UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

Eli Lilly and Company, Plaintiff, v. Genesis Lifestyle Medicine of Nevada, LLC, Defendant.	)	Case No. 1:24-CV-1862

PLAINTIFF ELI LILLY AND COMPANY'S COMPLAINT FOR FALSE ADVERTISING AND PROMOTION

INTRODUCTION

1. Defendant Genesis Lifestyle Medicine of Nevada, L.L.C. ("Genesis") has designed its website and advertising materials to communicate falsely to consumers that Genesis's untested, unapproved drug is clinically tested and proven to facilitate weight loss and improve blood sugar. In reality, these are unstudied, unapproved, and potentially dangerous drugs being falsely promoted as safe, effective, and clinically studied medicines for adults with type 2 diabetes or obesity. Genesis has no testing or proof to substantiate its representations. Plaintiff Eli Lilly and Company ("Lilly") therefore brings this action to protect the public from Genesis's dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has developed and delivered trusted and innovative medicines that save and improve patients' lives. Lilly's proprietary MOUNJARO® and ZEPBOUND® are two first-of-their-kind medicines indicated for serious conditions afflicting millions of Americans. Approximately one in ten Americans have type 2 diabetes, and four in ten Americans are obese. To advance the treatment of these chronic conditions, Lilly used its extensive experience and years of research to develop a new class of medicines that target patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptors. These medicines activate both receptors to improve blood sugar control and reduce appetite and food intake.[1] FDA has approved these medicines for specific, indicated conditions and populations: MOUNJARO® for adults with type 2 diabetes, and ZEPBOUND® for adults with obesity (BMI of 30 kg/m2 or greater) or those who are overweight (BMI ≥ 27 kg/m2 or greater)

[1] 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).

and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

3. Both MOUNJARO® and ZEPBOUND® contain the active pharmaceutical ingredient tirzepatide. MOUNJARO® and ZEPBOUND® are the *only* FDA-approved medications that contain tirzepatide. MOUNJARO® and ZEPBOUND® are administered exclusively by subcutaneous injection. Before obtaining FDA approval for MOUNJARO® and ZEPBOUND®, Lilly undertook years of randomized controlled clinical trials evaluating the safety and efficacy of tirzepatide administered by subcutaneous injection on thousands of patients.

4. Unlike MOUNJARO® and ZEPBOUND®, Genesis's products are not approved, nor even reviewed, by FDA. Genesis sells and administers compounded drugs that purport to contain tirzepatide from an unknown source. As FDA has warned, "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."[2]

5. Nevertheless, Genesis explicitly represents that its compounded products (Genesis's "Unapproved Compounded Drugs") are equivalent to Lilly's medicines, deceptively relying on *Lilly's* clinical trials for *Lilly's* FDA-approved MOUNJARO® and ZEPBOUND® to support Genesis's efficacy claims for its Unapproved Compounded Drugs.

6. Further, Genesis claims on its website and social media that its combination of tirzepatide and vitamin B12 offers enhanced weight loss benefits when compared to Lilly's FDA-approved medicines, again relying on *Lilly's* studies that do not investigate the impact of vitamin

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

B12 on clinical outcome. Genesis's statements draw a false and improper equivalence with Lilly's FDA-approved medicines and have the tendency to deceive and mislead the public into selecting Genesis's Unapproved Compounded Drugs over Lilly's FDA-approved medicines. Even more concerning, Genesis's false and misleading marketing of its Unapproved Compounded Drugs poses a direct patient-safety risk. Genesis's advertising ensures consumers have no notice of the risks associated with its products and deceives consumers as to the efficacy of those products.

7. FDA has warned that drugs like the one promoted by Genesis "pose a higher risk to patients than FDA-approved drugs," such as MOUNJARO® and ZEPBOUND®.[3] This is particularly true for drugs with manipulated combinations. As FDA has cautioned with respect to a GLP-1 medicine called semaglutide: "The safety and effectiveness of combining semaglutide with other ingredients"—including "cyanocobalamin (Vitamin B-12), pyridoxine (Vitamin B-6), levocarnitine (L-Carnitine) and nicotinamide adenine dinucleotide (NAD)"—"has not been established."[4] The same applies to tirzepatide. The Obesity Medicine Association likewise has stated, "the clinical benefit of combining semaglutide or tirzepatide with additives such as vitamin B12 [ ] currently lacks proven clinical evidence."[5]

8. Genesis's false and misleading statements have the tendency to mislead the public and lure individuals with serious health conditions away from safe and effective FDA-approved medicines in favor of untested, compounded drugs. Lilly therefore brings this false advertising action pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq*.

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

[4] *FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products*, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

[5] https://www.sciencedirect.com/science/article/pii/S266736812400024X

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 Genesis is a corporation organized under the laws of Nevada, with its principal place of business located at 3037 West Horizon Ridge Parkway, Henderson, NV 89052. Its registered agent is Alex Spinoso, with a registered agent address at 8539 Golden Amber Street, Las Vegas, NV 89139. Genesis's Nevada registration lists Alex Spinoso as its Managing Member, with an address at 7109 Garden Laurel Court, Plano, TX 75024.

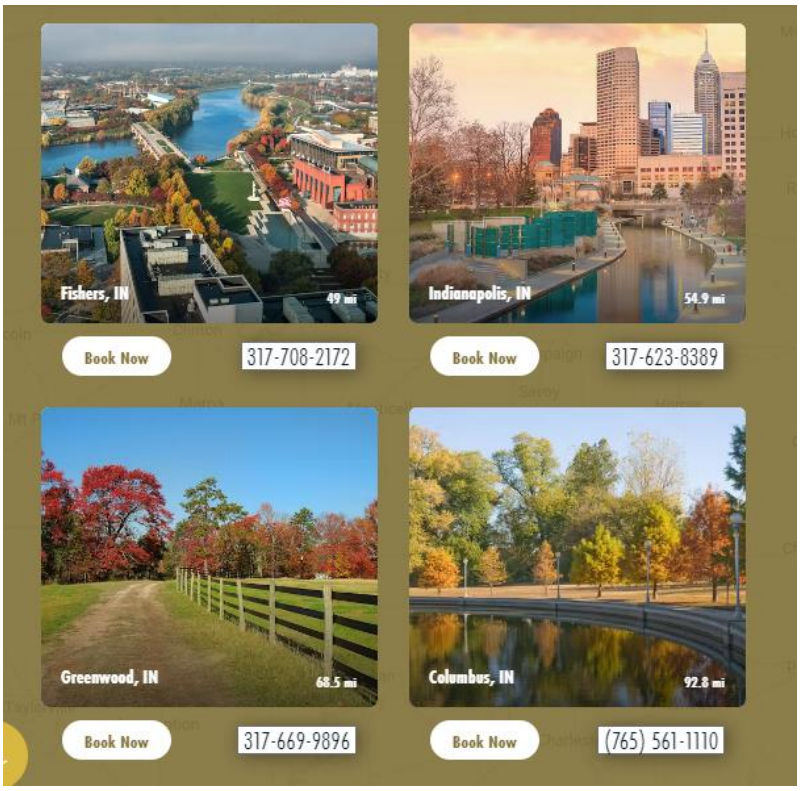
JURISDICTION AND VENUE

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

12. Genesis is subject to personal jurisdiction in this District because Genesis operates and conducts business in this District, including the unlawful promotion of its Unapproved Compounded Drugs.

13. Genesis has regular, continuous, and systematic contacts with Indiana and this District. Genesis' website lists sixty-six (66) locations from which Genesis conducts business, including four locations in Indiana, each of which are in this District:[6]

[6] https://www.genesislifestylemedicine.com/locations/.



14. On information and belief, Genesis operates physical locations at 9995 Allisonville Road, Fishers, IN 46038; 10425 Commerce Drive Suite 140, Carmel, IN 46032; 555 E. County Live Road, Suite 101, Greenwood, IN 46143; and 4050 25th Street, Columbus, IN 47203. Each of these locations employs Indiana residents, including but not limited to medical professionals who are licensed by the state of Indiana. These employees sell and offer for sale goods and services, including Genesis's Unapproved Compounded Drugs, to customers in Indiana.

15. On information and belief, Genesis directs its advertising and solicits business through its website, "https://www.genesislifestylemedicine.com/." This website is accessible from Indiana, is directed to Indiana residents, and has been and, on information and belief, continues to be accessed by Indiana residents.

16. Genesis's website further contains a "book now" button which facilitates the scheduling of services at Genesis's physical locations, including at each of its four locations in this District.

17. Genesis's contacts with Indiana and this District therefore consist of owning and operating physical storefronts in Indiana and this District, employing Indiana-licensed medical professionals to provide services at those locations, owning and operating a website accessible in Indiana and this District, advertising its Unapproved Compounded Drugs to potential customers in Indiana and this District, and providing functionality for Indiana residents to schedule an appointment at its locations in Indiana and this District.

18. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391(b)(1) because Genesis operates and conducts business in this District and Division. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because Genesis's infringing, unfair, and dangerous marketing has been and is currently directed at consumers in this District.

FACTUAL ALLEGATIONS

I. Lilly's FDA-Approved Tirzepatide Injectable Medications

A. Lilly's History of Producing Safe and Effective Medications

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

20. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("CGMP") across the design, monitoring, and control of manufacturing

processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

21. Lilly is also subject to—and encourages—FDA oversight and compliance obligations, including routine FDA inspections, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings, which themselves are approved by FDA.

B. MOUNJARO® and ZEPBOUND®

22. Using its experience and expertise, Lilly developed MOUNJARO® and ZEPBOUND®, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly promotes, offers, and sells MOUNJARO® and ZEPBOUND® throughout Indiana and the United States, among other geographies.

23. Both MOUNJARO® and ZEPBOUND® contain tirzepatide as their API, which targets both GIP and GLP-1 hormone receptors.

24. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."[7] MOUNJARO® targets this problem head-on. When used as directed,

[7] 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® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

25. ZEPBOUND® is designed to help the millions of American adults with obesity or overweight with weight-related medical problems. As FDA has noted, ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and maintenance)" through a new method of hormone receptor activation.[8] Accordingly, FDA has indicated ZEPBOUND® for adults with obesity (BMI of 30 kg/m2 or greater) or those who are overweight (BMI ≥ 27 kg/m2 or greater) and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

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

C. The FDA Approval Process

27. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[9] Over the course of nearly a decade, Lilly completed thirty-seven pre-clinical studies and clinical trials for these medicines.

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

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

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

II. Drug Compounding and Its Inherent Risks

A. The Risks of Compounding Generally

29. Compounding is a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[10]

30. For example, if an individual patient is allergic to an ingredient in an FDA-approved medicine, a compounding pharmacy could produce a version of that medication that does not contain the allergen.

31. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[11] This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, many compounded drugs do not require clinical testing and are not reviewed and approved by FDA for safety and efficacy. Further, many compounders are not subject to labeling requirements, need not comply with Good Manufacturing Practice regulations, their facilities are not subject to inspections by regulatory authorities, and they have no reporting requirements for adverse events.

32. For that reason, FDA has warned that "Compounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of

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

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

compounded drugs unnecessarily exposes patients to potentially serious health risks."[12] Indeed, FDA recently reiterated that compounded drugs that purport to contain tirzepatide "are not FDA-approved. This means the agency does not review compounded drugs for safety, effectiveness, or quality before they are marketed."[13]

33. Health risks from compounded drugs are serious. In 2021, a compounding 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.[14] 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.[15] 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 FDA.[16]

34. Lilly has seen problems firsthand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, low potency 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.

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

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

[14] 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).

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

[16] *Id.*

35. 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.[17] Afterwards, FDA commented:

> The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And, because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.[18]

Company executives were convicted and received sentences of up to 14 years in prison.[19]

36. 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.[20] There are also instances of close calls, particularly for sterile injectables. For example, in 2022 FDA issued a warning letter to North American Custom Laboratories, LLC d/b/a FarmaKeio Superior Custom Compounding for "serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk."[21] As a

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[17] *Id.*

[18] https://www.fda.gov/media/102493/download (FDA Compounding Progress Report).

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

[21] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-

result of these findings, FDA also recommended a voluntary recall of all of FarmaKeio's unexpired drug products that are intended to be sterile.[22]

37. These risks have extended to compounded tirzepatide.

38. Given the popularity of Lilly's MOUNJARO® and ZEPBOUND® medicines, numerous businesses, including Genesis, have begun to manufacture and/or market unapproved compounded products purportedly featuring tirzepatide.

39. As this conduct has become more prevalent, government agencies have warned the public as to the risks of such products. For instance, in July 2024, FDA sent a letter to compounding advocacy organizations warning that it has received "reports describing patients who experienced adverse events following the administration of compounded . . . tirzepatide."[23] FDA reiterated that "compounded drug products, including compounded . . . tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality."[24] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[25] Unsurprisingly, poison control centers across the United States have also reported a troubling trend, seeing "a nearly

11182022#:~:text=WARNING%20LETTER,-Dear%20Mr.&text=During%20the%20inspection%2C%20the%20investigator,firm%20on%20March%2010%2C%202022. (FDA Warning Letter to FarmaKeio).

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

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

[24] *Id.*

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

1,500% increase in calls since 2019 related to overdose or side effects of injectable weight-loss drugs."[26]

40. Leading organizations have also expressed concern. Earlier this year, the Obesity Society, Obesity Action Coalition, and Obesity Medicine issued a joint statement regarding compounded GLP-1 medicines, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[27]

41. 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 drugs promoted to aid with weight loss.[28] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[29] 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."[30]

[26] https://poisoncenters.org/track/GLP-1 (Poison Centers report on incretin overdoses).

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

[28] 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).

[29] *Id.*

[30] *Id.*

B. The Risk of Compounding with Untested Additives

42. Beyond offering compounded products that purport to contain the same API as FDA-approved medications, some compounders add additional bioactive ingredients to their formulations, including vitamin B12. These combinations are untested, unproven, and expose consumers to an unjustifiable risk of harm.

43. Lilly is unaware of any clinical testing exploring the safety and effectiveness of combining tirzepatide with vitamin B12. However, FDA recently cautioned that "[t]he safety and effectiveness of combining semaglutide with other ingredients has not been established."[31] Likewise, the Obesity Medicine Association stated, "the clinical benefit of combining semaglutide or tirzepatide with additives such as vitamin B12 [ ] currently lacks proven clinical evidence."[32]

III. Genesis's False and Misleading Claims

44. Genesis is a medspa operator with sixty-six (66) locations across twenty-one (21) states. Genesis also offers telehealth services in eight (8) states.

45. As part of its services, Genesis promotes (and encourages potential customers to use) a weight loss treatment that it claims is compounded tirzepatide with vitamin B12, *i.e.* its Unapproved Compounded Drugs. In particular, Genesis claims it "prioritize[s] your wellness and provide[s] innovative solutions that address your health concerns holistically. One such cutting-edge treatment is Tirzepatide compounded with B12."[33]

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[31] https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded (FDA warning on additives with compounded semaglutide).

[32] https://www.sciencedirect.com/science/article/pii/S266736812400024X (OMA statement on compounded peptides).

[33] https://www.genesislifestylemedicine.com/blog/what-is-tirzepatide-compounded-with-b12-and-how-can-you-get-it/

46. As set forth in detail below, Genesis has made and continues to make numerous false and misleading statements throughout its advertising pertaining to the inherent quality of its Unapproved Compounded Drugs, including (i) statements that necessarily imply that Genesis's Unapproved Compounded Drugs have been proven safe and effective at weight loss and (ii) express statements regarding the *superior* benefits offered by its Unapproved Compounded Drugs. These false and misleading statements go to the inherent nature of Genesis's Unapproved Compounded Drugs and deceive consumers as to the nature and quality of Genesis's unapproved and untested drugs.

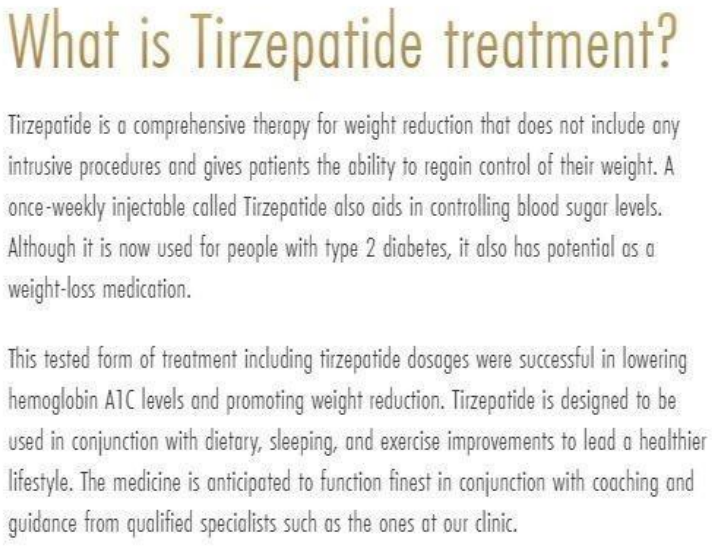
47. A compilation of certain of Genesis's false and misleading advertising are discussed below and are attached hereto as **Exhibit A**.

A. Defendant's False and Misleading "Clinical Trial" Claims

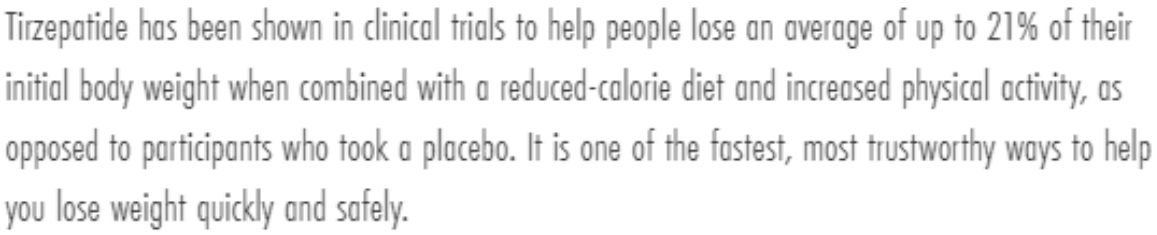
48. Genesis's website, located at https://www.genesislifestylemedicine.com/, offers tirzepatide for sale.[34] Upon information and belief, Genesis sells, offers and prescribes to its customers compounded tirzepatide. In promoting that compounded product, Genesis repeatedly and exclusively refers to "tirzepatide" generically, without naming MOUNJARO® or ZEPBOUND®. Yet, Genesis then relies on studies of ***Lilly's*** medicines on its website and on its social media channels when making statements that expressly state or necessarily imply that its Unapproved Compounded Drugs are FDA-approved medications indicated to achieve certain therapeutic outcomes. These clinical trials have no bearing on, and cannot substantiate claims about, Genesis's Unapproved Compounded Drugs, which upon information and belief are sold without having undergone ***any*** testing for safety or effectiveness in achieving any of the therapeutic outcomes claimed.

[34] https://www.genesislifestylemedicine.com/medical-weight-loss/tirzepatide/.

49. Genesis necessarily implies through its website that its Unapproved Compounded Drugs are clinically tested and verified to be safe and effective:



50. Further down, Genesis expressly references clinical trials on its website:



51. This advertisement necessarily communicates to consumers that Genesis's Unapproved Compounded Drugs have been clinically tested and shown to facilitate weight loss, yet no such clinical trials have been conducted.

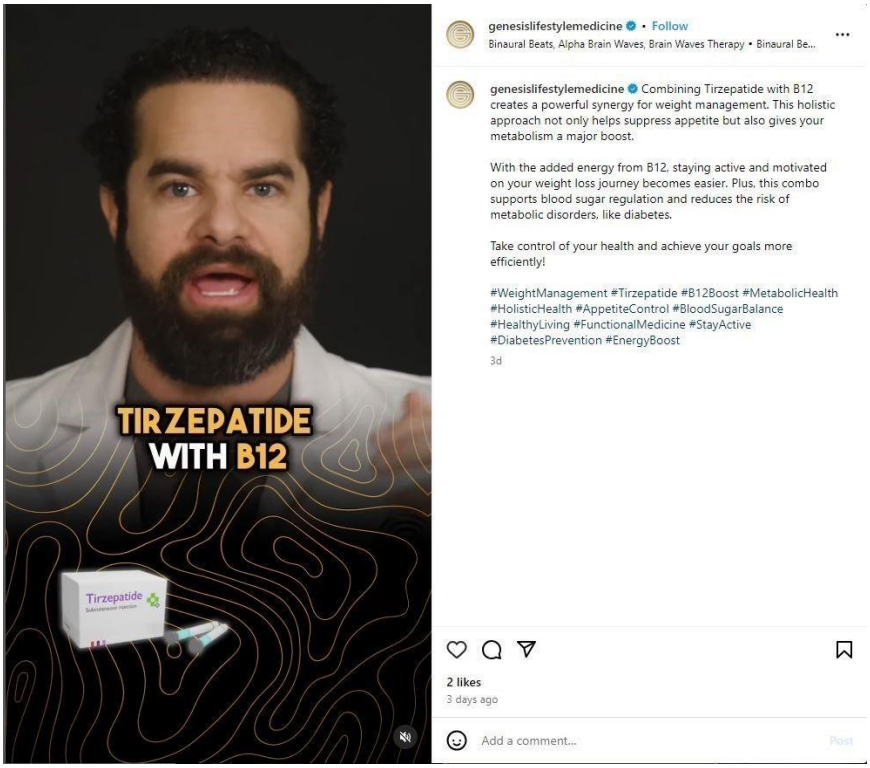
52. Genesis's references to clinical trials are clear establishment claims. An establishment claim (*i.e.*, a "tests prove" type of claim) must be supported by the kind of testing described in the advertisement. If the advertiser lacks the testing discussed in its advertising, its

claims are false. Here, Genesis's advertising expressly and repeatedly references clinical trials in discussing the safety and efficacy of its Unapproved Compounded Drugs—*i.e.*, tirzepatide with vitamin B12. Thus, Genesis must have clinical studies proving that its formula—*i.e.*, tirzepatide with vitamin B12—is safe and effective at weight loss and improving blood sugar. Upon information and belief, Genesis does not have any clinical data assessing the safety or effectiveness of its Tirzepatide compounded with vitamin B12 formula.

53. Further, Genesis cannot rely on Lilly's clinical trials for its FDA-approved MOUNJARO® and ZEPBOUND® to support these claims, because neither MOUNJARO® nor ZEPBOUND® contain vitamin B12. Likewise, neither MOUNJARO® nor ZEPBOUND® were tested in conjunction with vitamin B12. Thus, Lilly's clinical studies are irrelevant to the safety and efficacy of Genesis's Unapproved Compounded Drugs.

B. Defendant's False and Misleading "More Effective" Claims

54. Further, Genesis makes numerous claims that its use of vitamin B12 in the Unapproved Compounded Drugs actually provides *superior* benefits than using tirzepatide alone—again, without any support for that claim. For example, Genesis's social media notes that Genesis's Unapproved Compounded Drugs contain vitamin B12, and claims in this video (posted on October 4, 2024) that "combining tirzepatide with B12 creates a powerful synergy that *enhances the benefits of both compounds* . . . The appetite suppressing effects of tirzepatide coupled with the metabolic boost of B12 leads to more effective weight loss.":



55. These aggressive and utterly unfounded health benefit claims necessarily imply that Genesis not only has testing that establishes the safety and efficacy of its Unapproved Compounded Drugs with vitamin B12, but that it has testing that establishes that tirzepatide compounded with vitamin B12 actually provides superior weight loss. As noted above, and on information and belief, Genesis has no such testing or data to support its advertising claims, and the Obesity Medicine Association stated, "the clinical benefit of combining semaglutide or tirzepatide with additives such as vitamin B12 [ ] currently lacks proven clinical evidence." Yet, Genesis continues to advance these health benefit claims and placed the public at risk from taking untested and unapproved compounded drugs.

56. Likewise, Genesis's website further promotes its Unapproved Compounded Drugs, including the webpage "https://www.genesislifestylemedicine.com/blog/what-is-tirzepatide-compounded-with-b12-and-how-can-you-get-it/," which claims that Genesis's combination of

compounded tirzepatide and vitamin B12 "maximizes the efficacy of weight loss and metabolic health management."

How does the combination work?

Tirzepatide works by mimicking the effects of GLP-1 and GIP, which play key roles in regulating appetite, insulin secretion, and glucose metabolism. When compounded with B12, the treatment not only targets these pathways but also provides the added benefits of B12, such as increased energy production and improved metabolism. This dual-action approach maximizes the efficacy of weight loss and metabolic health management.

57. Genesis goes on to list those purported benefits it claims consumers receive when they use tirzepatide with vitamin B12, as opposed to tirzepatide alone:[35]

The synergy of Tirzepatide compounded with B12

Combining Tirzepatide with B12 creates a powerful synergy that enhances the benefits of both compounds. This combination offers a holistic approach t weight management by addressing multiple aspects of your health:

- **Enhanced Weight Loss:** The appetite-suppressing effects of Tirzepatide, coupled with the metabolic boost from B12, lead to more effectiv weight loss. This dual approach helps you achieve and maintain a healthier weight more efficiently.
- **Improved Energy Levels:** B12 ensures you have the energy needed to stay active and motivated throughout your weight loss journey. This can make it easier to adhere to an exercise routine and stay engaged in physical activities.
- **Better Metabolic Health:** The combination helps regulate blood sugar levels and supports metabolic health, reducing the risk of diabetes and other metabolic disorders. Improved metabolic health is key to long-term weight management and overall well-being.

[35] https://www.genesislifestylemedicine.com/blog/what-is-tirzepatide-compounded-with-b12-and-how-can-you-get-it/

58. As shown above, Genesis expressly tells consumers that its "Tirzepatide compounded with B12" leads to "more effective weight loss" and helps patients "achieve and maintain a healthier weight more efficiently" and provides "better metabolic health."

59. Genesis's advertising necessarily communicates that its Unapproved Compounded Drugs have not only been clinically proven to be safe and effective, but its "Tirzepatide compounded with B12" product has been proven *more effective* at weight loss and *better* for improved blood sugar levels. Again, Genesis must possess such clinical data in order to substantiate its claims. Yet, Genesis's "Tirzepatide compounded with B12" has ***not*** been demonstrated to function at all in any clinical trial, let alone "more effectively" than tirzepatide alone (*i.e.*, it has not been clinically proven to provide better weight loss that MOUNJARO® or ZEPBOUND®).

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60. In short, throughout its advertising, Genesis makes a series of false and misleading claims that expressly state and/or necessarily imply that its Unapproved Compounded Drugs—Tirzepatide compounded with B12—has been clinically tested and backed by specific scientific research to not only provide safe and effective weight loss benefits, but to provide superior benefits over tirzepatide alone. These statements—individually and collectively—communicate to prospective purchasers that Genesis's untested and unapproved drugs are proven safe and effective for the treatment of that person's type 2 diabetes or obesity and provide better outcomes than Lilly's FDA-approved tirzepatide medicines. Quite the contrary: no regulator—let alone FDA—has evaluated the safety or effectiveness of Genesis's Unapproved Compounded Drugs. Lilly is unaware of any data supporting Genesis's representation that its Unapproved Compounded

Drugs—whether claiming to be tirzepatide or to be tirzepatide combined with vitamin B12—are safe and effective.

61. Genesis's false and misleading statements are intended—and likely—to cause confusion, to cause mistake, or to deceive consumers as to the nature and quality of Genesis's products. Further, these statements present a significant patient safety risk, as these statements have the tendency to lure the unassuming public away from using safe, effective, FDA-approved medicines and encourage the use of untested, unapproved compounded drugs.

IV. Harm from Defendant's Conduct

62. Genesis's false, misleading, and reckless promotion and sale of its products has harmed Lilly and consumers and will continue to do so if left unchecked.

63. First, Genesis's misrepresentations lure reasonable consumers away from obtaining safe and effective treatment with MOUNJARO® or ZEPBOUND® on the false promise that Genesis's Unapproved Compounded Drugs are as or *more* effective in helping people treat diabetes and address weight-related medical problems. This not only has and will continue to result in lost sales for Lilly, but more importantly risks severe harm to consumers—at best financially, but potentially far worse.

64. Second, Genesis's misrepresentations cause irreparable damage to Lilly's brand and customer goodwill by placing consumers at an impermissibly elevated risk of harm. Should injury befall one of Genesis's patients, Genesis's false and misleading advertising is likely to confuse consumers, who will undoubtedly draw negative inferences as to Lilly's medicines as well.

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

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

66. Genesis'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).

67. Genesis has knowingly and willfully made materially false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs (including its website and social media). These statements regarding alleged clinical studies on the safety, quality, and effectiveness of Genesis's Unapproved Compounded Drugs have influenced and are likely to continue to influence consumers' purchasing decision—specifically, the decision to purchase Genesis's Unapproved Compounded Drugs instead of Lilly's FDA-approved medicines. As a result, Genesis is steering individuals with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. Genesis's unlawful conduct is putting health, safety, and lives at risk.

68. Genesis has caused its false statements to enter interstate trade or commerce.

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

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

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

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

PRAYER FOR RELIEF

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

1. An Order declaring that Genesis:

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

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

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

   a. Falsely stating or suggesting that Genesis's Unapproved Compounded Drugs have been the subject of clinical studies or achieve certain therapeutic outcomes;

   b. Falsely claiming that its vitamin B12 compounded product offers superior or enhanced benefits over tirzepatide alone;

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

   d. Engaging in any deceptive or unfair acts.

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

a. Genesis's Unapproved Compounded Drugs are not MOUNJARO® or ZEPBOUND®;

b. Genesis's Unapproved Compounded Drugs do not contain the same formulation as MOUNJARO® or ZEPBOUND®;

c. Genesis's Unapproved Compounded Drugs are not and have never been approved by FDA;

d. Genesis's Unapproved Compounded Drugs have never been studied in clinical trials;

e. Genesis's Unapproved Compounded Drugs have never been demonstrated to be safe or effective; and

f. Genesis's tirzepatide compounded with vitamin B12 does not offer enhanced or superior outcomes or weight loss.

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

5. An Order requiring Genesis to account for and pay to Lilly any and all profits arising from the foregoing acts of false advertising.

6. An Order requiring Genesis to pay Lilly compensatory damages in an amount as yet undetermined caused by the false advertising and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws.

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

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

9. Other relief as the Court may deem appropriate.

JURY DEMAND

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

Dated: October 21, 2024

Respectfully submitted

s/ J.T. Larson

J.T. Larson (IN 31392-29)
Amanda Jane Gallagher (IN 32662-79)
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204
Telephone: (317) 231-7729
jt.larson@btlaw.com
amanda.gallagher@btlaw.com

James F. Hurst, P.C. (*pro hac vice* forthcoming)
Diana M. Watral, P.C. (*pro hac vice* forthcoming)
Robin A. McCue (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, Illinois 60654
Telephone: (312) 862-2000
james.hurst@kirkland.com
diana.watral@kirkland.com
robin.mccue@kirkland.com

Joshua L. Simmons, P.C. (*pro hac vice* forthcoming)
Jeanna M. Wacker, P.C. (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Telephone: (212) 446-4800
joshua.simmons@kirkland.com
jeanna.wacker@kirkland.com

Michael A. Glick (*pro hac vice* forthcoming)
Ragan Naresh, P.C. (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.

Washington, D.C. 20004
Telephone: (202) 389-5000
michael.glick@kirkland.com
ragan.nagash@kirkland.com

Attorneys for Plaintiff
ELI LILLY AND COMPANY