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Attorneys for Plaintiff
ELI LILLY AND COMPANY

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

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

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

INTRODUCTION

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

medicines, when in reality Defendant offers no such thing.[1] Lilly therefore brings this action under federal and state law to protect patients from Defendant's dangerous, deceptive, and unlawful practices.

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

3. Before obtaining FDA approval, Lilly's new medicines underwent years-long clinical trials, which tested them for safety, quality, and effectiveness on thousands of patients. When approving these medicines, the FDA called Lilly's

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

"novel" MOUNJARO® an "important advance" and observed that Lilly's ZEPBOUND® "addresses an unmet medical need." https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

4. Compounded products sold as "tirzepatide," meanwhile, are not approved or even reviewed by the FDA. Pharmacies currently offering compounded versions of tirzepatide are not required to follow the FDA's "good manufacturing practices," nor to comply with the same controls on sterility and safe storage as manufacturers of FDA-approved medicines. They are also not required to report adverse events—an important regulatory requirement imposed on manufacturers of FDA-approved medicines for patient safety. Compounded drugs are not tested for safety, quality, or efficacy in clinical trials. Accordingly, and as the FDA has warned, "compounded drugs pose a higher risk to patients than FDA-approved drugs," such as MOUNJARO® and ZEPBOUND®. https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages (FDA explainer on Drug Compounding).

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

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

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

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

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

THE PARTIES

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

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

JURISDICTION AND VENUE

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

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

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

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

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

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

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

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

17. As with MOUNJARO®, the safety, quality, and effectiveness of ZEPBOUND® was established through rigorous clinical trials featuring thousands of patients. The FDA recently approved ZEPBOUND® and indicated it for adults with obesity (with a BMI of 30 kg/m2 or greater) or those who are overweight (with a BMI ≥ 27 kg/m2 or greater) and also have at least one weight-related additional condition, such as hypertension (high blood pressure), dyslipidemia

(high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease, to lose weight. It should be used with a reduced-calorie diet and increased physical activity.

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

19. Countless highly specialized personnel ensure Lilly medicines meet quality and safety standards. Lilly manufactures its medicines under strict controls in state-of-the-art facilities. Transforming tirzepatide API to medicine is a complex, methodical, and science-based process. Lilly follows Good Manufacturing Practices (GMP), which are regulations that "provide[] for systems that assure proper design, monitoring, and control of manufacturing processes and facilities." https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp (FDA explainer on GMP). GMPs include "establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories." *Id.* GMPs help "prevent instances of contamination, mix-ups, deviations, failures, and errors." *Id.*

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

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

LILLY'S MOUNJARO® AND ZEPBOUND® TRADEMARKS

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

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

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

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

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

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

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

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

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

THE RISKS OF COMPOUNDING

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

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

of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (FDA guidance on drug compounding law compliance). This narrow exception applies, for instance, where a patient cannot safely take a commercially manufactured FDA-approved drug due to an allergy to a particular dye.

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

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

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

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

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

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

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

Id. (emphasis added).

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

36. Health risks from compounded drugs are serious. In 2021, a pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement re guilty plea). At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though patients suffered near-immediate adverse events, including permanent blindness. https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak). One patient had believed "every pill you take, every shot you take is tested" and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by the FDA. *Id.*

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

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

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

39. Consequences from compounded drugs may be deadly. In October 2012, compounded drugs contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. After these contaminated

products were injected into nearly 14,000 patients, more than 60 people died of fungal meningitis. *Id.* Regarding this outbreak, the FDA has written:

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

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

WIDESPREAD SAFETY CONCERNS ABOUT COMPOUNDED TIRZEPATIDE

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

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

Office of Unapproved Drugs and Labeling Compliance has issued multiple warning letters to compounding pharmacies purportedly selling compounded tirzepatide products because they are not safe or effective. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024 (FDA warning letter re US Chem Labs); https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024 (FDA warning letter re Synthetix Inc. DBA Helix Chemical Supply).

42. Across the country, at least nine state pharmacy boards, along with several state poison centers, have issued guidance and warnings regarding the risks to patients of compounded incretins. The Alabama Board of Pharmacy notified all licensed pharmacists and pharmacies that "even when compounding of [incretins] is allowable under [federal law], . . . the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited." https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists (Alabama Board of Medical Examiners press release). And the Maryland Poison Control Center warned that buying compounded incretins "online puts people at risk due to the medicine not being regulated and/or being sold from a source that is not licensed," including

because those compounded products "have not been evaluated for safety and effectiveness by the FDA." https://blog.mdpoison.com/2024/03/semaglutide (Blog of the Maryland Poison Center).

43. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded incretin drugs. The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®." https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (Australia Minister for Health and Aged Care press release). As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives." *Id.*

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

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

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

DEFENDANT'S FALSE ADVERTISING AND TRADEMARK INFRINGEMENT

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

47. On information and belief, Defendant does not sell Lilly's MOUNJARO® and ZEPBOUND® and has no association with Lilly. Yet Defendant boldly and falsely appropriates the Lilly Marks to market and sell Unapproved Compounded Drugs purporting to contain tirzepatide. These drugs are ***not*** MOUNJARO® or ZEPBOUND®. Rather, Defendant passes off Unapproved Compounded Drugs as "MOUNJARO," "ZEPBOUND," "GENERIC MOUNJARO," and/or "GENERIC ZEPBOUND." Defendant also operates under

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

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

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

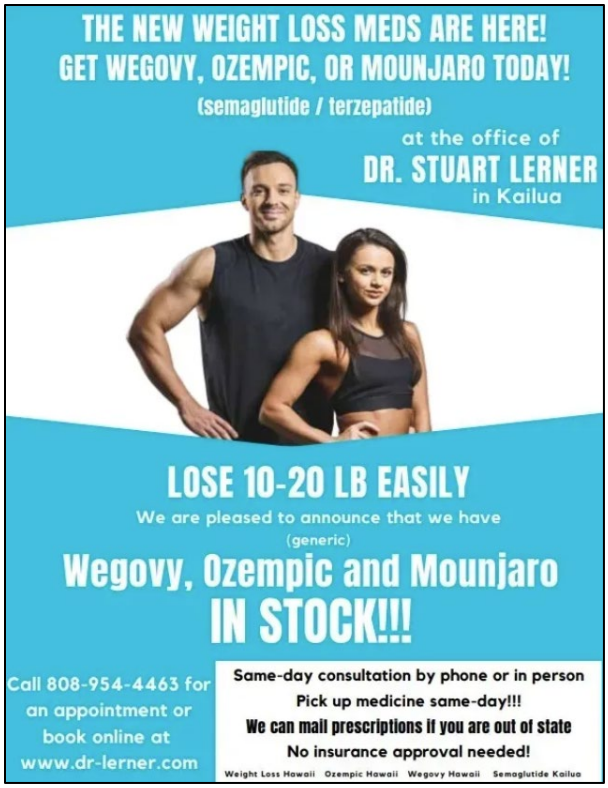
50. Examples of Defendant's trademark infringement and false advertising are shown below and are attached hereto as **Exhibit B**.

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

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

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

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

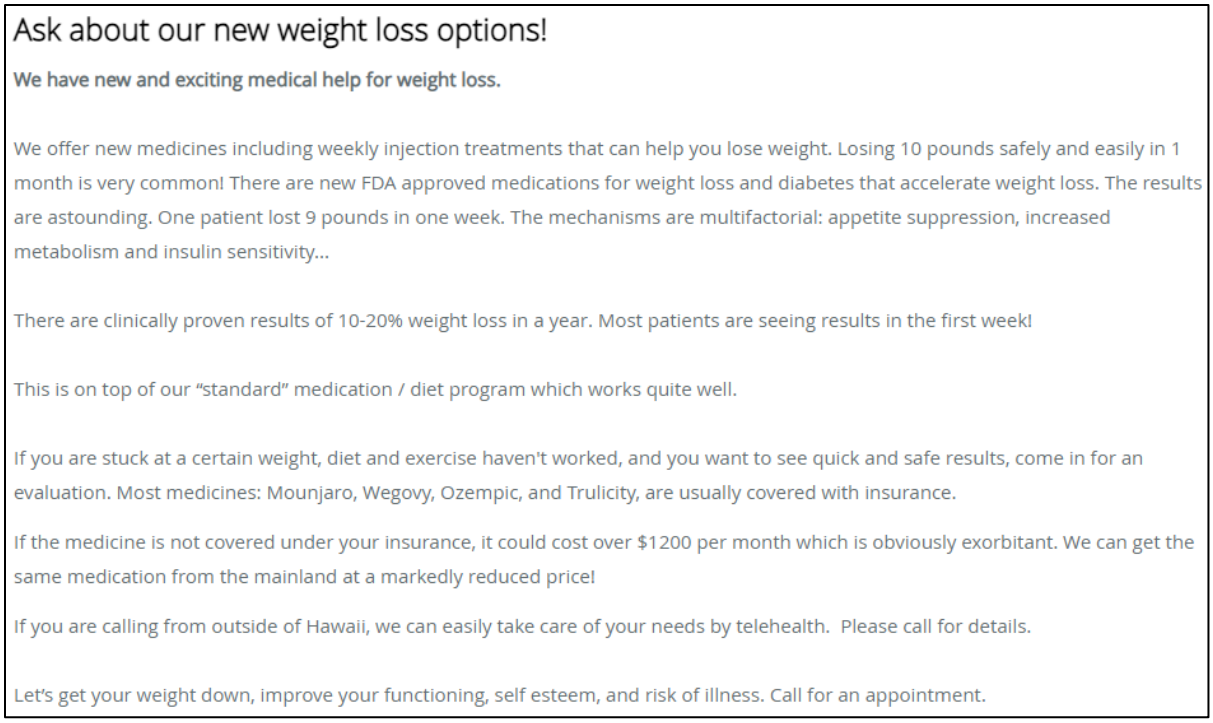


55. Defendant's website conveys the unmistakable impression that Defendant is offering for sale Lilly's MOUNJARO® and ZEPBOUND®, and/or an FDA-approved generic version thereof. But Lilly is the only approved source of MOUNJARO® and ZEPBOUND® in the United States, and Lilly does not sell either medicine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

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

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

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



Ask about our new weight loss options!

We have new and exciting medical help for weight loss.

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

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

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

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

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

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

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

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

60. Defendant continues to use the Lilly Marks, including in advertising and promotion on its website, to deceive patients who, upon information and belief, are seeking to buy but are in fact not buying genuine FDA-approved MOUNJARO® and/or ZEPBOUND® to treat their serious health conditions.

61. Defendant's prominent and misleading use of the Lilly Marks is likely to cause consumers to falsely believe that they are purchasing MOUNJARO® and/or ZEPBOUND®, that Defendant is a source for Lilly's FDA-approved

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

62. Defendant's use of the Lilly Marks is without the permission, consent, or authorization of Lilly. Defendant has no right to use, and Defendant knows that it has no right to use, the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs or otherwise. Defendant's advertising and promotional materials are false and misleading where they suggest and/or state an association with Lilly's FDA-approved MOUNJARO® and ZEPBOUND®, because no such association exists.

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

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

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

DEFENDANT'S CYBERSQUATTING

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

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

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

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

HARM TO THE PEOPLE OF HAWAI'I AND LILLY

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

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

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

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

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

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

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

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

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

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

79. As a direct and proximate result of the actions of Defendant alleged above, Lilly has been damaged and will continue to be damaged. Defendant's conduct, unless enjoined by the Court, will further impair the value of the Lilly

Marks' name, reputation, and goodwill. This harm constitutes an injury for which Lilly has no adequate remedy at law.

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

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

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

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

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

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

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

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

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

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

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

89. Based on such conduct, Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and

1118, including Defendant's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

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

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

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

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

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

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

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

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

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

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

FOURTH CAUSE OF ACTION
Cybersquatting
in Violation of 15 U.S.C. § 1125(d)

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

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

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

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

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

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

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

106. Defendant's acts are willful and malicious.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

138. Consumers who encounter Defendant's unauthorized use of the Lilly Marks in connection with Defendant's Unapproved Compounded Drugs and related goods and services are likely to think that they are provided, licensed,

sponsored, authorized, or approved by, or otherwise associated or affiliated with, Lilly.

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

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

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

PRAYER FOR RELIEF

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

1. An Order declaring that Defendant:

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

b. Infringed the Lilly Marks and engaged in trademark infringement, false designation of origin, and unfair competition, in violation of 15 U.S.C. § 1125(a)(1)(A);

c. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B);

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

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

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

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

a. Using the Lilly Marks or any mark confusingly similar to them, in connection with the advertising, promoting, marketing, selling or offering for sale of any goods or services (including, but not limited to, Unapproved

Compounded Drugs) or otherwise engaging in any activity that is likely to cause confusion, cause mistake, or deceive or otherwise infringe any rights of Plaintiff Lilly in the Lilly Marks or any similar mark;

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

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

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

e. Engaging in any deceptive or unfair acts.

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

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

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

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

6. An Order requiring Defendant to pay Lilly compensatory damages in an amount as yet undetermined caused by the foregoing acts of infringement, false designation of origin, false advertising, and unfair competition, and trebling such

compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117 and other applicable laws;

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

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

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

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

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

12. Other relief as the Court may deem appropriate.

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

/s/ Ross T. Shinyama
JOYCE W.Y. TAM-SUGIYAMA
ROSS T. SHINYAMA
RIHUI YUAN
WATANABE ING LLP

JOSHUA L. SIMMONS (*pro hac vice* forthcoming)
JEANNA M. WACKER (*pro hac vice* forthcoming)
ASHLEY ROSS (*pro hac vice* forthcoming)
JOSHUA C. BERLOWITZ (*pro hac vice* forthcoming)
DIANA M. WATRAL (*pro hac vice* forthcoming)
JAMES F. HURST (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP

Attorneys 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

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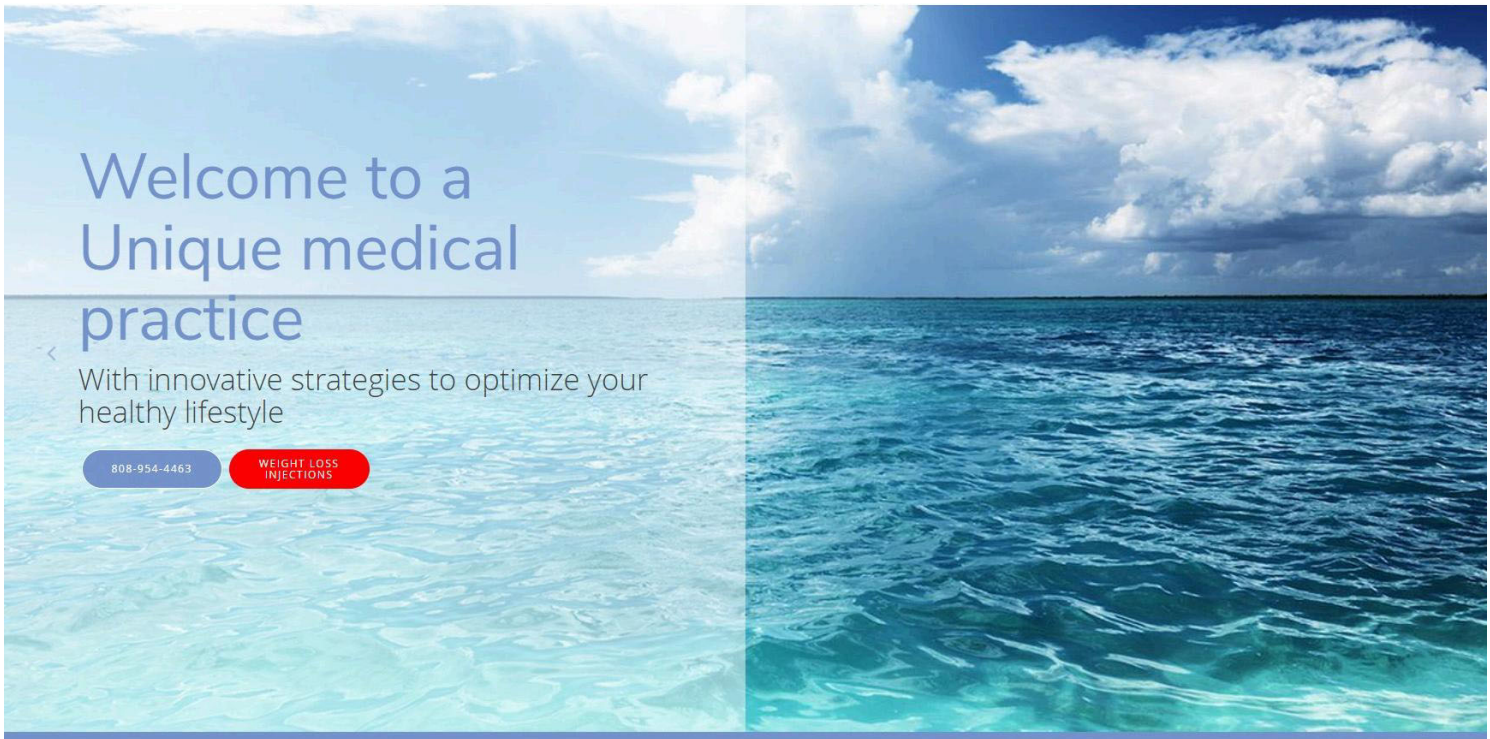
EXHIBIT B

NEW MEDICAL WEIGHT LOSS OPTIONS: MOUNJARO, OZEMPIC, WEGOVY, ZEPBOUND!

WE HAVE SEMAGLUTIDE AND TIRZEPATIDE (GENERIC WEGOVY, OZEMPIC, MOUNJARO and the new ZEPBOUND) IN STOCK. No insurance approval needed



Stuart Lerner, MD

Family Medicine, Holistic Medicine, & Urgent Care in Kailua, HI

"Dr. Lerner's staff is the best! They are like family."

TIFFANY B. GOOGLE

Our philosophy is a little more holistic then a "regular" medical office.

We work with you to find out the cause of your illness and eliminate it. Whether it is a hormone-based problem, lifestyle problem, a diet problem.

We are open minded to alternative treatments such as safe HRT for men and women, eliminating toxins in your body, naturopathic treatments for leaky gut, advanced laboratory testing for allergies and heart disease risk.

Also if you come in as a walk-in we will see you. Sometimes it is hard to get through on the phones. If you come in as a walk-in we will see you that day.

General Medical Care

Ask about medical services being offered, including advanced procedures:

- General medical care, urgent care, and preventive care ages 8 to 108! All are welcome (vaccinated or not). Telehealth available.
- Care for diabetes, hypertension, cholesterol, home care, weight management... adolescents, contraception, womens health, elderly care
- URGENT CARE AND MOST WALK-INS CAN BE SEEN THE SAME DAY
- Complete MENS AND WOMENS HEALTH by experienced male and female doctors and nurse practitioners
- NEW ADVANCED MEDICAL WEIGHT LOSS program with terrific results! 10 lbs in a month is average. Get the poison out of your diet!
- Testosterone for men with low T, part of our Kailua Men's Clinic
- Bioidentical HRT for women
- Advanced testing and herbal treatments to Improve energy, libido, stress, low thyroid
- Botox cosmetic & Juvederm facial rejuvenation
- BOTOX for TMJ GRINDING TEETH. **** BOTOX for HEADACHE, NECK PAIN may be covered by insurance
- Same day COVID TESTING for individuals, families, or work exposure. NO LINES!
- IVERMECTIN FOR COVID PREVENTION AND TREATMENT (not fda approved)
- Advanced pain management, including Suboxone / Buprenorphine to get off narcotics

- Regenerative therapy for back and joint pain including laser therapy
- Nutrition guidance and supplements for diabetes, fatigue, sleep
- Concierge Medical Service - hotel or home visits for select patients who need discretion and privacy
- Ask about CBD for pain, anxiety, inflammation, sleep
- Medical marijuana certificate available

Weight loss

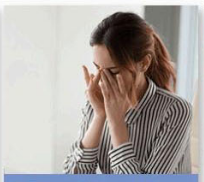
Exciting news! Mounjaro was just just given FDA approval for weight loss!

If your Wegovy or Mounjaro prescription is not covered by insurance you can get generic Semaglutide and Terzepatide

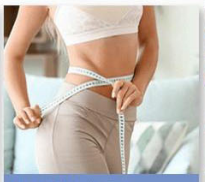
If you cannot get the medication at Kaiser, Straub or the military, we have them in the office for you!

FEATURED SERVICES

Urgent Care



Fatigue & Thyroid Disorders



NEW Weight Loss Rx!!!

Low Testosterone & Bioidentical Hormone Therapy

BOTOX for Headache and Neck Pain, TMJ / Grinding Teeth

Concierge Home / Hotel Medical Visits and IV or Vitamin Infusions

Medical Marijuana

As of Jan 1 2024 we will no longer be offering this service for new patients

UHA Patients

Welcome to a Unique Medical Practice

Combining Old Style Family Medicine for ages 8 - 108

including urgent care and house calls
with innovative strategies to optimize your healthy lifestyle
including holistic, preventive, and integrative medicine.

About the Practice

Welcome to Stuart Lerner, MD, a Family Medicine practice offering both traditional and holistic medicine, along with Urgent Care in Kailua.

The team at Stuart Lerner, MD, prevents and treats a wide range of ailments, including acute illnesses and injuries, as well as chronic conditions such as diabetes. Our goal is to find the cause for your illness, eliminate the cause, especially if it is diet related, and get you off your medications if possible! This includes medicines for blood pressure, diabetes and even pain medicines. We also concentrate on optimizing health, hormone balance, and lifestyle medicine.

The family practice also offers Covid testing, physical exams, adolescent to elderly care, assistance with weight-loss, and offers aesthetic treatments, including Botox and Juvederm ®.

We are excited to announce expansion of our medical services with:

"Hawaii Integrative Family Medicine and Urgent Care"

The new title better encompasses the breadth of services we offer.

We have added a new medical doctor for traditional care, Dr Economos.

We have added a new Nurse Practitioner, who specializes in Geriatrics and Women's Health.

Our office is home to the Kailua Men's Clinic for Low T for men and we are the only specialized center for Mens' health on the windward side.

We will also be updating our medical record system and phone capabilities to accommodate our growing need for scheduling and refills.

If you're ready to get to the root of your health problems, or are interested in optimizing your wellness, call on Dr. Lerner and the Hawaii Integrative Family Medicine team at his practice today.

To schedule a consultaion or appointment please call:

808-954-4463

Our Physicians and Providers

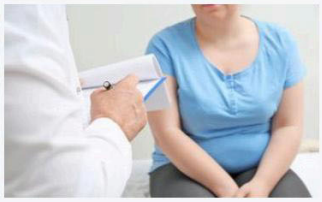
Stuart Lerner, MD
Family Medicine

Katherine Filbeck, APRN-Rx, NP-C
Family Nurse Practitioner

Jennifer Williams, NP
Women's Health Nurse Practitioner

Christina Economos , MD
General Medicine

Advanced medical therapeutics with traditional and holistic approaches.
Preventing and treating the cause of illness and promoting longevity.

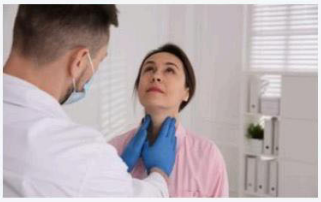


Tirzepatide And Semaglutide: Learn About These New Weapons In The Weight Loss Battle

Beyond traditional diets: Discover the next-generation solutions revolutionizing weight management. Weight loss injectables offer hope to the many Americans struggling with their weight.

Bothered By Teeth Grinding? Botox Can Help

Do you get jaw pain or headaches from grinding your teeth? BOTOX can help....



5 Symptoms That Suggest You May Have A Thyroid Disorder

Do you feel exhausted most of the time? Do you find it difficult to control your weight? Is "brain fog" an ongoing problem? If you answered yes to these questions, a thyroid disorder could be the culprit. Learn more here.

LOCATION

Stuart Lerner, MD

OFFICE HOURS

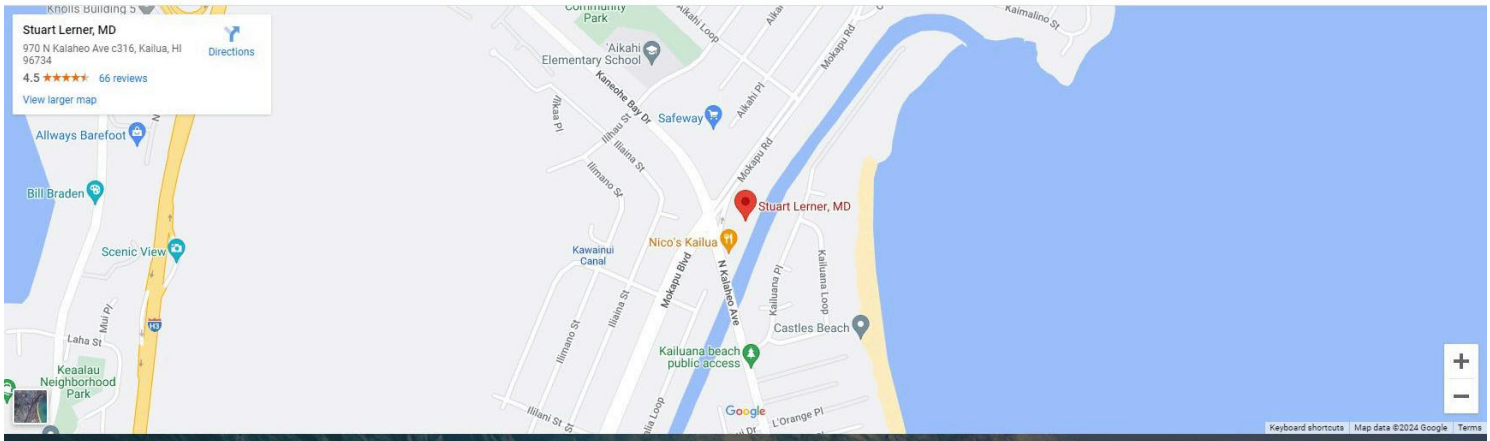
Monday 8:30 am - 5:00 pm

GET IN TOUCH

970 N Kalaheo Avenue, Suite C316
Kailua, HI 96734
Phone: 808-954-4463
Fax: 888-364-2014

Tuesday	8:30 am - 5:00 pm
Wednesday	8:30 am - 5:00 pm
Thursday	8:30 am - 5:00 pm
Friday	8:30 am - 5:00 pm
Saturday	NEW: We have opened Saturday mornings for weight loss consultations 8:30 am - 11:00 am!
Sunday	Closed

SCHEDULE APPOINTMENT ONLINE



"I have been a patient of Dr. Lerner for more than 6 months and you just can not beat his bedside manners and knowledge of medical experience."

ROBERT V.

Pause

Stuart Lerner, MD, Kailua, HI
Phone (appointments): 808-954-4463 | Phone (general inquiries): 808-954-4463
Address: 970 N Kalaheo Avenue, Suite C316, Kailua, HI 96734

4.88 / 5 (40 reviews)

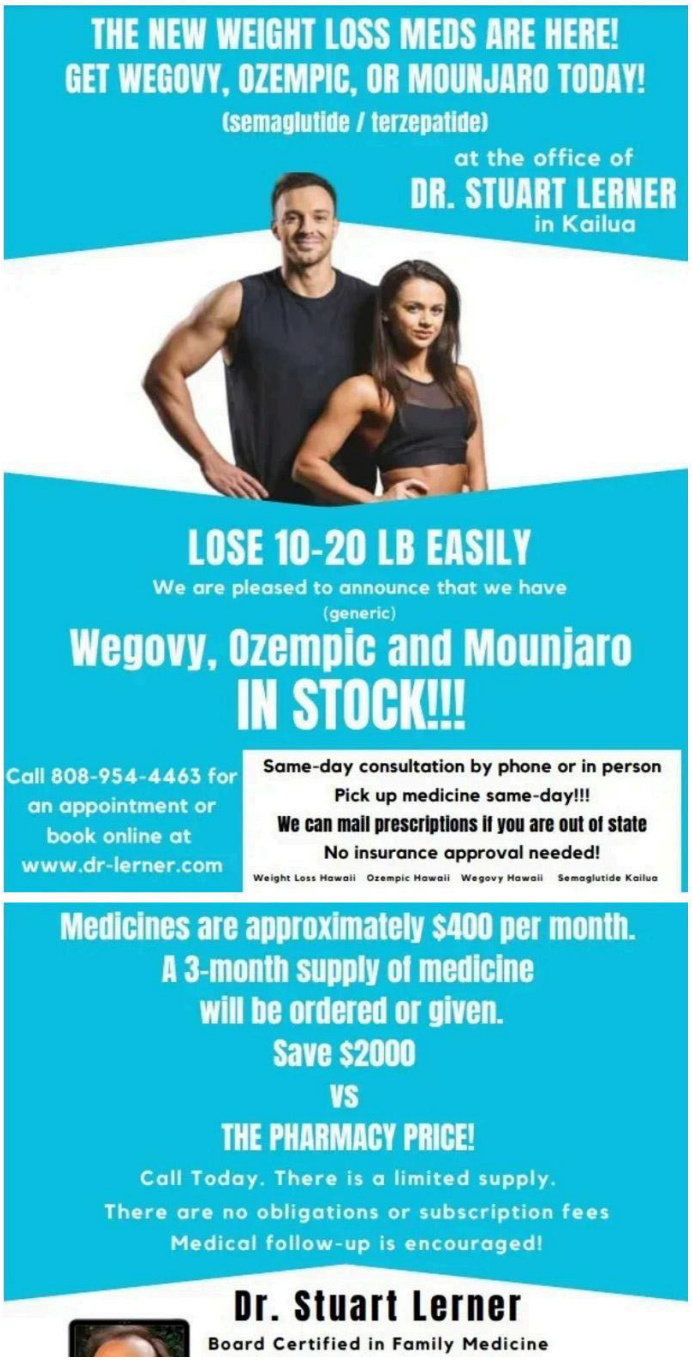
Medical website powered by Tebra

NEW MEDICAL WEIGHT LOSS OPTIONS: MOUNJARO, OZEMPIC, WEGOVY, ZEPBOUND!
WE HAVE SEMAGLUTIDE AND TIRZEPATIDE (GENERIC WEGOVY, OZEMPIC, MOUNJARO and the new ZEPBOUND) IN STOCK. No insurance approval needed

Weight Loss

If your Wegovy or Mounjaro prescription is not covered by insurance you can get generic Semaglutide and Terzepatide in our office at 1/3 the cost!

WE HAVE GENERIC WEGOVY OZEMPIC SEMAGLUTIDE WEIGHT LOSS injectables



Traditional and Holistic Medicine
970 N. Kalaheo Ave., #C316
Kailua, HI 96734
FREE Parking
For an appointment, please call
808.954.4463

Dr. Lerner's office has been a leader in Lifestyle Medicine, in safe testosterone hormone replacement for men, and in women's health for many years. We have added new practitioners for women's HRT, and general medical care.

Katherine Filbeck, APRN-Rx, NP-C
Family Nurse Practitioner

Jennifer Williams, DNP, APRN
Women's Health Nurse Practitioner

Christina Economos , MD
General Medicine

For more info or to book an online appointment please visit
www.dr-lerner.com

Ask about our new weight loss options!

We have new and exciting medical help for weight loss.

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

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

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

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

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

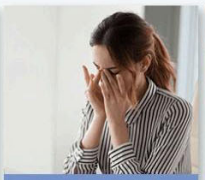
If you are calling from outside of Hawaii, we can easily take care of your needs by telehealth. Please call for details.

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

Separately, if you struggle with weight, you may have a hormonal problem that actually prevents you from losing weight, even if you exercise!. Most physicians do not test for this. This can be easily fixed with hormone balancing and possibly medications. We make easy to follow programs that help patients, from young otherwise healthy people to older cardiac patients. Collectively in our practice, patients have lost approximately 850 lb in the last 2 years, many without even exercising. (But we do recommend exercise if you can.) If you would like results, come to Dr. Lerner for weight-related medical services. Find the right solution by scheduling an appointment online or over the phone today.

FEATURED SERVICES

Urgent Care



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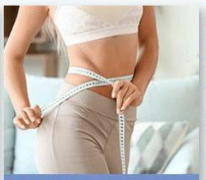

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Address: 970 N Kalaheo Avenue, Suite C316, Kailua, HI 96734

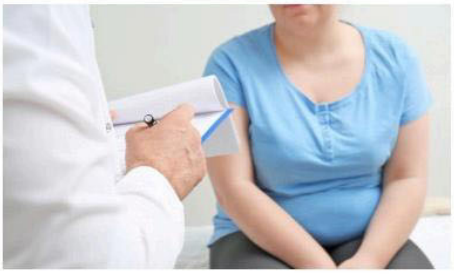
4.88 / 5 ★★★★★ (40 reviews)

New weight loss options!

New studies are showing an **average** of 15-20%, equal to 50 pounds weight loss!
We have Mounjaro, Wegovy, Ozempic, Semaglutide, weight loss injectables...in STOCK!!!
My own patients have safely lost 10 lb in 2 weeks!

Go home with meds in your hand!
Or we can order and ship to your house if you are on the mainland or outer island..
Start losing weight today! Proven results averaging 10- 20% of your body weight. You will be followed by a physician or nurse practitioner one on one. . We have opened our office on Saturday mornings to meet demand!
Book an appointment online today as medicines are in short supply.

You Might Also Enjoy...



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Beyond traditional diets: Discover the next-generation solutions revolutionizing weight management. Weight loss injectables offer hope to the many Americans struggling with their weight.

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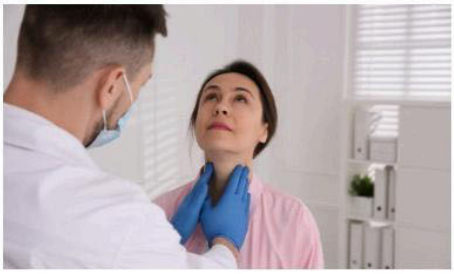

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Can Medical Marijuana Help My Digestive Disorder?

If you live with a persistent digestive disorder, front-line treatments may not always provide effective relief. Learn how medical marijuana works to ease hard-to-manage gastrointestinal symptoms — and find out how it can help you.

Weight-loss drug Wegovy cuts heart attack, stroke risk by 20%, study says

A new study shows the popular weight loss drug Wegovy can also reduce the risk of a heart attack or stroke by 20%.

Urgent Care

We offer same-day, walk-in and urgent care appointments. Skip the lines and the phone calls, and just come in for evaluation for flu symptoms, back pain, work notes, COVID tests...

Stuart Lerner, MD, Kailua, HI

Phone (appointments): 808-954-4463 | Phone (general inquiries): 808-954-4463

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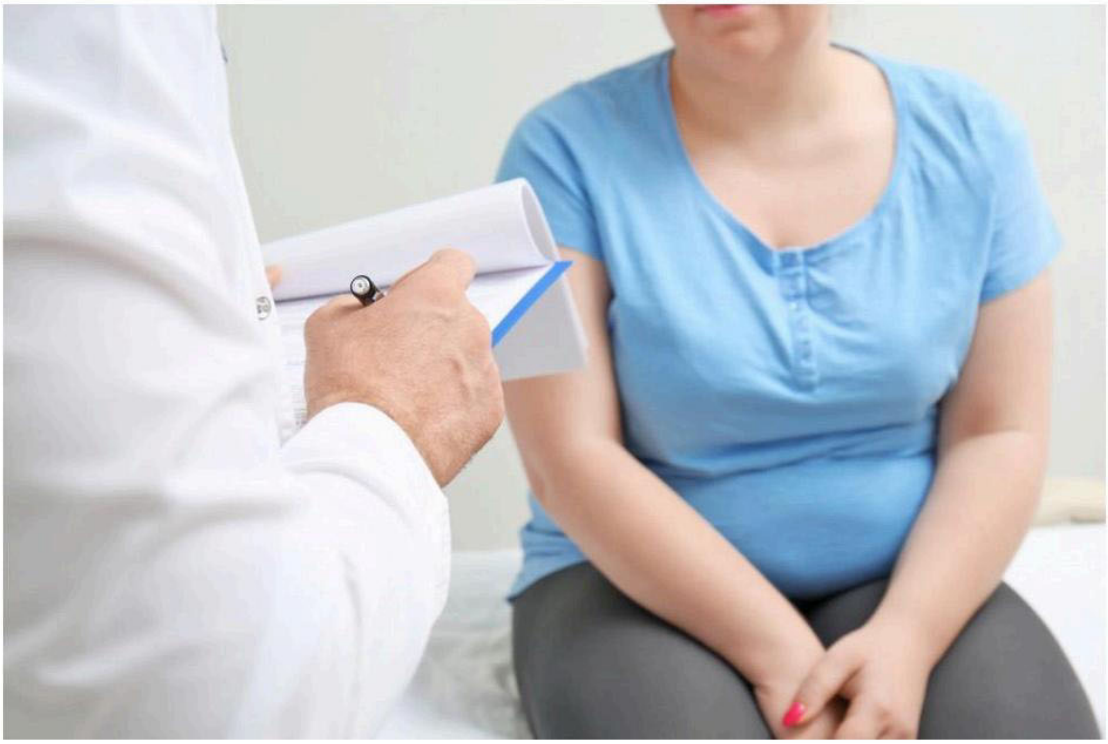
Tirzepatide and Semaglutide: Learn About These New Weapons in the Weight Loss Battle



Tackling weight loss can sometimes feel like a never-ending roller coaster. The cycle of shedding and regaining weight can be disheartening. The good news is that innovation in the realm of weight loss has brought promising solutions like tirzepatide and semaglutide.

At our serene clinic nestled in Kailua, Hawaii, Dr. Stewart Lerner, MD, and our proficient team are committed to your well-being. Specializing in metabolic, regenerative, anti-aging, and functional medicine, Dr. Lerner recognizes the unique challenges tied to weight loss.

To help patients tackle excess weight, our team provides individualized weight management plans, which may include breakthrough medications like tirzepatide and semaglutide.

A deep dive into tirzepatide and semaglutide

While both tirzepatide (known commercially as Mounjaro®) and semaglutide (Ozempic®) were initially designed to regulate blood glucose for patients with Type 2 diabetes, their potential for weight management has become evident.

Semaglutide has secured its position with Food and Drug Administration approval under the brand name Wegovy® to address obesity. Tirzepatide is racing toward approval due to its impressive outcomes, often surpassing other weight-loss injections. As of this writing, it is used off-label for weight management.

The mechanisms of these medications differ slightly, with tirzepatide boasting dual-action capabilities that may elevate weight loss

effectiveness.

Understanding how Tirzepatide and Semaglutide influence weight

At their core, both semaglutide and tirzepatide manage weight by moderating hunger, ensuring reduced food intake.

Semaglutide

Falling under the glucagon-like peptide-1 (GLP-1) receptor agonists category, semaglutide imitates the GLP-1 hormone actions, which the digestive system releases after you eat. This hormone helps produce insulin and taps into the brain's appetite center, signaling satiation.

Tirzepatide

Pioneering its drug category, tirzepatide is a dual receptor agonist for both GLP-1 and glucose-dependent insulinotropic polypeptide (GIP). GIP, another digestive hormone, stimulates insulin release.

With the injections, heightened GIP levels prolong the digestion process, ensuring prolonged satiety. These medications also appear to cut down food cravings, further regulating calorie intake.

Is this the right choice for me?

We have generic semaglutide and tirzepatide (usually) in stock and can dispense it to any patient who is overweight. There are no "restrictions" or "approvals" needed off the insurance, and because of this we can offer a substantial discount from the pharmacy price. Please come in to discuss your individual needs. There are no obligations or commitments, and we will teach you how to stop or wean off the medicine if you desire. You do not have to stay on the medicine forever. We will guide you through the process. Many of our patients have lost 15 pounds in the first month and a few have lost 50 pounds in 5 months. The results can be life-changing.

For optimal results, these injections should align with a balanced diet and consistent exercise. On average, individuals might experience a 12% weight loss with semaglutide and an astounding 20% with tirzepatide over a span of 16 months.

There's more to weight loss than willpower. Modern medicinal advances provide hope. If you're eager to explore these options further, connect with our dedicated team for a comprehensive weight management discussion.

With the help of medical intervention, the odds of lasting weight loss are finally in your favor. Get started today by contacting our office in Kailua, Hawaii, today.

You Might Also Enjoy...

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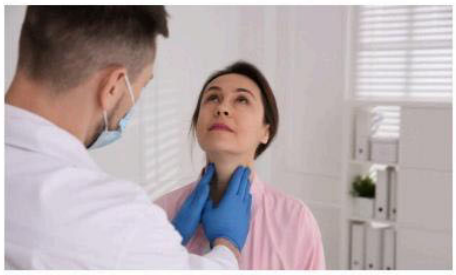

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Urgent Care

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Skip the lines and the phone calls, and just come in for evaluation for flu symptoms, back pain, work notes, COVID tests...

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EXHIBIT C

Home > Whois Lookup > MoUnjaRoHawaii.com

Whois Record for MoUnjaRoHawaii.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	406 days old Created on 2023-05-07 Expires on 2025-05-07 Updated on 2024-05-08
Name Servers	NS49.DOMAINCONTROL.COM (has 59,678,358 domains) NS50.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	1 change on 1 unique IP addresses over 1 years
Registrar History	1 registrar
Hosting History	1 change on 2 unique name servers over 1 year

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

```
Domain Name: mounjarohawaii.com
Registry Domain ID: 2779032455_DOMAIN_COM-VRSN
Registrar WHOIS Server: whois.godaddy.com
Registrar URL: https://www.godaddy.com
Updated Date: 2024-05-08T13:47:03Z
Creation Date: 2023-05-07T23:23:12Z
Registrar Registration Expiration Date: 2025-05-07T23:23:12Z
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=mounjarohawaii.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=mounjarohawaii.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=mounjarohawaii.com
Name Server: NS49.DOMAINCONTROL.COM
Name Server: NS50.DOMAINCONTROL.COM
DNSSEC: unsigned
URL of the ICANN WHOIS Data Problem Reporting System: http://wdprs.internic.net/

Tools

Hosting History

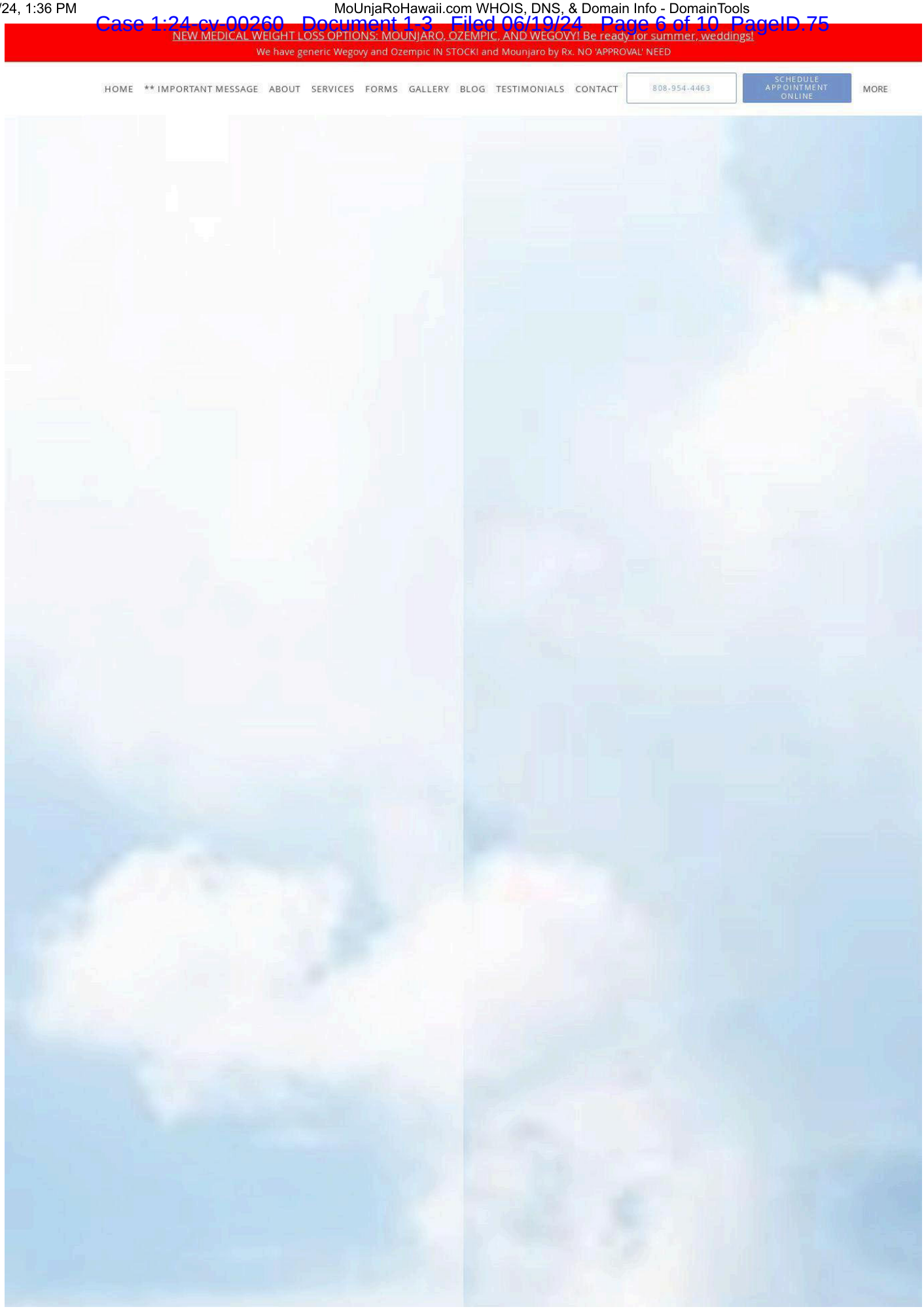
Monitor Domain Properties

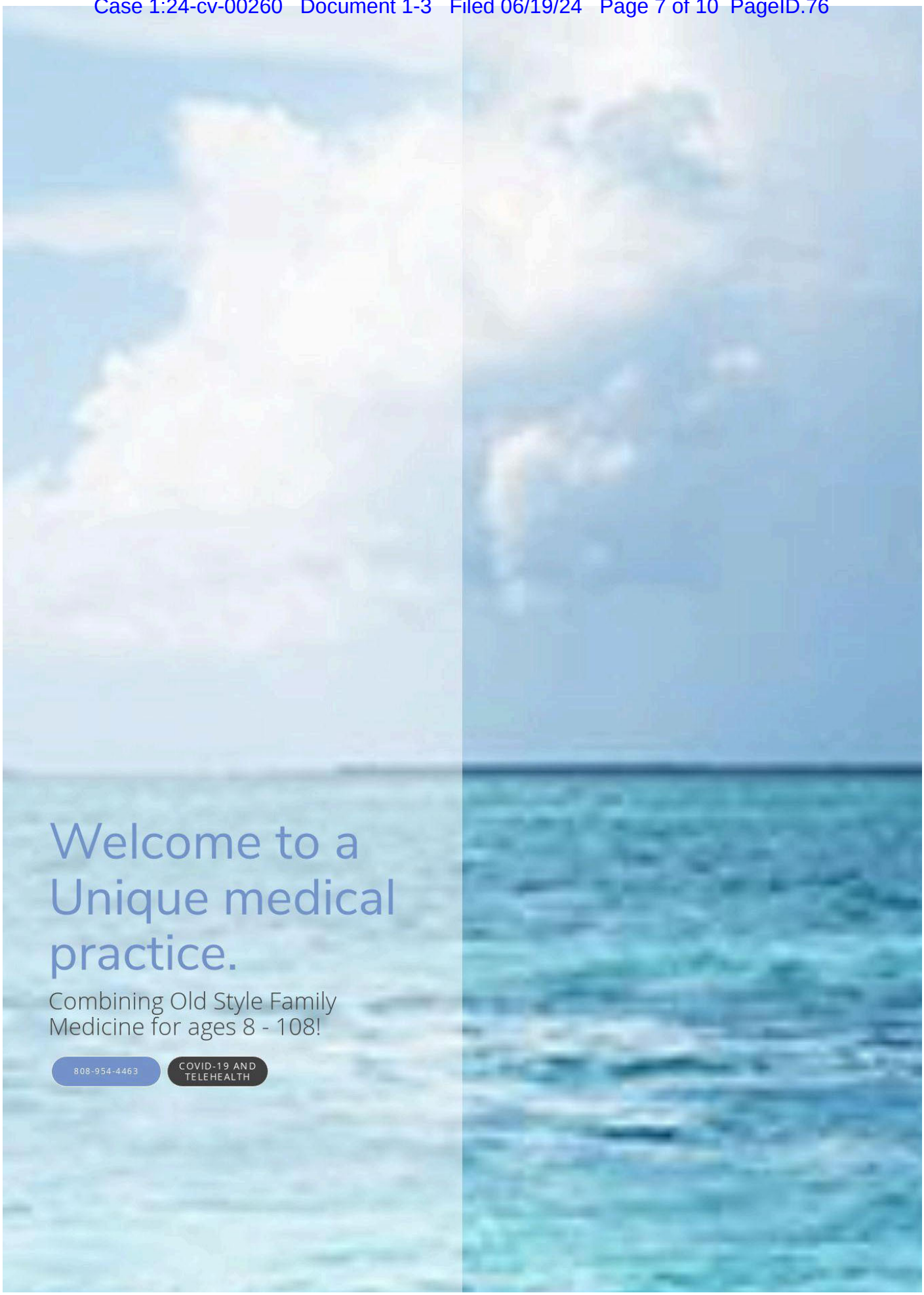
Reverse IP Address Lookup

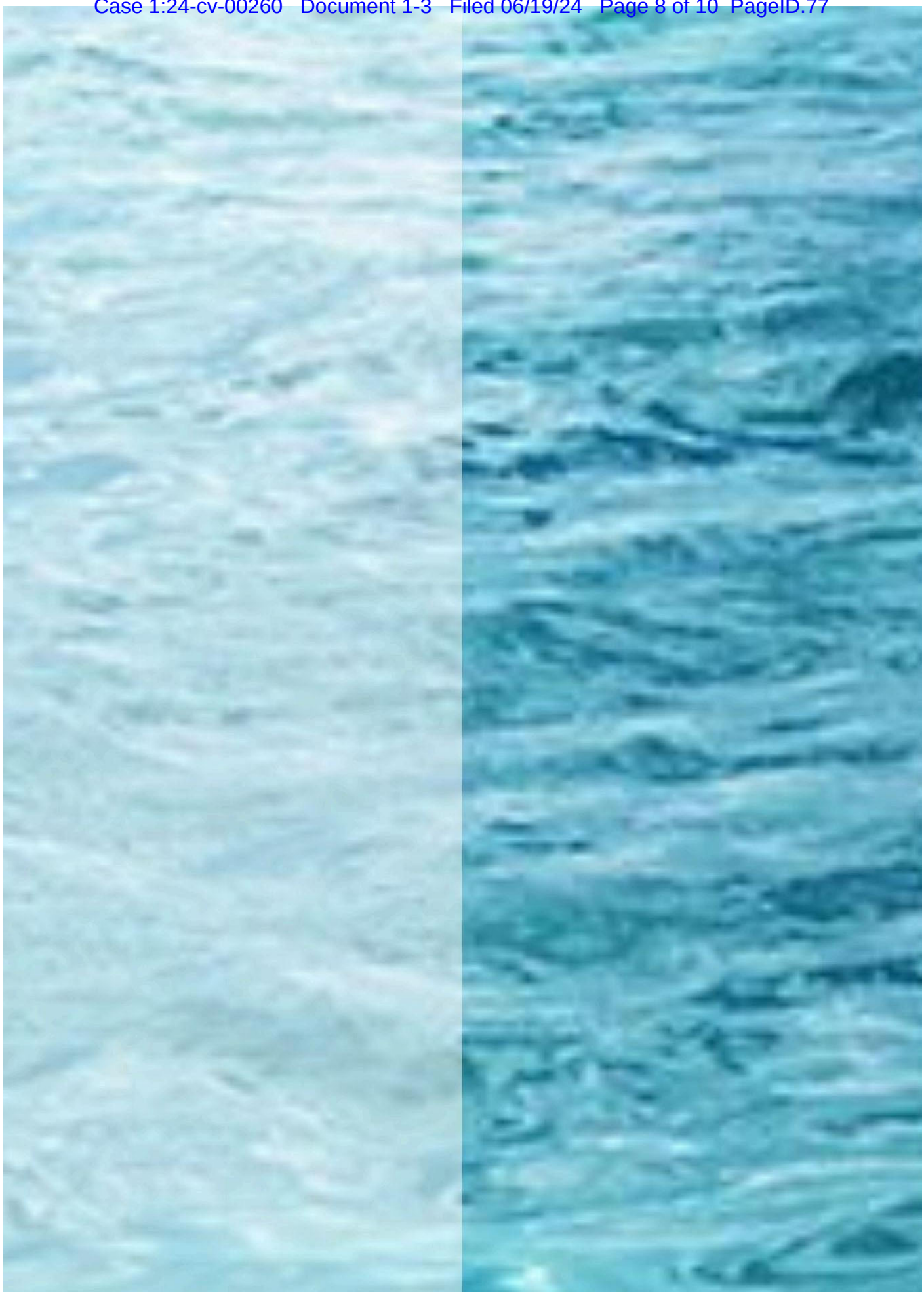
Network Tools

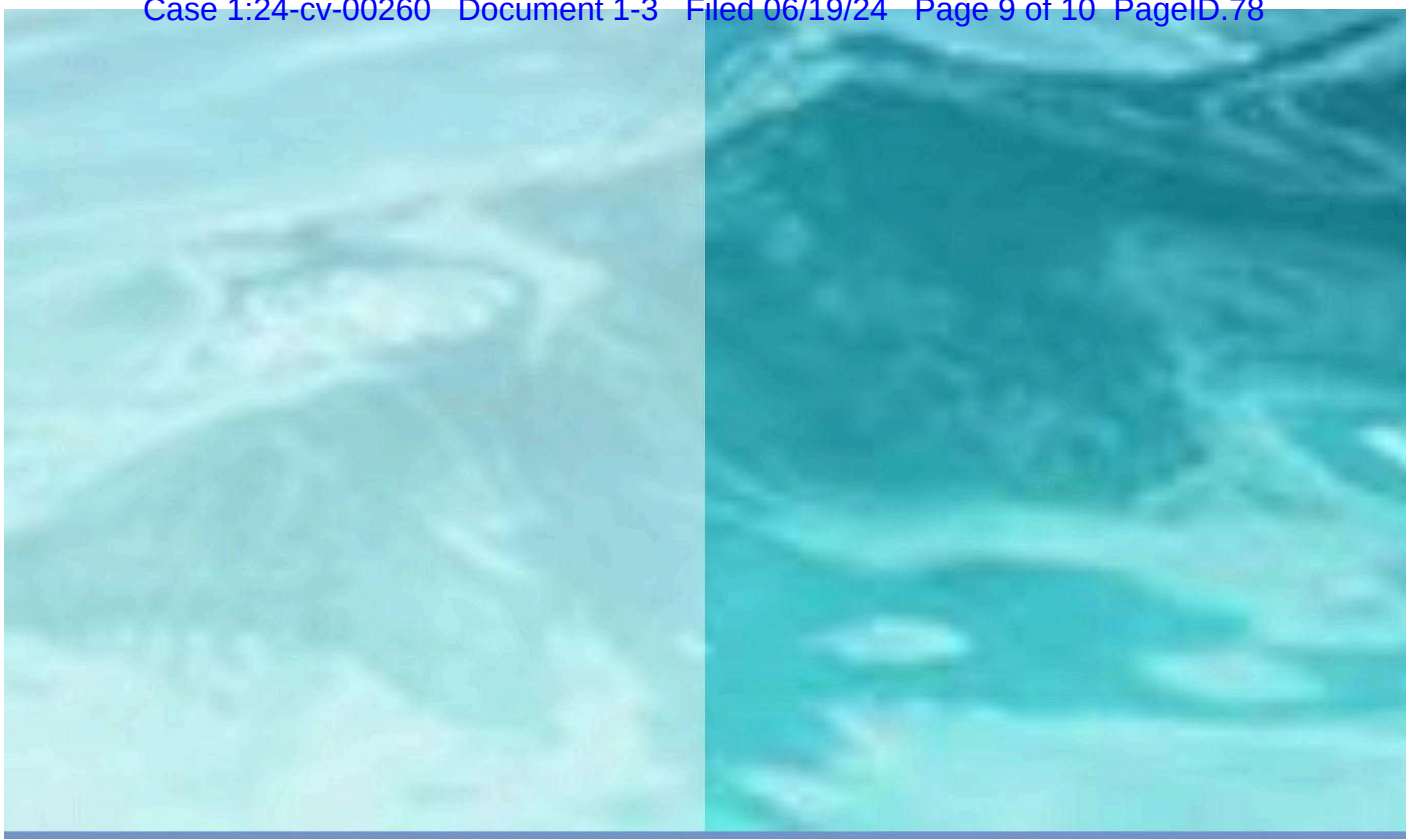
Visit Website

Preview the Full Domain Report


NEW MEDICAL WEIGHT LOSS OPTIONS: MOUNJARO, OZEMPIC, AND WEGOVY! Be ready for summer, weddings!
We have generic Wegovy and Ozempic IN STOCK! and Mounjaro by Rx. NO 'APPROVAL' NEED
HOME
** IMPORTANT MESSAGE
ABOUT
SERVICES
FORMS
GALLERY
BLOG
TESTIMONIALS
CONTACT
808-954-4463
SCHEDULE APPOINTMENT ONLINE
MORE


Welcome to a Unique medical practice.
Combining Old Style Family Medicine for ages 8 - 108!
808-954-4463
COVID-19 AND TELEHEALTH





Stuart Lerner, MD

Family Medicine, Holistic Medicine, & Urgent Care in Kailua, HI

"Dr. Lerner and his excellent staff make office visits painless."

CHRISTINE P. GOOGLE

Our philosophy is a little more holistic then a "regular" medical office.

We work with you to find out the cause of your illness and eliminate it. Whether it is a hormone-based problem, lifestyle problem, a diet problem.

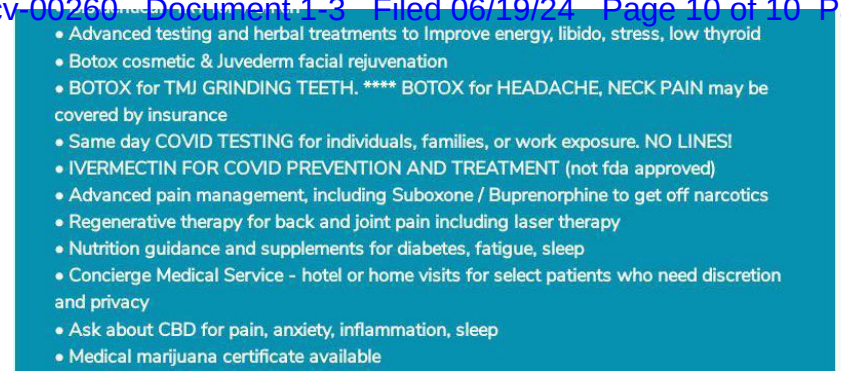
We are open minded to alternative treatments such as safe HRT for men and women, eliminating toxins in your body, naturopathic treatments for leaky gut, advanced laboratory testing for allergies and heart disease risk.

Also if you come in as a walk-in we will see you. Sometimes it is hard to get through on the phones. If you come in as a walk-in we will see you that day.

General Medical Care

Ask about medical services being offered, including advanced procedures:

- General medical care, urgent care, and preventive care ages 8 to 108! All are welcome (vaccinated or not). Telehealth available.
- Care for diabetes, hypertension, cholesterol, home care, weight management... adolescents, contraception, womens health, elderly care
- URGENT CARE AND MOST WALK-INS CAN BE SEEN THE SAME DAY
- Complete MENS AND WOMENS HEALTH by experienced male and female doctors and nurse practitioners
- NEW ADVANCED MEDICAL WEIGHT LOSS program with terrific results! 10 lbs in a month is average. Get the poison out of your diet!
- Testosterone for men with low T, part of our Kailua Men's Clinic
- Bioidentical HRT for women



View Screenshot History

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.

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

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

ELI LILLY AND COMPANY, Plaintiff, vs. STUART LERNER M.D., LLC D/B/A “STUART LERNER, MD” AND UNREGISTERED TRADE NAME “MOUNJARO HAWAII”, Defendant.	CASE NO. _____ **DEMAND FOR JURY TRIAL**

DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff ELI LILLY AND COMPANY, by and through its undersigned counsel, pursuant to Rule 38 of the Federal Rules of Civil Procedure, hereby demands a trial by jury of all issues in this case.

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

/s/ Ross T. Shinyama
JOYCE W.Y. TAM-SUGIYAMA
ROSS T. SHINYAMA
RIHUI YUAN
WATANABE ING LLP

JOSHUA L. SIMMONS (*pro hac vice* forthcoming)
JEANNA M. WACKER (*pro hac vice* forthcoming)
ASHLEY ROSS (*pro hac vice* forthcoming)
JOSHUA C. BERLOWITZ (*pro hac vice* forthcoming)
DIANA M. WATRAL (*pro hac vice* forthcoming)
JAMES F. HURST (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP

Attorneys for Plaintiff
ELI LILLY AND COMPANY

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Eli Lilly and Company

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

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

DEFENDANTS

Stuart Lerner M.D., LLC d/b/a "Stuart Lerner, MD" and Unregistered Trade Name "Mounjaro Hawaii"

County of Residence of First Listed Defendant Honolulu, HI
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ☒ 840 Trademark

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

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

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
15 U.S.C. § § 1114, 1125

Brief description of cause:
Trademark infringement, false designation of origin, false advertising

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
06/19/2024

SIGNATURE OF ATTORNEY OF RECORD
/s/ Ross T. Shinyama

FOR OFFICE USE ONLY

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

Civil Cover Sheet Attachment

Eli Lilly and Company v. Stuart Lerner M.D., LLC d/b/a "Stuart Lerner, MD" and Unregistered Trade Name "Mounjaro Hawaii"

I(c), Plaintiff's Attorneys (Firm Name, Address, and Telephone Number)

WATANABE ING LLP
A Limited Liability Law Partnership

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RIHUI YUAN #11535-0
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jtam@wik.com
ryuan@wik.com

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JEANNA M. WACKER (*pro hac vice* forthcoming)
ASHLEY ROSS (*pro hac vice* forthcoming)
JOSHUA C. BERLOWITZ (*pro hac vice* forthcoming)
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ashley.ross@kirkland.com

josh.berlowitz@kirkland.com
diana.watral@kirland.com
james.hurst@kirland.com

VII. Requested in Complaint

- Demand $: Unspecified/Injunction