

**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 insulintropic 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.

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* be "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 \geq 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/synthetic-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**.

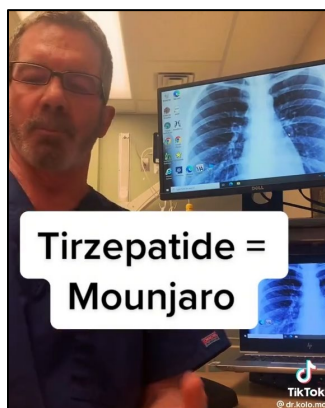
52. One example, shown above as well as repeated below, is Defendant’s use of the MOUNJARO® autoinjector pen, when Defendant does not in fact offer this medicine.



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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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

EXHIBIT A

United States of America

United States Patent and Trademark Office

MOUNJARO

Reg. No. 6,809,369

Registered Aug. 02, 2022

Int. Cl.: 5

Trademark

Principal Register

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

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

FIRST USE 6-3-2022; IN COMMERCE 6-3-2022

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

SER. NO. 88-680,946, FILED 11-05-2019



Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office



REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

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

Requirements in the First Ten Years*

What and When to File:

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

Requirements in Successive Ten-Year Periods*

What and When to File:

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

Grace Period Filings*

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

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

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

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

United States of America
United States Patent and Trademark Office

MOUNJARO

Reg. No. 7,068,463

Registered May 30, 2023

Int. Cl.: 44

Service Mark

Principal Register

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

CLASS 44: Medical information services in the field of diabetes

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

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

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

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office



REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

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

Requirements in the First Ten Years*

What and When to File:

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

Requirements in Successive Ten-Year Periods*

What and When to File:

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

Grace Period Filings*

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

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

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

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

United States of America
United States Patent and Trademark Office

ZEPBOUND

Reg. No. 7,288,373

Registered Jan. 23, 2024

Int. Cl.: 5

Trademark

Principal Register

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

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

FIRST USE 11-30-2023; IN COMMERCE 11-30-2023

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

SER. NO. 97-362,818, FILED 04-14-2022

Katherine Kelly Vidal

Director of the United States
Patent and Trademark Office



REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

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

Requirements in the First Ten Years*

What and When to File:

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

Requirements in Successive Ten-Year Periods*

What and When to File:

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

Grace Period Filings*

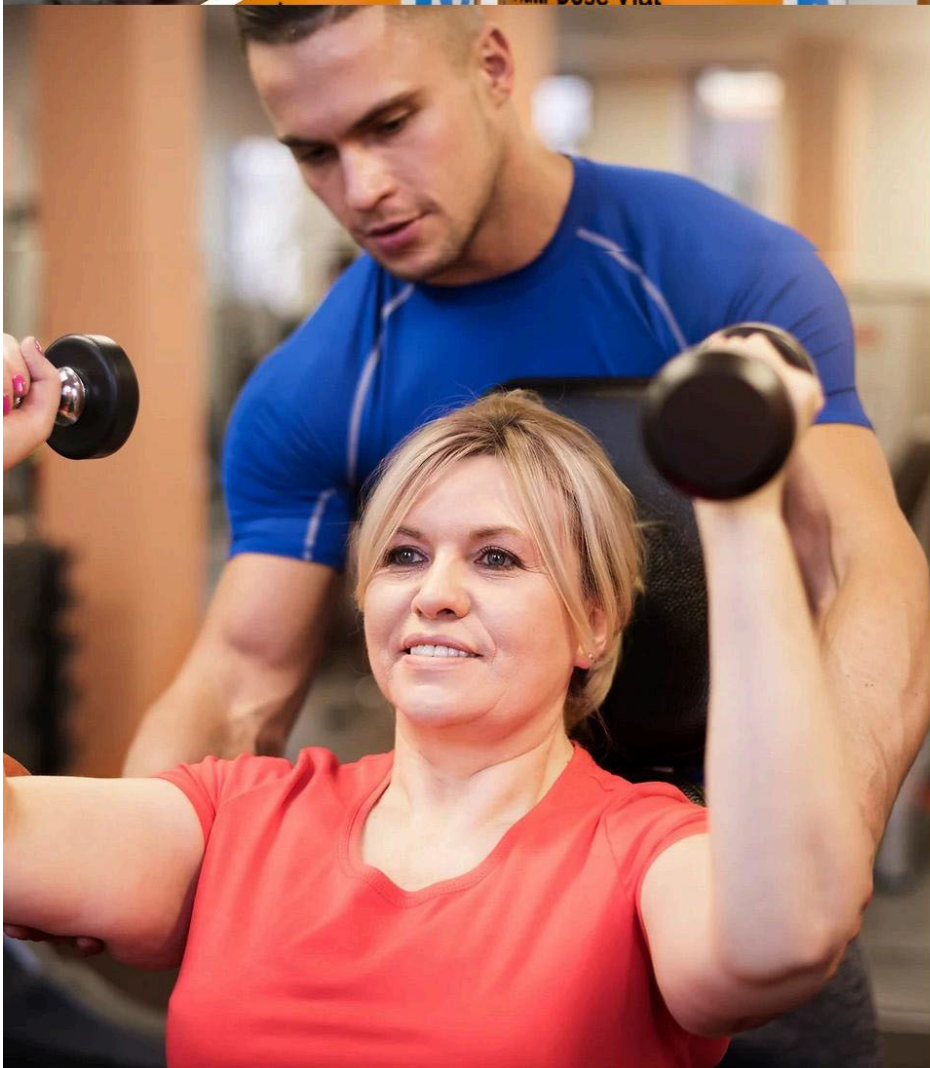
The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

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

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

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

EXHIBIT B



GLP-1 Medication Program Philosophy

GLP-1 Medications can be effective at both helping our patients get a jumpstart on weight loss and improved health, and working through a possible plateau in a weight loss journey. However, these medications are not without potential downsides. Downsides include:

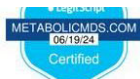
- Medication side effects
- Muscle mass loss while taking the medication
- Weight being regained when the medication is stopped.

Dr. Paul believes that for most patients, GLP-1 medication use should be for limited periods of time, and, when possible, at a lower effective dosage. His goal for his patients is to have them meet their weight loss and health goals, and avoid ongoing dependency on medication to maintain weight loss and good health. In other words, as he tells his patients, "Begin With The End In Mind." The end being maintaining a lower weight and improved health well after the medication is stopped.

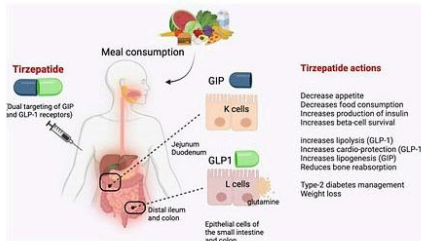
This goal is achieved by our patients because other program components have been implemented during medication treatment, and become habits that are sustained for a lifetime:

- Low Carb Diet
- Intermittent Fasting
- Exercise Regimen with Emphasis on Strength Training

If you are interested in integrating GLP-1 medication in your treatment plan, let Dr. Paul know this at the time of your complementary consultation.



About Mounjaro



What is Mounjaro ?

Mounjaro (tirzepatide) has received much attention recently for its effectiveness as a weight loss medication. Mounjaro is an FDA-approved medication originally prescribed to diabetics for the purpose of controlling blood glucose. This medication (exact same medication) has also been branded as Zepbound when used for weight loss. Compounded Tirzepatide is also available through providers such as Metabolic MD who arrange to have the medication supplied to our patients through licensed pharmacies. Compounded Tirzepatide is prescribed to patients who have specialized dosing needs or specific clinical issues requiring the compounded medication. All three formulations (Mounjaro, Zepbound, Compounded Tirzepatide) are once-weekly injectable medications. When treatment is initiated, they are started as a low dose, and the dose is gradually increased until a therapeutically effective dose is reached. These drugs belong to a class of medications called the "GLP-1 Agonists". They mimic the body's natural GLP-1 gastrointestinal hormones.

In the initial studies on diabetics the GLP-1 medications were found to be very effective at lowering blood sugar with the added benefit of achieving weight loss. After seeing the weight loss these medicines 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, which has the advantage of more succinct titration of dosing, came on the market in 2023 as well.

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.

The type of Tirzepatide prescribed to a patient is dependent on both that person's medical conditions and need to titrate medications up and down precisely.

For diabetics, Mounjaro is usually the most appropriate medication, and is usually covered by insurance. Out of pocket costs are often low. For patients who are not diabetic, however, insurance coverage for Mounjaro is limited.

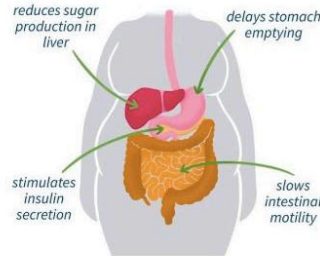
Zepbound can be prescribed for obesity or for overweight individuals who are not diabetic. However, insurance coverage for Zepbound is very limited. In our experience, only 5-10% of private health insurances cover Zepbound. Medicaid and Medicare do not cover Zepbound, and only very generous privately insurances provide coverage for this medication.

The cost for the two branded medications (Mounjaro and Zepbound) without insurance coverage can be well over \$1,000 dollars per month.

Tirzepatide, the compounded version of Zepbound and Mounjaro, can be prescribed to patients who are diabetic or not diabetic. Metabolic MD has been providing this medication to our patients since its first availability in 2023. It has been shown to be safe and effective in our patients. However, compounded Tirzepatide is prescribed only to patients who require specialized dosing needs or who have a clinical need requiring this medication.

Book an Appointment

Schedule online. It's easy, fast and secure.



When & How Should These Medications be Prescribed for Weight Loss?

Metabolic MD prescribes Tirzepatide with a focus on using lower doses and only as part of a comprehensive weight loss and metabolic health program. We use these medications in two instances:



- For a patient who wants to get a jump start on their weight loss program, but only with the understanding that other lifestyle changes be implemented simultaneously (low carb diet, intermittent fasting, exercise routine emphasizing strength training)
- Temporarily (usually a period of months or about a year) for a patient who stalls without medication or plateaus during their weight loss effort, despite participation in a comprehensive program (as outlined above).

We believe that one of the goals when using these medications, is that their use be temporary. We do not believe Tirzepatide should be prescribed to patients in a manner that commits them to lifetime medication. We believe these medications should be used as part of a comprehensive program as outlined above. We use limited (not maximum) dosing so we can eventually titrate our patients off the medication and be able to gradually regain the weight upon medication discontinuation. This is very common, often up to 60% of the weight lost, and can only be avoided with the institution of diet and exercise lifestyle changes while on medication.

How does Tirzepatide (Mounjaro/Zepbound) work?

Tirzepatide (Mounjaro / Zepbound) is effective for several reasons. First, it acts on the hypothalamus to regulate our sensation of hunger. With this action on the hypothalamus, it prolongs our sense of fullness (satiety). Tirzepatide also slows down the emptying of the stomach, keeping you full longer. Finally, it lowers blood glucose, which is used by the body as an energy source. It also slows down the absorption of fat in the gut, which helps with weight loss.

How Much Weight Can I Lose?.

We believe a comprehensive program utilizing the following components best achieves optimal weight loss and health improvement:

- A focused low carb diet (best guided by the use of a continuous glucose monitor)
- Intermittent fasting
- An exercise regimen with a focus on strength training.

Tirzepatide (Mounjaro/Zepbound) can help you lose weight, but that weight loss is likely not to be permanent after medication discontinuation, without lifestyle changes. Weight regain after stopping the medication is common, unless diet and exercise lifestyle changes have been ingrained. In our practice, we help our patients address the root causes of weight gain with a comprehensive program. We look to help our patients implement healthy lifestyle changes that will last a lifetime, and prevent weight regain when the medication is discontinued. In studies using Tirzepatide, some patients achieved a weight loss of 25% of their body weight.

How Fast Does Tirzepatide (Mounjaro/Zepbound) Work?

The short answer is that many of our patients begin to lose weight in the first month. The first dose is small, but then the dose is titrated up over the following months. These lower doses are primarily used to gently introduce the medication to the body without risking developing significant side effects (mostly nausea).

Most studies done on weight loss with this medication, Tirzepatide (Mounjaro/Zepbound), have shown effectiveness only when it is used in combination with an effective diet and exercise plan. At Metabolic MD, we believe the most effective dietary approach is a low carb diet, and the best exercise plan includes strength training. Our Tirzepatide prescribing always is accompanied by detailed guidance related to your diet and an appropriate associated exercise regimen. We have proven that an extremely effective approach to weight loss is a continuous glucose monitor guided low carb diet in conjunction with Tirzepatide.

Who is Eligible for Weight Loss Treatment with Tirzepatide (Mounjaro/Zepbound) ?

Mounjaro is often covered by most private insurance for those diagnosed with type 2 diabetes.

Zepbound is the brand name approved for weight loss in nondiabetics. It can be prescribed to patients with a weight meeting the BMI criteria of a BMI of 30 or greater, or a BMI of 27 in association with a metabolic health issues such as prediabetes, hypertension, high cholesterol, sleep apnea, or fatty liver disease. At this time, insurance coverage for Zepbound is limited, meaning its cost may not be covered by most insurances, including Medicaid, Medicare, and a majority of private insurances.

Does Tirzepatide (Mounjaro/Zepbound) have side effects?

Some people can have mild to moderate side effects, however most of these are manageable by proper dosing. Significant side effects may occur, but in our experience are very rare. Sometimes compounded medication offers an option for more precise dosing.

The most common side effects are: nausea, diarrhea, vomiting, constipation, mild stomach pain, mild headache, fatigue, feeling bloated, belching, gas, stomach flu, and heartburn. We see some mild nausea in many patients, however based on our dosing regimens, we have found that both significant side effects and other side effects are very rare.

How Fast Can You Increase the Dose?

Tirzepatide (Mounjaro/Zepbound) is taken as a once weekly injection "escalating" dose. This means you start the medication at a low dose, and increase the dosage gradually over a period of months. Progression on this regimen assumes side-effects are minimal. We have not had any patients need to discontinue treatment due to side effects.

We weigh several factors when deciding how and when to increase the dose for our patients. The first is whether you experienced significant side effects during your week of treatment during initiation or as the dose is increased. How fast

dosing is increased for our patients is individualized and tailored to the needs of each patient. The individualized approach allows us to maximize the benefits of the medication while keeping side effects to a minimum.

Metabolic MD also has a philosophy of utilizing the lowest dose necessary to achieve effective weight loss. This is for two reasons. Avoiding high doses helps to avoid weight regain when patients are titrated back down and off the medication. Also, higher doses of medication can result in significant muscle loss. Lower dosing (in conjunction with the strength training guidance we provide) helps avoid muscle loss. This is especially important for older patients and in women at risk for osteoporosis.

How Do You Administer Tirzepatide (Mounjaro/Zepbound)?

This medication is taken as a once-weekly subcutaneous injection. This injection is self-administered at home with a VERY SMALL (31 gauge) needle into the abdominal area. If the brand name medicines are utilized, they are provided as an injectable pen. If a compounded formulation is provided, it must be drawn up into an insulin syringe from a vial. It is then injected in a manner similar to an insulin injection. The injection cannot be said to be 100% painless, but causes very minimal discomfort for most patients. We walk all our patients through the injection process either in office or by telemedicine.

Who Should Not Use Tirzepatide (Mounjaro/Zepbound)?

There are some situations where Mounjaro is "contraindicated," meaning an individual with a condition should not use this medicine. The major contraindications to treatment are:

- patients with a personal or family history of medullary thyroid carcinoma
- patients with a personal or family history of Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- diabetic retinopathy, a type of damage to the eye from diabetes
- a history of recurrent low blood sugar
- recurrent disease of the gallbladder (patients who have had their gallbladder removed are not included in this group)
- decreased kidney function
- pancreatitis
- Inflammatory bowel disease
- patients on any medications that lower blood sugar
- patients on the blood thinner coumadin (also called warfarin)

I Have heard Tirzepatide (Mounjaro/Zepbound) Is in Short Supply, and Medication Availability is subject to "Supply Chain" Issues.

Due to the demand for Tirzepatide (Mounjaro/Zepbound) at times these medications have been in short supply. This has been especially true of both Mounjaro and Zepbound. It is less true with the compounded version.

Regarding less expensive Compounded Tirzepatide, Metabolic MD, through our relationship with multiple licensed compounding pharmacies, has not had our patients experience any interruption in timely delivery of their medication. However, any patient choosing to pursue treatment with Tirzepatide should be aware of the potential risk of a supply chain issue, and potential medication unavailability. This is one reason our programs emphasize a comprehensive approach. We believe patients should not become solely dependent on this medication to achieve their weight loss and metabolic health goals.

Metabolic MD Pharmacies Network

To see the compounded pharmacies Metabolic MD utilizes to obtain medications for our patients click here: [INSERT INFO HERE](#)

[DCA PHARMACY](#)

[REDROCK PHARMACY](#)

Is Tirzepatide (Mounjaro/Zepbound) Covered by Insurance?

As mentioned above Mounjaro is covered by most private insurances for those diagnosed with Type 2 Diabetes.

Zepbound is the brand name approved for weight loss in nondiabetics. It can be prescribed to patients with excess weight meeting the high BMI criteria as outlined above. At this time, insurance coverage for Zepbound is very limited, meaning its cost may not be covered by most insurances, including Medicaid, Medicare, and a majority of private insurances.

How Can I Learn More?

If you have an interest in being prescribed Tirzepatide (Mounjaro/Zepbound/Compounded Tirzepatide) as part of a comprehensive weight loss and metabolic health program please contact Metabolic MD at this link for a complimentary phone consultation.

Our initial goal is to work with patients and guide them in the process of determining if they are eligible for insurance coverage of Mounjaro or Zepbound. We will also assess, based on dosing considerations, if compounded medication use is appropriate.

Please click on the above link and complete our short patient inquiry form, and a member of the Metabolic MD team will

be in touch with you to arrange your no cost phone consultation. This form is also on our website under the Contacts Tab.

Pharmacies

> Schedule your consultation [Get Started Now](#)

937.800.4246
info@doctorkolo.com



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The image shows an Instagram post from the account 'metabolicmds'. On the left, a video player shows a man with glasses and a dark jacket speaking. A white text box is overlaid on the video with the text 'Mounjaro = Terzipitide'. The video has a TikTok watermark for 'dir.kolo.md'. On the right, the post's caption and engagement details are visible. The caption reads: 'metabolicmds if you are on a GLP1 medication, such as semaglutide (Ozempic and Wegovy) or tirzepatide (Mounjaro), it's recommended to participate in diet and lifestyle modification. To sustain the long term results, this medication should be considered a "lifeboat" and a means to get you from point A to point B. To maintain the progress this can help you make, it's crucial to understand your metabolic health and how big an impact proper nutrition and exercise plays in overall health. 80w'. Below the caption are engagement icons for likes, comments, and shares, showing 35 likes and a date of November 17, 2022. A comment input field at the bottom says 'Add a comment...'. The Instagram navigation bar is visible on the far left.

Instagram

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- Reels
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- Notifications
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- Profile
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NEW FDA APPROVED WEIGHT LOSS MEDICATIONS GLP-1

FOR DIABETICS	FOR NON-DIABETICS	GENERIC NAME
OZEMPIC	WAGOVY	SEMAGLUTIDE
MOUNJARO	ZEPBOUND	TIRZEPATIDE

metabolicmds.com

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Dr. Paul Kolodzik spoke with Good Day Dayton about GLP-1 medications: their use, pros, cons, and if they may be a right fit for you. Check out the full segment at <https://dayton247now.com/good-day-dayton/new-fda-approved-weight-loss-medications#>.

1 like
January 13

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The Oregon District

metabolicmds #MOUNJARO ❤️ tirzepatide is a newly approved FDA medication for weight loss in those with type 2 diabetes. Tirzepatide is the first medication in its class and comes as a once-weekly injection. It works by impacting your body's insulin levels, blood sugar production, and hunger hormones. Similar to Ozempic and Wegovy, Mounjaro works by slowing down digestion while helping you feel full faster. Combined with proper diet and lifestyle modification, those using Mounjaro lost around 20% of their body weight. Semaglutide medications are seriously life changing and can help you lose weight and improve your metabolic health. Interested to learn more about this medication and if you're a candidate? Request a free consultation by completing the new inquiry survey in our link in bio
#Semaglutide #tirzepatide #weightlossinjection #metabolicsyndrome #type2diabetes #DaytonOhio

4 likes
November 5, 2022

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**TIRZEPATIDE:
New Weight Loss
Drug About To
Be Approved**

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metaboliccmds Tirzepatide for weight loss?!
.
#metaboliccmds #intermittentfasting #prediabetes #weightloss #health #wellness #dayton #ohio
83w

metaboliccmds #LowCarb #lowcarbdiet #keto #ketolife #ketodiet #ketoaf #ketoweightloss #weightlossprogram #nocarb #lowcarbblunch #lowcarbdinner #lowcarbsnacks #nocarbsnacks #healthysnacks #lowcarbweightloss #weightloss #healthydiet #healthyliving #foodasmedicine #preventivehealth #medicalweightloss #intermittentfasting #healthandwellness

59 views
October 23, 2022

Add a comment... Post









The image shows a screenshot of an Instagram post. On the left is the Instagram navigation menu with icons for Home, Search, Explore, Reels, Messages, Notifications, Create, Profile, and More. The main content is a video from a TikTok account '@ dr.' with a play button overlay and the text: **TIRZEPATIDE: New Weight Loss Drug About To Be Approved**. The video background shows a man in a blue shirt sitting in front of a computer monitor displaying a chest X-ray. To the right of the video is the post's interface, including the username 'metabolicmds' with a 'Follow' button, the caption 'Tirzepatide-new weight loss drug to be approved!', and a comment from user 'sbrdh5' asking about thyroid cancer risk. The post has 118 views and is dated October 19, 2022.

EXHIBIT C

Home > Whois Lookup > MoUnjaRoDoctor.com

Whois Record for MoUnjaRoDoctor.com

— Domain Profile

Registrar	GoDaddy.com, LLC IANA ID: 146 URL: https://www.godaddy.com , http://www.godaddy.com Whois Server: whois.godaddy.com abuse@godaddy.com (p) +1.4806242505	
Registrar Status	clientDeleteProhibited, clientRenewProhibited, clientTransferProhibited, clientUpdateProhibited	
Dates	733 days old Created on 2022-06-14 Expires on 2025-06-14 Updated on 2024-06-16	
Name Servers	NS41.DOMAINCONTROL.COM (has 59,678,358 domains) NS42.DOMAINCONTROL.COM (has 59,678,358 domains)	
IP Address	3.33.152.147 - 9,159,981 other sites hosted on this server	
IP Location	 - New Jersey - Princeton - Amazon Technologies Inc.	
ASN	 AS16509 AMAZON-02, US (registered May 04, 2000)	
Domain Status	Registered And No Website	
IP History	3 changes on 3 unique IP addresses over 2 years	
Registrar History	1 registrar	
Hosting History	1 change on 2 unique name servers over 2 years	

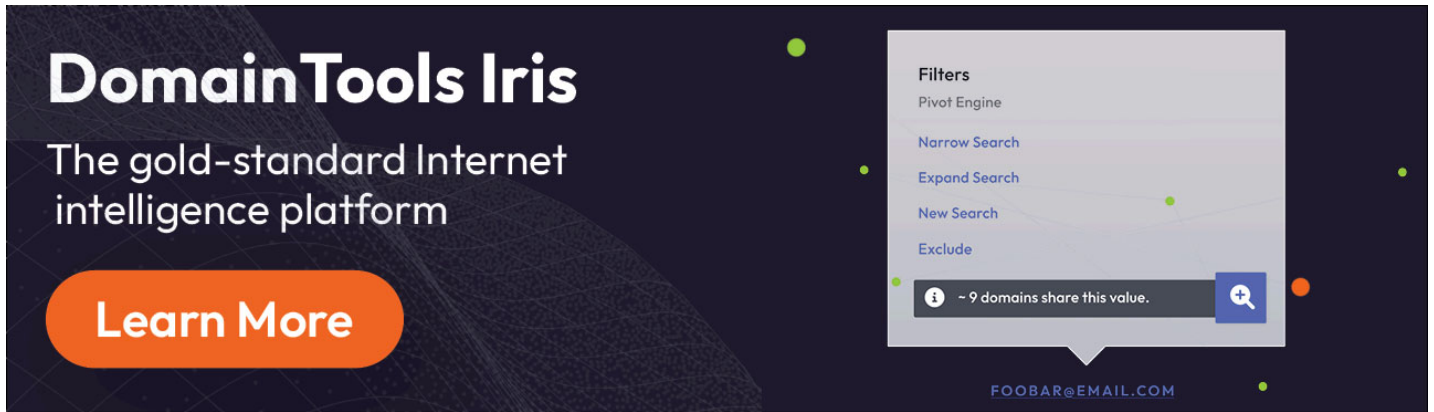
Whois Record (last updated on 2024-06-16)

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Domain Name: mounjarodoctor.com
Registry Domain ID: 2703923305_DOMAIN_COM-VRSN
Registrar WHOIS Server: whois.godaddy.com
Registrar URL: https://www.godaddy.com
Updated Date: 2024-06-16T11:26:07Z
Creation Date: 2022-06-14T15:25:50Z
Registrar Registration Expiration Date: 2025-06-14T15:25:50Z
Registrar: GoDaddy.com, LLC
Registrar IANA ID: 146

```

Registrar Abuse Contact Email: abuse@godaddy.com
Registrar Abuse Contact Phone: +1.4806242505
Domain Status: clientTransferProhibited <https://icann.org/epp#clientTransferProhibited>
Domain Status: clientUpdateProhibited <https://icann.org/epp#clientUpdateProhibited>
Domain Status: clientRenewProhibited <https://icann.org/epp#clientRenewProhibited>
Domain Status: clientDeleteProhibited <https://icann.org/epp#clientDeleteProhibited>
Registry Registrant ID: Not Available From Registry
Registrant Name: Registration Private
Registrant Organization: Domains By Proxy, LLC
Registrant Street: DomainsByProxy.com
Registrant Street: 100 S. Mill Ave, Suite 1600
Registrant City: Tempe
Registrant State/Province: Arizona
Registrant Postal Code: 85281
Registrant Country: US
Registrant Phone: +1.4806242599
Registrant Phone Ext:
Registrant Fax:
Registrant Fax Ext:
Registrant Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodoctor.com>
Registry Admin ID: Not Available From Registry
Admin Name: Registration Private
Admin Organization: Domains By Proxy, LLC
Admin Street: DomainsByProxy.com
Admin Street: 100 S. Mill Ave, Suite 1600
Admin City: Tempe
Admin State/Province: Arizona
Admin Postal Code: 85281
Admin Country: US
Admin Phone: +1.4806242599
Admin Phone Ext:
Admin Fax:
Admin Fax Ext:
Admin Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodoctor.com>
Registry Tech ID: Not Available From Registry
Tech Name: Registration Private
Tech Organization: Domains By Proxy, LLC
Tech Street: DomainsByProxy.com
Tech Street: 100 S. Mill Ave, Suite 1600
Tech City: Tempe
Tech State/Province: Arizona
Tech Postal Code: 85281
Tech Country: US
Tech Phone: +1.4806242599
Tech Phone Ext:
Tech Fax:
Tech Fax Ext:
Tech Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodoctor.com>
Name Server: NS41.DOMAINCONTROL.COM
Name Server: NS42.DOMAINCONTROL.COM
DNSSEC: unsigned
URL of the ICANN WHOIS Data Problem Reporting System: <http://wdprs.internic.net/>



Tools

Hosting History	
Monitor Domain Properties	▼
Reverse IP Address Lookup	▼
Network Tools	▼
Visit Website	
📄 Preview the Full Domain Report	

Available TLDs

General TLDs	Country TLDs
---------------------	--------------

The following domains are available through our preferred partners. Select domains below for more information. (3rd party site)

- Taken domain.
- Available domain.
- Deleted previously owned domain.









MoUnjaRoDoctor.com	View Whois
MoUnjaRoDoctor.net	Buy Domain
MoUnjaRoDoctor.org	Buy Domain
MoUnjaRoDoctor.info	Buy Domain
MoUnjaRoDoctor.biz	Buy Domain
MoUnjaRoDoctor.us	Buy Domain



Home > Whois Lookup > MoUnjaRoDr.com

Whois Record for MoUnjaRoDr.com

— Domain Profile

Registrar	GoDaddy.com, LLC IANA ID: 146 URL: https://www.godaddy.com,http://www.godaddy.com Whois Server: whois.godaddy.com abuse@godaddy.com (p) +1.4806242505	
Registrar Status	clientDeleteProhibited, clientRenewProhibited, clientTransferProhibited, clientUpdateProhibited	
Dates	733 days old Created on 2022-06-14 Expires on 2024-06-14 Updated on 2023-06-15	
Name Servers	NS63.DOMAINCONTROL.COM (has 59,678,358 domains) NS64.DOMAINCONTROL.COM (has 59,678,358 domains)	
IP Address	3.33.152.147 - 9,159,981 other sites hosted on this server	
IP Location	 - New Jersey - Princeton - Amazon Technologies Inc.	
ASN	 AS16509 AMAZON-02, US (registered May 04, 2000)	
Domain Status	Registered And No Website	
IP History	3 changes on 3 unique IP addresses over 2 years	
Registrar History	1 registrar	
Hosting History	1 change on 2 unique name servers over 2 years	

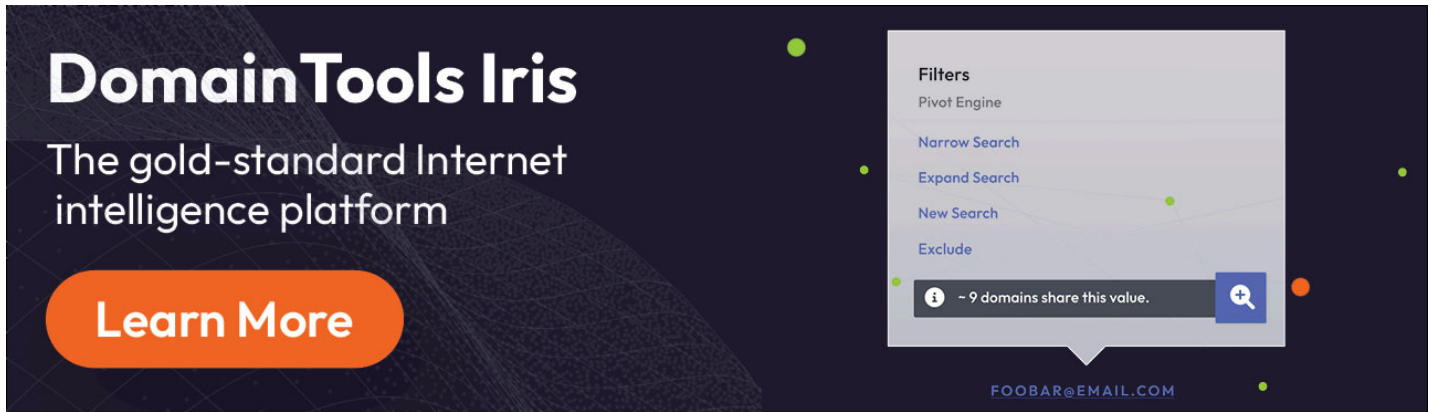
Whois Record (last updated on 2024-06-16)

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Domain Name: mounjarodr.com
Registry Domain ID: 2703923304_DOMAIN_COM-VRSN
Registrar WHOIS Server: whois.godaddy.com
Registrar URL: https://www.godaddy.com
Updated Date: 2023-06-15T12:00:47Z
Creation Date: 2022-06-14T15:25:50Z
Registrar Registration Expiration Date: 2024-06-14T15:25:50Z
Registrar: GoDaddy.com, LLC
Registrar IANA ID: 146

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Registrar Abuse Contact Email: abuse@godaddy.com
Registrar Abuse Contact Phone:
Domain Status: clientTransferProhibited <https://icann.org/epp#clientTransferProhibited>
Domain Status: clientUpdateProhibited <https://icann.org/epp#clientUpdateProhibited>
Domain Status: clientRenewProhibited <https://icann.org/epp#clientRenewProhibited>
Domain Status: clientDeleteProhibited <https://icann.org/epp#clientDeleteProhibited>
Registry Registrant ID: Not Available From Registry
Registrant Name: Registration Private
Registrant Organization: Domains By Proxy, LLC
Registrant Street: DomainsByProxy.com
Registrant Street: 100 S. Mill Ave, Suite 1600
Registrant City: Tempe
Registrant State/Province: Arizona
Registrant Postal Code: 85281
Registrant Country: US
Registrant Phone:
Registrant Phone Ext:
Registrant Fax:
Registrant Fax Ext:
Registrant Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodr.com>
Registry Admin ID: Not Available From Registry
Admin Name: Registration Private
Admin Organization: Domains By Proxy, LLC
Admin Street: DomainsByProxy.com
Admin Street: 100 S. Mill Ave, Suite 1600
Admin City: Tempe
Admin State/Province: Arizona
Admin Postal Code: 85281
Admin Country: US
Admin Phone:
Admin Phone Ext:
Admin Fax:
Admin Fax Ext:
Admin Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodr.com>
Registry Tech ID: Not Available From Registry
Tech Name: Registration Private
Tech Organization: Domains By Proxy, LLC
Tech Street: DomainsByProxy.com
Tech Street: 100 S. Mill Ave, Suite 1600
Tech City: Tempe
Tech State/Province: Arizona
Tech Postal Code: 85281
Tech Country: US
Tech Phone:
Tech Phone Ext:
Tech Fax:
Tech Fax Ext:
Tech Email: Select Contact Domain Holder link at
<https://www.godaddy.com/whois/results.aspx?domain=mounjarodr.com>
Name Server: NS63.DOMAINCONTROL.COM
Name Server: NS64.DOMAINCONTROL.COM
DNSSEC: unsigned
URL of the ICANN WHOIS Data Problem Reporting System: <http://wdprs.internic.net/>



Tools

Hosting History	
Monitor Domain Properties	▼
Reverse IP Address Lookup	▼
Network Tools	▼
Visit Website	
📄 Preview the Full Domain Report	

Available TLDs

General TLDs	Country TLDs
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The following domains are available through our preferred partners. Select domains below for more information. (3rd party site)

- Taken domain.
- Available domain.
- Deleted previously owned domain.

MoUnjaRoDr.com	View Whois
MoUnjaRoDr.net	Buy Domain
MoUnjaRoDr.org	Buy Domain
MoUnjaRoDr.info	Buy Domain
MoUnjaRoDr.biz	Buy Domain
MoUnjaRoDr.us	Buy Domain



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

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

)
)
)
)
)
)
)
)
)
)
)
)
)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

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

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

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

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*: _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
(b) County of Residence of First Listed Plaintiff
(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS
County of Residence of First Listed Defendant
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
PTF DEF
Citizen of This State 1 1
Citizen of Another State 2 2
Citizen or Subject of a Foreign Country 3 3
Incorporated or Principal Place of Business In This State 4 4
Incorporated and Principal Place of Business In Another State 5 5
Foreign Nation 6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, INTELLECTUAL PROPERTY RIGHTS, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)
1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Brief description of cause:

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

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