA defines as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision

of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/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.

32. The Food, Drug, and Cosmetic Act (FDCA), in section 503A, prescribes a rigid set of requirements that compounding pharmacies must meet, including a requirement that compounding occur only "on the prescription order that a compounded product is necessary for the identified patient." This restriction is important because compounding pharmacies are not required to comply with GMP, so they are only permitted to produce a small amount based on the specific needs of specific patients. The FDA has explained the importance of this requirement to ensure that compounding pharmacies "are not actually operating as conventional manufacturers":

> The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A, [including that] compounding is for an identified individual patient, drugs compounded

> in advance of receiving prescriptions are compounded only in limited quantities, and drugs are distributed pursuant to a valid patient-specific prescription. These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry).

33. As the FDA further explained, "The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to []GMP requirements, are provided to a patient only based on individual patient need." *Id.* (emphasis in original).

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

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

Id. (emphasis added).

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

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/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.*

37. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events and at least 116 deaths. https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/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).

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

39. Consequences from compounded drugs may be deadly. In 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

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

41. The FDA, for example, has consistently and repeatedly raised its concerns with compounding generally and compounded incretins more specifically. https://www.fda.gov/media/97347/download (FDA prescription requirement compliance guidance for industry). The FDA specifically has targeted compounded tirzepatide as a threat to consumer safety. The Director of the FDA's

Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective. https://www.fda.gov/inspections-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).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-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).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/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.*

44. Doctors and patient groups recognize the problems with compounded incretins, and they are sharing their concerns, too. The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association, for example, issued a joint statement warning that when people use incretin "alternatives, you may not be getting what you hoped for. You may also get something you did not want (other

active substances have been found in some compounded versions)." https://www.obesityaction.org/wp-content/uploads/GLP-1-Compounded-Alternative-Statement_Final_Logos-1.pdf (joint statement from leading obesity expert organizations).

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

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

47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and 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," "ZEPBOUND," "GENERIC MOUNJARO," and/or "GENERIC ZEPBOUND." Defendant also operates under

the unregistered trade name "Mounjaro Hawaii" to sell Unapproved Compounded Drugs. Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

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

49. Defendant also passes off as "MOUNJARO" and/or "GENERIC MOUNJARO" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

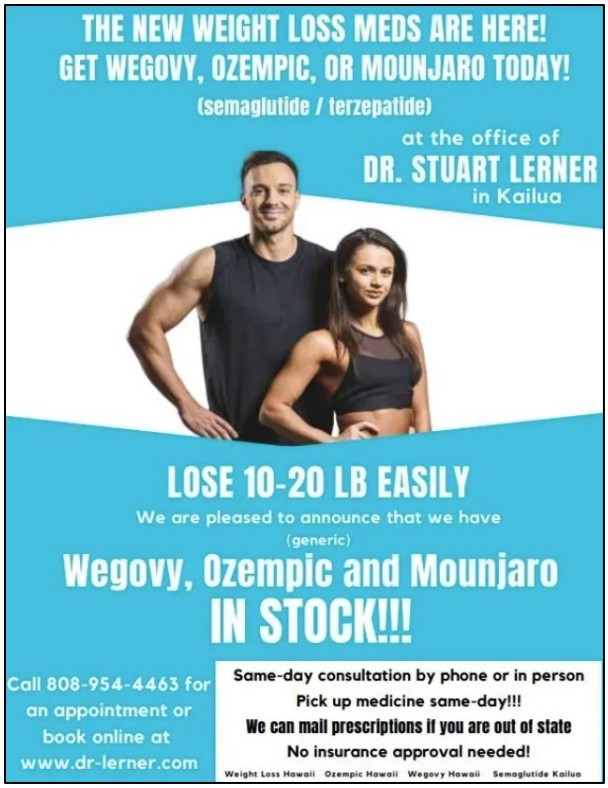
50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

51. An example of Defendant's unauthorized use of the Lilly Marks, on the homepage of Defendant's website (https://www.dr-lerner.com/), is shown below. This same banner appears on ***every page*** on Defendant's website.

52. As the image shows, Defendant promotes its Unapproved Compounded Drugs as "MOUNJARO," "ZEPBOUND," "GENERIC . . . MOUNJARO," and/or "GENERIC . . . ZEPBOUND."

53. From the homepage of Defendant's website, if a user clicks on the button labeled "Weight Loss Injections," the user is directed to a page titled "Weight Loss" that contains information about Defendant's Unapproved Compounded Drugs, including "MOUNJARO." The user can also navigate to this page by selecting "NEW Weight Loss Rx!!!" on Defendant's "About Services" page, or by clicking on the red banner shown above, which appears on every page of Defendant's website. The webpage also is available at https://www.dr-lerner.com/services/weight-loss.

54. On Defendant's "Weight Loss" webpage, Defendant claims to offer "generic Terzepatide [*sic*]" if a patient's MOUNJARO® prescription is not covered by insurance. Defendant further advertises the availability of "MOUNJARO . . . at the office of DR. STUART LERNER in Kailua," for sale in-state and around the country as shown below. In small text, the webpage adds that Defendant has "(generic) . . . Mounjaro"—which, again, does not exist.

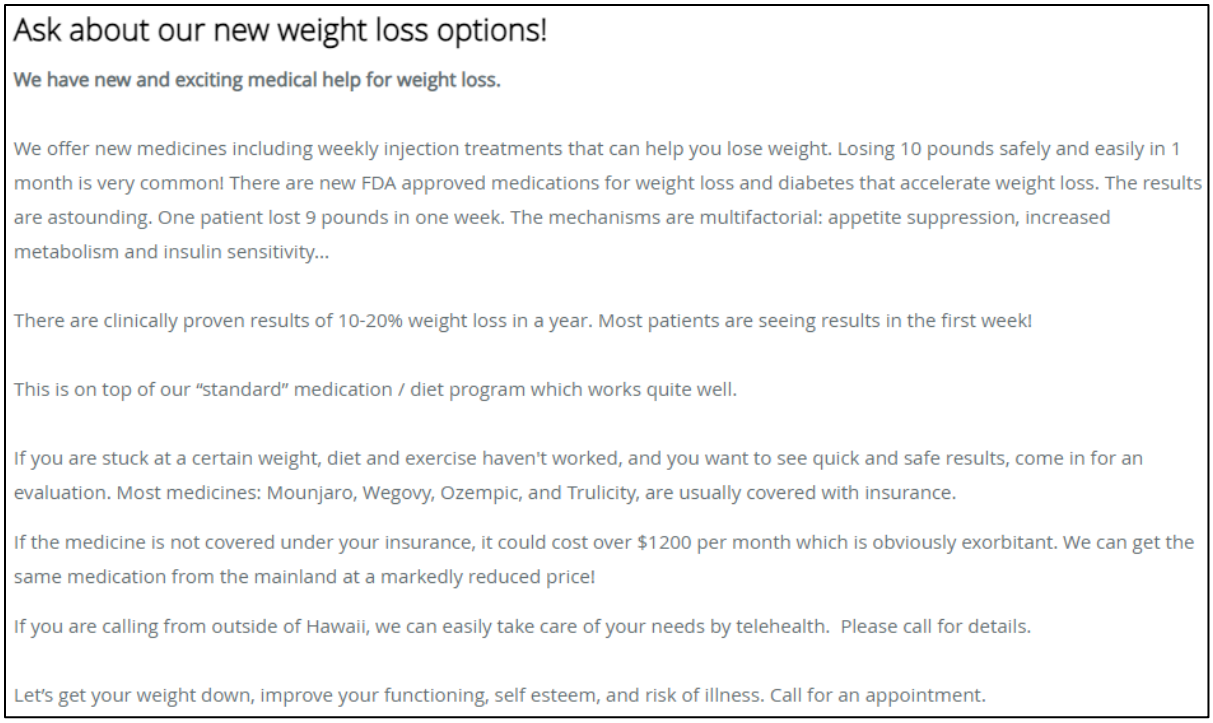


55. Defendant's website conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved generic version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine to Defendant for resale or redistribution. Moreover, there are ***no*** "generic" versions of either MOUNJARO® and ZEPBOUND®.

56. Defendant first started using the Lilly Marks to advertise its Unapproved Compounded Drugs long after Lilly had adopted them. Defendant's use can only have been intended to benefit from the goodwill Lilly generated around the Lilly Marks.

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

58. For example, as shown below, Defendant's "Weight Loss" webpage advertises that: "We offer new medicines including weekly injection treatments that can help you lose weight. Losing 10 pounds safely and easily in 1 month is very common! There are new FDA approved medications for weight loss and diabetes that accelerate weight loss. The results are astounding. One patient lost 9 pounds in one week. . . . There are clinically proven results of 10-20% weight loss in a year."



Ask about our new weight loss options!

We have new and exciting medical help for weight loss.

We offer new medicines including weekly injection treatments that can help you lose weight. Losing 10 pounds safely and easily in 1 month is very common! There are new FDA approved medications for weight loss and diabetes that accelerate weight loss. The results are astounding. One patient lost 9 pounds in one week. The mechanisms are multifactorial: appetite suppression, increased metabolism and insulin sensitivity...

There are clinically proven results of 10-20% weight loss in a year. Most patients are seeing results in the first week!

This is on top of our "standard" medication / diet program which works quite well.

If you are stuck at a certain weight, diet and exercise haven't worked, and you want to see quick and safe results, come in for an evaluation. Most medicines: Mounjaro, Wegovy, Ozempic, and Trulicity, are usually covered with insurance.

If the medicine is not covered under your insurance, it could cost over $1200 per month which is obviously exorbitant. We can get the same medication from the mainland at a markedly reduced price!

If you are calling from outside of Hawaii, we can easily take care of your needs by telehealth. Please call for details.

Let's get your weight down, improve your functioning, self esteem, and risk of illness. Call for an appointment.

59. 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*** subjected to clinical trials, and therefore are ***not*** "clinically proven" to achieve any results.

60. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, 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.

61. 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.

62. 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.

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

64. 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.

65. 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.

DEFENDANT'S CYBERSQUATTING

66. Upon information and belief, on May 7, 2023, Defendant registered the domain name "mounjarohawaii.com." This was long after Lilly first adopted and used the MOUNJARO® mark (at least as early as June 3, 2022) and long after Lilly became the owner of U.S. Trademark Reg. No. 6,809,369 (August 2, 2022). When Defendant registered the domain name "mounjarohawaii.com," Defendant took steps to make Defendant's ownership of the domain name private and not accessible to the public. For example, Defendant registered the domain using a proxy service called Domains by Proxy, LLC, which means Defendant's identifying information does not appear in publicly available WHOIS data. https://whois.domaintools.com/mounjarohawaii.com (WHOIS data for "mounjarohawaii.com"). A true and correct copy of WHOIS data for "mounjarohawaii.com" is attached hereto as **Exhibit C**.

67. The domain name used by Defendant includes Lilly's MOUNJARO® mark in its entirety and is intended to falsely suggest that Defendant's business is associated with Lilly and/or Lilly's MOUNJARO® medicine.

68. Despite Defendant's use of the domain name "mounjarohawaii.com," and the use of the Lilly Marks on Defendant's website, Defendant is not affiliated with Lilly in any way. Indeed, Lilly has not authorized Defendant to use the MOUNJARO® trademark in any way.

69. Defendant's registration of the domain name "mounjarohawaii.com" was a bad faith attempt by Defendant to trade on Lilly's reputation and goodwill and to profit from Lilly's rights in the MOUNJARO® trademark.

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

73. Not only does this deceitful content expose the people of Hawai'i 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
Cybersquatting
in Violation of 15 U.S.C. § 1125(d)

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

100. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks as well as federal trademark registrations for the MOUNJARO® mark.

101. Lilly has not authorized Defendant to use the Lilly Marks as a portion of an Internet domain name.

102. Defendant is the domain name registrant for the domain name "mounjarohawaii.com," which Defendant uses to redirect consumers to Defendant's website.

103. Defendant's domain name "mounjarohawaii.com" includes the MOUNJARO® mark in its entirety, coupled with the name of the state in which Defendant operates: "Hawaii."

104. The domain name "mounjarohawaii.com" used by Defendant is confusingly similar to Lilly's MOUNJARO® mark.

105. Defendant's registration and use of the domain name "mounjarohawaii.com" commenced long after Lilly first adopted and used the MOUNJARO® mark and became the owner of U.S. Trademark Reg. No. 6,809,369 for the MOUNJARO® mark. Defendant therefore had actual and/or constructive knowledge of Lilly's rights prior to its registration and use of the domain name "mounjarohawaii.com," which demonstrates Defendant's bad faith intent to profit from Lilly's MOUNJARO® mark, goodwill, and reputation.

106. Defendant's acts are willful and malicious.

107. Defendant's registration and use of the "mounjarohawaii.com" domain name constitutes cybersquatting in violation of 15 U.S.C. § 1125(d), entitling Lilly to relief.

108. Unless the "mounjarohawaii.com" domain name registration is forfeited, canceled, or transferred to Lilly, Defendant will in fact profit, as described above. Lilly's remedy at law is not adequate to compensate it for the injuries inflicted by Defendant by its acts of cybersquatting. Lilly is therefore entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

109. By reason of Defendant's acts of cybersquatting alleged herein, Lilly is entitled to recover Defendant's profits and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "mounjarohawaii.com" domain name to Lilly.

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

111. Lilly is entitled to injunctive relief and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "mounjarohawaii.com" domain name to Lilly, as well as other remedies provided

by Sections 1116, 1117, and 1118, including Defendant's profits, reasonable attorneys' fees, costs, and prejudgment interest.

FIFTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of Haw. Rev. Stat. § 481A–1 *et seq*.

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

113. The above-described acts of Defendant constitute deceptive trade practices in violation Haw. Rev. Stat. ("HRS") § 481A–1 *et seq*.

114. Among other things, HRS § 481A-3 defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (1) Passes off goods or services as those of another;
>
> (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
>
> * * *
>
> (5) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
>
> * * *
>
> (9) Advertises goods or services with intent not to sell them as advertised;
>
> * * *
>
> (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

115. As set forth herein, Defendant's actions fit within the scope of HRS § 481A-3.

116. 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.

117. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of Haw. Rev. Stat. § 481A–1 *et seq*.

118. 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 with the intent to deceive.

119. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's

Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

120. 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.

121. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

122. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief. In addition, Lilly is entitled to attorneys' fees and costs.

SIXTH CAUSE OF ACTION
Unfair and Deceptive Methods of Competition in Violation of Haw. Rev. Stat. § 480–1 *et seq.*

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

124. Defendant's acts constitute unfair and deceptive methods of competition, in violation of the laws of the State of Hawai'i, including Haw. Rev. Stat. § 480–1 *et seq*.

125. HRS § 480-2(a) states that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful."

126. Plaintiff is a "person" within the meaning of HRS § 480-1 and has standing to bring an action based on unfair competition under HRS § 480-2(e).

127. Defendant's acts wrongfully, immorally, unethically, oppressively and unscrupulously exploit the Lilly Marks in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public and reasonable consumers. These acts therefore offend the established public policy of the State of Hawai'i.

128. Defendant's acts include wrongfully, immorally, unethically, oppressively and unscrupulously making false or misleading representations in its advertising and promotional materials in a material manner likely to deceive and mislead, and therefore be substantially injurious to, the public and reasonable consumers. These acts therefore offend the established public policy of the State of Hawai'i.

129. Lilly and Defendant are competitors, and Defendant's misconduct has affected competition in the State of Hawai'i, as well as elsewhere. Defendant's acts are made in the conduct of Defendant's business, trade, or commerce.

130. Members of the public are also likely to suffer injury from Defendant's acts by purchasing Defendant's Unapproved Compounded Drugs that they believe to be Lilly's MOUNJARO® or ZEPBOUND® because Defendant advertises, promotes, and markets its Unapproved Compounded Drugs as an alternative to Lilly's MOUNJARO® or ZEPBOUND®.

131. Lilly, too, has suffered injury from Defendant's acts where patients have purchased Defendant's Unapproved Compounded Drugs that they believe to be Lilly's MOUNJARO® or ZEPBOUND®, including to the extent patients have associated any adverse events or other consequences of taking Defendant's Unapproved Compounded Drugs with Lilly or the Lilly Marks.

132. As a direct and proximate result of Defendant's unfair and deceptive methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

133. By reason of Defendant's acts, Lilly's remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Lilly is

entitled to entry of preliminary and permanent injunctive relief, in addition to treble damages, attorneys' fees, and costs.

SEVENTH CAUSE OF ACTION
Trademark Infringement and Unfair Competition in Violation of Hawai‘i Common Law

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

135. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Hawai‘i common law.

136. 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®.

137. 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.

138. 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.

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

140. As a direct and proximate result of Defendant's trademark infringement and 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. Defendant therefore has unfairly profited from the actions alleged.

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

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 cybersquatting in violation of 15 U.S.C. § 1125(d);

e. Engaged in deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Haw. Rev. Stat. §§ 481A–1 *et seq*. and § 480–1 *et seq.* and in violation of the common law of Hawai‘i;

f. 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. Using or otherwise doing business under the trade name "Mounjaro Hawaii";

d. Engaging in any unfair competition with Plaintiff Lilly; and

e. 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, cybersquatting, and unfair and deceptive trade practices;

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 requiring the forfeiture or cancellation of the "mounjarohawaii.com" domain name and/or the transfer of the domain name to Plaintiff Lilly, together with any other domain names containing "mounjaro" or "zepbound" in Defendant's ownership, possession, or control;

8. An Order requiring that Defendant pay statutory damages under 15 U.S.C. § 1117(d), on election by Plaintiff Lilly;

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

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

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

12. Other relief as the Court may deem appropriate.

DATED: Honolulu, Hawai‘i, June 19, 2024.

/s/ Ross T. Shinyama
JOYCE W.Y. TAM-SUGIYAMA
ROSS T. SHINYAMA
RIHUI YUAN
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JOSHUA L. SIMMONS (*pro hac vice* forthcoming)
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Attorneys for Plaintiff
ELI LILLY AND COMPANY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

ELI LILLY AND COMPANY,

Plaintiff,

v.

WELLNESS & HEALTH CARE COST CONSULTANTS, LLC D/B/A METABOLIC MD D/B/A UNREGISTERED TRADE NAME "MOUNJARO DOCTOR"

Defendant.

Case No. 1:24-cv-333

JURY TRIAL DEMANDED

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

INTRODUCTION

1. This is an action to protect patients from unstudied, unapproved, and unsafe drugs masquerading as Plaintiff Eli Lilly and Company's ("Lilly") FDA-approved medicines for adults with type 2 diabetes, obesity, or excess weight and weight-related medical problems. Defendant Wellness & Health Care Cost Consultants, LLC d/b/a Metabolic MD d/b/a Unregistered Trade Name "Mounjaro Doctor" ("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.

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[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.

When approving these medicines, the FDA called Lilly's "novel" MOUNJARO® an "important advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/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 or generic versions thereof. But Defendant does not offer Lilly's proprietary MOUNJARO® and ZEPBOUND® medicines, nor any FDA-approved "generic" version of them. Indeed, Defendant's drugs have undergone ***none*** of the rigorous studies or approval processes

that Lilly's medicines have. Passing Defendant's compounded drugs off as Lilly's MOUNJARO® and ZEPBOUND® is not merely deceptive—it's dangerous.

6. Defendant's intentional deception is evident from its registration of the domain names "mounjarodr.com" and "mounjarodoctor.com," both of which redirect to Defendant's website, "https://www.metabolicmds.com."

7. Once a prospective patient is lured in to Defendant's website and navigates to its "GLP-1 Tirzepatide" webpage, they are greeted by the graphic shown below, which prominently includes (1) a picture of a MOUNJARO® autoinjector pen alongside (2) a bottle labeled "Tirzepatide 20mg" that is further labeled as "Generic Mounjaro®" and "FDA Approved."

8. Despite this impossible-to-miss advertisement, Defendant does ***not*** offer Lilly's in MOUNJARO® in autoinjector or any other form. Moreover, the contents of the vial ***cannot*** by "Generic Mounjaro®," because no such thing exists. Nor can it be "FDA Approved," because Lilly is the only source for FDA-approved products containing the active pharmaceutical ingredient tirzepatide, and this vial is not a Lilly product. And to top it all off, Defendant is offering its alleged tirzepatide product in a dosage that not even Lilly's FDA-approved medicines are offered in. Far from "FDA Approved," Defendant's product is unstudied, unapproved, and unsafe.

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

THE PARTIES

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

11. Defendant is an Ohio limited liability company d/b/a Metabolic MD d/b/a Unregistered Trade Name "Mounjaro Doctor," with a principal place of business at 1108 Paxon Court, Bellbrook, Ohio, 45305 in this District. Its registered agent is Paul W. Kolodzik with registered agent address at 1108 Paxon Court, Bellbrook, Ohio, 45305.

12. Defendant also does business using the domain names "https://www.metabolicmds.com," "https://www.mounjarodoctor.com," and "https://www.mounjarodr.com."

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

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

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 Ohio 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 the same as "Mounjaro" or as "generic Mounjaro."

Defendant also operates under the unregistered trade name "Mounjaro Doctor" to sell Unapproved Compounded Drugs. Defendant's unlawful use of the Lilly Marks can only be intended to deceptively lure in patients in pursuit of revenues and profits.

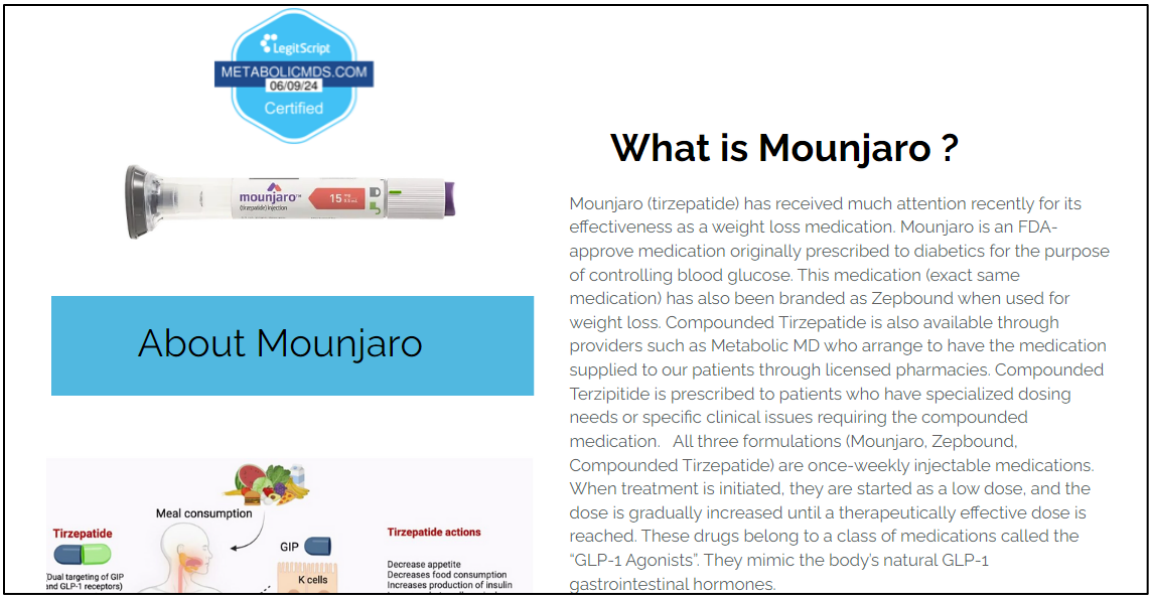
49. Because Defendant is not offering genuine MOUNJARO® or ZEPBOUND®, Lilly has no control over the safety, quality, or effectiveness of the Unapproved Compounded Drugs sold by Defendant.

50. Defendant also passes off as "Mounjaro" or "Generic Mounjaro®" its own Unapproved Compounded Drugs for a use for which it is not approved or indicated, namely "weight loss."

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

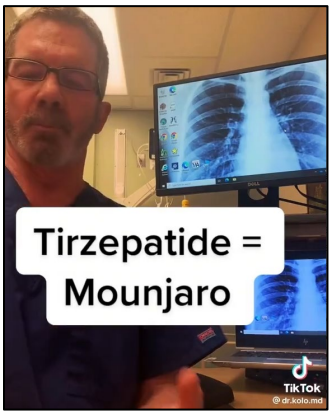
52. One example, shown above as well as repeated below, is Defendant's use of the MOUNJARO® autoinjector pen, when Defendant does not in fact offer this medicine.

53. In fact, Defendant's entire "GLP-1 Tirzepatide" webpage appears intended to convince prospective patients they will be receiving Lilly's MOUNJARO®. Just below this autoinjector pen graphic, Defendant includes the following explanatory text and pictures:



54. As the image shows, Defendant promotes its Unapproved Compounded Drugs by describing MOUNJARO®, repeatedly showing Lilly's MOUNJARO® autoinjector pen, and purporting to tell patients all about Mounjaro—when Defendant actually sells "Compounded Tirzepatide," as only a patient reading the fine print will discover.

55. Defendant's promotion of its Unapproved Compounded Drugs by using the Lilly Marks is also evident on social media. In the excerpt from one of Defendant's TikTok videos, which Defendant posted to Instagram as well, Defendant notes in a bold caption that "Tirzepatide = Mounjaro." Tirzepatide is an ***ingredient*** in MOUNJARO®, but they are not the same thing.

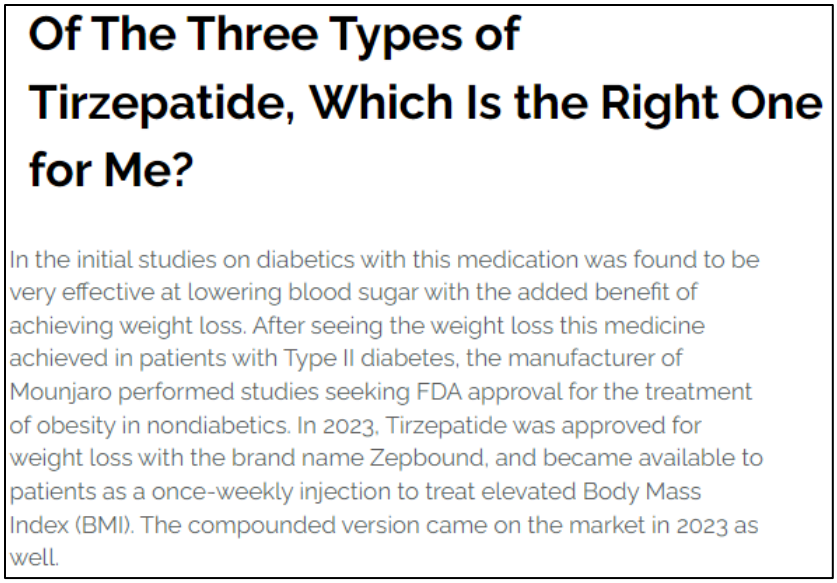


56. Defendant's social media and website convey the unmistakable impression that Defendant is offering for sale a product that either is, has the same source as, or is the same as, Lilly's MOUNJARO® and ZEPBOUND®. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, 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 "GLP-1 Tirzepatide" webpage includes a description of "Three Types of Tirzepatide" that describes ***Lilly's*** clinical trial results, ***Lilly's*** FDA approvals, and ***Lilly's*** manufacturing. Only at the end of the paragraph does Defendant described the alleged third type of tirzepatide, a "compounded version," which defendant does without clarifying that it is—unlike the two medications presented before it—unstudied, unapproved, and not made by Lilly. The text in this paragraph even appears twice on Defendant's "GLP-1 Tirzepatide" webpage, despite its misleading content.



Of The Three Types of Tirzepatide, Which Is the Right One for Me?

In the initial studies on diabetics with this medication was found to be very effective at lowering blood sugar with the added benefit of achieving weight loss. After seeing the weight loss this medicine achieved in patients with Type II diabetes, the manufacturer of Mounjaro performed studies seeking FDA approval for the treatment of obesity in nondiabetics. In 2023, Tirzepatide was approved for weight loss with the brand name Zepbound, and became available to patients as a once-weekly injection to treat elevated Body Mass Index (BMI). The compounded version came on the market in 2023 as well.

60. Upon information and belief, these statements are false and/or misleading as to Defendant's Unapproved Compounded Drugs, which are ***not*** "generic MOUNJARO®," are ***not*** "FDA approved," were ***not*** subjected to clinical trials, and therefore are ***not*** "clinically proven" to achieve any results.

61. 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.

62. 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.

63. 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.

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

65. 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.

66. 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.

DEFENDANT'S CYBERSQUATTING

67. Upon information and belief, on June 14, 2022, Defendant registered the domain names "mounjarodr.com" and "mounjarodoctor.com." This was after Lilly first adopted and used the MOUNJARO® mark (at least as early as June 3, 2022).

68. When Defendant registered the domain names "mounjarodr.com" and "mounjarodoctor.com," Defendant took steps to make Defendant's ownership of the domain

name private and not accessible to the public. For example, Defendant registered the domain using a proxy service called Domains by Proxy, LLC, which means Defendant's identifying information does not appear in publicly available WHOIS data. https://whois.domaintools.com/mounjarodr.com (WHOIS data for "mounjarodr.com"); https://whois.domaintools.com/mounjarodoctor.com (WHOIS data for "mounjarodoctor.com"). True and correct copies of the WHOIS data for each of these domain names are attached hereto as part of **Exhibit C**.

69. The domain names used by Defendant include Lilly's MOUNJARO® mark in its entirety and are intended to falsely suggest that Defendant's business is associated with Lilly and/or Lilly's MOUNJARO® medicine.

70. Despite Defendant's use of the domain names "mounjarodr.com" and "mounjarodoctor.com," and the use of the Lilly Marks on Defendant's website, Defendant is not affiliated with Lilly in any way. Indeed, Lilly has not authorized Defendant to use the MOUNJARO® trademark in any way.

71. Defendant's registration of the domain names "mounjarodr.com" and "mounjarodoctor.com" was a bad faith attempt by Defendant to trade on Lilly's reputation and goodwill and to profit from Lilly's rights in the MOUNJARO® trademark.

HARM TO THE PEOPLE OF OHIO AND LILLY

72. 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.

73. 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.

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

75. Not only does this deceitful content expose the people of Ohio 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

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

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

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

83. 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

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

85. 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.

86. 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.

87. 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).

88. 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.

89. 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.

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

91. 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)

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

93. 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).

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

95. 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.

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

97. 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.

98. 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.

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

100. 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
Cybersquatting
in Violation of 15 U.S.C. § 1125(d)

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

102. Lilly is the owner of all right, title, and interest in the inherently distinctive Lilly Marks as well as federal trademark registrations for the MOUNJARO® mark.

103. Lilly has not authorized Defendant to use the Lilly Marks as a portion of an Internet domain name.

104. Defendant is the domain name registrant for the domain names "mounjarodr.com" and "mounjarodoctor.com," which Defendant uses to redirect consumers to Defendant's website.

105. Defendant's domain names "mounjarodr.com" and "mounjarodoctor.com" include the MOUNJARO® mark in its entirety, coupled with the name of the word "doctor" or abbreviation "dr," implying that Defendant is medically associated with MOUNJARO®.

106. The domain names "mounjarodr.com" and "mounjarodoctor.com" used by Defendant are confusingly similar to Lilly's MOUNJARO® mark.

107. Defendant's registration and use of the domain names "mounjarodr.com" and "mounjarodoctor.com" commenced after Lilly first adopted and used the MOUNJARO® mark. Defendant therefore had actual and/or constructive knowledge of Lilly's rights prior to its

registration and use of the domain names "mounjarodr.com" and "mounjarodoctor.com," which demonstrates Defendant's bad faith intent to profit from Lilly's MOUNJARO® mark, goodwill, and reputation.

108. Defendant's acts are willful and malicious.

109. Defendant's registration and use of the "mounjarodr.com" and "mounjarodoctor.com" domain names constitutes cybersquatting in violation of 15 U.S.C. § 1125(d), entitling Lilly to relief.

110. Unless the names "mounjarodr.com" and "mounjarodoctor.com" domain name registrations are forfeited, canceled, or transferred to Lilly, Defendant will in fact profit, as described above. Lilly's remedy at law is not adequate to compensate it for the injuries inflicted by Defendant by its acts of cybersquatting. Lilly is therefore entitled to preliminary and permanent injunctive relief pursuant to 15 U.S.C. § 1116.

111. By reason of Defendant's acts of cybersquatting alleged herein, Lilly is entitled to recover Defendant's profits and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "mounjarodr.com" and "mounjarodoctor.com" domain names to Lilly.

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

113. Lilly is entitled to injunctive relief and Lilly's actual damages, or, at Lilly's election, an award of statutory damages under 15 U.S.C. § 1117(d); the costs of this action; and an order of the Court transferring the "mounjarodr.com" and "mounjarodoctor.com" domain names to Lilly, as well as other remedies provided by Sections 1116, 1117, and 1118, including Defendant's profits, reasonable attorneys' fees, costs, and prejudgment interest.

FIFTH CAUSE OF ACTION
Deceptive Trade Practices
in Violation of Ohio Rev. Code § 4165.01 *et seq*.

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

115. The above-described acts of Defendant constitute deceptive trade practices in violation of Ohio Rev. Code § 4165.01 *et seq.*

116. Among other things, Ohio Rev. Code § 4165.02 defines actions that constitute a "deceptive trade practice" as including, but not limited to, the following:

> (1) Passes off goods or services as those of another;
> (2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) Causes likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another;
> * * *
> (7) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
> * * *
> (9) Represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> * * *
> (11) Advertises goods or services with intent not to sell them as advertised;

117. As set forth herein, Defendant's actions fit within the scope of Ohio Rev. Code § 4165.02.

118. 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.

119. Defendant's actions are likely to cause confusion, or to cause mistake, or to deceive the public and consumers as to the origin, sponsorship, or approval of the products and services and commercial activities of Defendant, and thus constitute deceptive trade practices with respect to the Lilly Marks, in violation of Ohio Rev. Code § 4165.01 *et seq.*

120. 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 with the intent to deceive.

121. Defendant's actions additionally include deceptively relying on Lilly's clinical trials for MOUNJARO® and ZEPBOUND® to advertise Defendant's Unapproved Compounded Drugs. These representations amount to false assurances of the safety, quality, and effectiveness of Defendant's Unapproved Compounded Drugs. Defendant's false and misleading misrepresentations and omissions were material because they involve information that would be important to consumers, and therefore, likely their use of, or conduct, regarding Defendant's Unapproved Compounded Drugs.

122. 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.

123. Members of the public are also likely to suffer injury from the above-described acts of Defendant by purchasing a drug that they believe to be genuine MOUNJARO® and ZEPBOUND®, not an Unapproved Compounded Drug.

124. Under the principles of equity, Lilly is entitled to entry of preliminary and permanent injunctive relief. In addition, Lilly is entitled to attorneys' fees and costs.

SIXTH CAUSE OF ACTION
Trademark Infringement and Unfair Competition in Violation of Ohio Common Law

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

126. The above-described acts of Defendant constitute trademark infringement and unfair competition in violation of Ohio common law.

127. 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®.

128. 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.

129. 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.

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

131. As a direct and proximate result of Defendant's trademark infringement and unfair methods of competition, Lilly has suffered and will continue to suffer significant monetary damages and a loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® medicines and the Lilly Marks. Defendant therefore has unfairly profited from the actions alleged.

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

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 cybersquatting in violation of 15 U.S.C. § 1125(d);

   e. Engaged in deceptive trade practices, false advertising, unfair competition, and trademark infringement in violation of Ohio Rev. Code § 4165.01 *et seq.* and Ohio common law;

   f. 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. Using or otherwise doing business under the trade name "Mounjaro Doctor" or any variant thereof;

d. Engaging in any unfair competition with Plaintiff Lilly; and

e. 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, cybersquatting, and unfair and deceptive trade practices.

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 requiring the forfeiture or cancellation of the "mounjarodr.com" and "mounjarodoctor.com" domain names and/or the transfer of the domain names to Plaintiff Lilly, together with any other domain names containing "mounjaro" or "zepbound" in Defendant's ownership, possession, or control.

8. An Order requiring that Defendant pay statutory damages under 15 U.S.C. § 1117(d), on election by Plaintiff Lilly.

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

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

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

12. Other relief as the Court may deem appropriate.

Dated: June 20, 2024

Respectfully submitted,
/s/Matthew J. Cavanagh

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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/ Matthew J. Cavanagh

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Attorney for Plaintiff
ELI LILLY AND COMPANY