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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. EMPOWER CLINIC SERVICES, LLC d/b/a EMPOWER PHARMACY, EMPOWER CLINIC SERVICES NEW JERSEY LLC d/b/a EMPOWER PHARMA, Defendant.	)	Case No.: *Electronically Filed*

COMPLAINT

1. Empower claims to be our country's "most advanced 503A compounding pharmacy and 503B outsourcing facility."[1] In reality, Empower has a long history of cutting corners and leaving serious safety risks in its wake. Plaintiff Eli Lilly and Company ("Lilly") files this action to stop Empower from selling two knockoff drugs that deceive consumers, in violation of state and federal law. With Empower's history of dangerous practices, the stakes could not be higher.

[1] Empower Pharmacy, *About Us,* https://www.empowerpharmacy.com/about/ (last visited Mar. 20, 2025).

2. ***First***, Empower makes and sells two tirzepatide knockoff drugs that deceive consumers into believing they are purchasing medicines that are safe and effective to treat their obesity: an orally disintegrating tablet—so-called "Tirzepatide ODT"—and an injectable tirzepatide/niacinamide combination drug.[2] Tirzepatide is the active ingredient found in Lilly's MOUNJARO® and ZEPBOUND®, which are the only FDA-approved tirzepatide medicines. MOUNJARO® and ZEPBOUND® were approved, after nearly a decade of development, to treat type 2 diabetes and help certain adults with weight management and obstructive sleep apnea, respectively. They have undergone 37 clinical trials. Lilly's tirzepatide medicines are tested and approved for under-the-skin injections only—not in any oral form.

3. Tirzepatide ODT, by contrast, is an untested knockoff that exposes patients to safety risks without *any* clinical data showing that it even works. No clinical study says oral tirzepatide is safe or effective. By selling Tirzepatide ODT, Empower is essentially conducting a mass testing experiment on consumers: testing its oral tirzepatide on the general population now, without obtaining any informed consent and without the safety controls of a proper clinical trial. And in doing so, Empower trades on the reputation of Lilly, an international medicine company with 150 years' experience as a pharmaceutical manufacturer, and with whom Empower has no affiliation.

4. Empower similarly attempts to ride on Lilly's clinical testing to make and sell its combination tirzepatide/niacinamide injection with the promise that it is safe and effective. No clinical study demonstrates—or even suggests—that tirzepatide combined with niacinamide is safe and effective for any indicated use in humans. None of the 37 clinical studies that Lilly completed

[2] Empower Pharmacy Tirzepatide ODT Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-odt/ (last visited Mar. 21, 2025); Empower Pharmacy Tirzepatide/Niacinamide Injection Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 20, 2025).

for its tirzepatide medicines tested tirzepatide combined with niacinamide. Like its Tirzepatide ODT, Empower is, again, experimenting on consumers with untested and unproven products.

5. ***Second***, Empower makes and sells both its Tirzepatide ODT and tirzepatide/niacinamide injection with the promise that they are custom-made, "personalized" products. But Empower does not sell "personalized" tirzepatide at all. Instead, Empower mass produces a standardized Tirzepatide ODT and tirzepatide/niacinamide combination injectable drug under the false premise that they are tailor-made for each patient.

6. ***Third***, to further entice consumers to buy its oral and manipulated combination product, Empower falsely advertises that it adheres to state and federal regulations and that it goes above and beyond to ensure safety and quality. But that is not true. State and federal regulators have observed Empower's repeated failures to maintain manufacturing procedures and conditions that adhere to regulatory standards. Empower's own former Director of Supply Chain has alleged that Empower intentionally conceals its violations from regulators. Empower creates hazards for consumers—failures to maintain sterile conditions, failures to use pharmaceutical grade ingredients, and failures to report adverse events, among others. There are countless examples of companies causing patients serious harm by cutting corners the way that state and federal regulators have found that Empower does.

7. Empower's false marketing claims and deceptive business practices create dangerous patient safety risks. Empower's practices lure consumers away from Lilly's safe and effective FDA-approved medicines in favor of Empower's untested and unapproved products that are mass produced in unsanitary, noncompliant conditions—all under false pretenses. To protect patient safety and stop Empower's deception, Lilly brings this action pursuant to state law and the Lanham Act.

THE PARTIES

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

9. Defendant Empower Clinic Services, LLC is a Texas limited liability company with a principal place of business at 5980 West Sam Houston Parkway North, Suite 300, Houston, Texas, 77041. Empower Clinic Services, LLC holds two out-of-state pharmacy licenses in New Jersey and is the ultimate owner of a facility that operates as a 503A compounding pharmacy and 503B outsourcing facility located at 203 Windsor Center Drive, Suite A16, East Windsor, New Jersey 08520 ("East Windsor Facility").

10. Empower Clinic Services New Jersey LLC ("Empower NJ" and together with Empower Clinic Services, LLC, "Empower") is a Delaware limited liability company with its principal place of business at 203 Windsor Center Drive, Suite A16, East Windsor, New Jersey 08520. Empower Clinic Services New Jersey LLC is also a registered foreign limited liability company in the state of New Jersey.

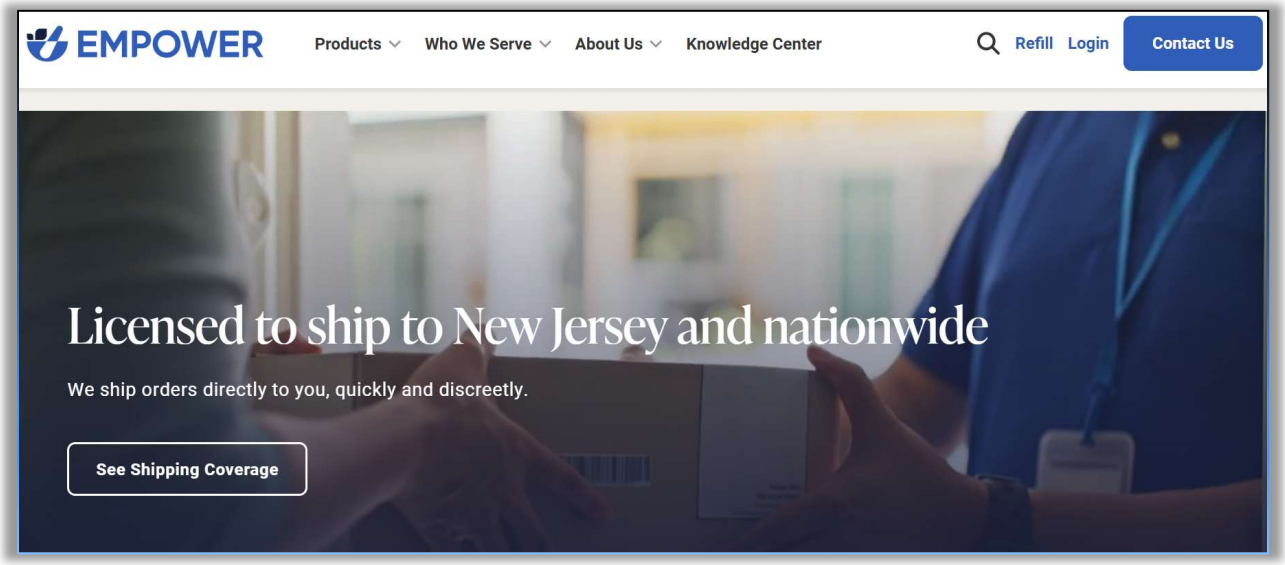
JURISDICTION AND VENUE

11. The Court has subject matter jurisdiction over the Lanham Act cause of action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331. The Court has supplemental jurisdiction over the state law cause of action pursuant to 28 U.S.C. § 1367(a), as it is part of the same case or controversy as the federal claim. Alternatively, and, in addition, the Court has subject matter jurisdiction on diversity grounds pursuant to 28 U.S.C. § 1332 because the matter in controversy exceeds the sum or value of $75,000 and is between citizens of different states.

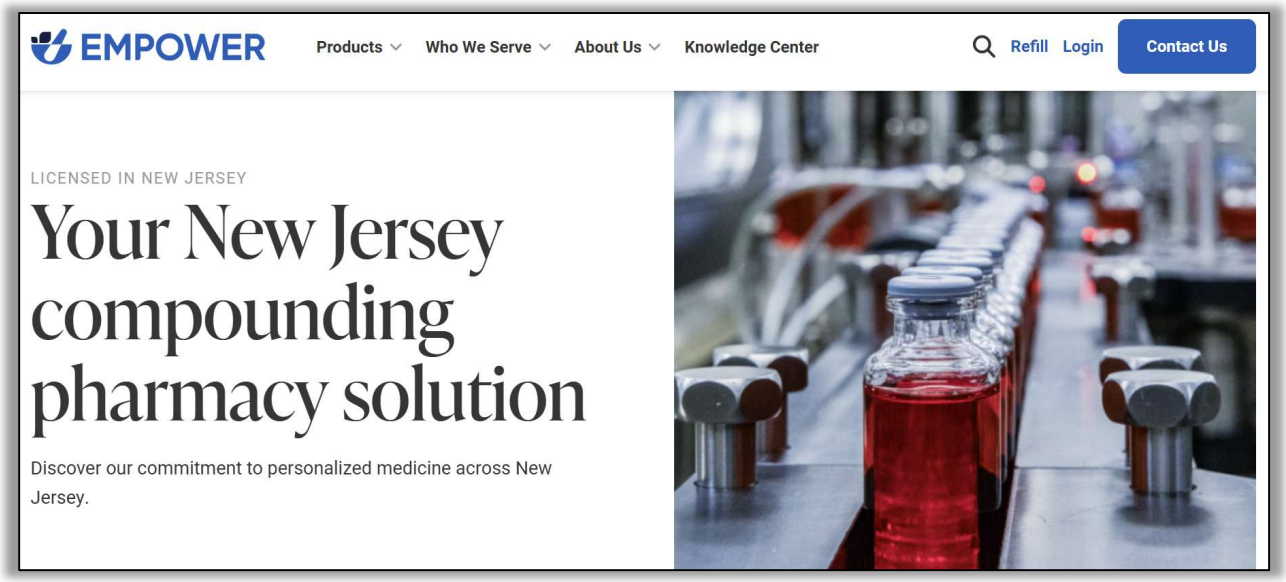
12. Empower is subject to personal jurisdiction in New Jersey. Empower has purposefully availed itself of the privilege of conducting business in New Jersey and has sought

the benefits and protections of the state's laws. Empower Clinic Services, LLC and Empower NJ are licensed to conduct business in New Jersey pursuant to two out-of-state pharmacy licenses.

13. Empower further operates and conducts business in New Jersey by promoting and selling its tirzepatide products here. Empower promotes its tirzepatide products through its website "https://www.empowerpharmacy.com/." Empower's website is designed and intended to reach customers in New Jersey. By promising customers that Empower is "[l]icensed to ship to New Jersey" and that Empower is "Your New Jersey compounding pharmacy solution," Empower specifically targets residents and providers here in order to conduct business with them.[3]



[3] Empower Pharmacy Shipping Coverage – New Jersey Page, https://www.empowerpharmacy.com/compounding-pharmacy-shipping-coverage/new-jersey/ (last visited Mar. 20, 2025).



14. Empower further promises New Jerseyans that they can buy Empower products: "With New Jersey Board of Pharmacy certifications in both patient specific and office-use medications, we support practitioners, healthcare businesses, and patients across the state. Whether it be Newark, Paterson, Elizabeth, or Edison – business and patients living in New Jersey can receive our products[.]"[4]

15. Empower conducts business with health care providers who operate in New Jersey so that Empower can sell its tirzepatide products here. For example, Empower supplies

[4] *Id.*

compounded tirzepatide to VIO Med Spa in Holmdel, New Jersey.[5] Empower also supplies its compounded drugs to Prime IV Hydration & Wellness, located in Marlton, New Jersey,[6] as well as to Ethos Spa, which has six locations, all in New Jersey.[7]

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claim occurred in this District. Empower operates and conducts business in New Jersey, including by engaging in its unlawful promotion and deceptive sale of tirzepatide products here pursuant to several New Jersey professional licenses and by shipping the at-issue products here.

FACT ALLEGATIONS

I. LILLY'S TIRZEPATIDE INJECTABLE MEDICINES

A. Lilly's Long History of Developing and Manufacturing Safe and Effective Medicines

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

18. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its

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[5] VIO Med Spa Holmdel (viomedspa.holmdel), *Now Offering Tirzepatide!*, INSTAGRAM (June 5, 2024), https://www.instagram.com/viomedspa.holmdel/reel/C71oWBfA2SK/.

[6] Prime IV Hydration & Wellness (Marlton, NJ), *November Specials at Prime IV Marlton!*, FACEBOOK (Nov. 14, 2024), https://www.facebook.com/groups/645790755486725/posts/november-specials-at-prime-iv-marlton-/8739432376122482/ (advertising "Weight Loss peptide packages" including tirzepatide and showing NAD injections provided by Empower); Prime IV Hydration & Wellness (Marlton, NJ), *Ready for a glow-up?*, FACEBOOK (Oct. 23, 2024), https://www.facebook.com/photo/?fbid=122201027354035065&set=gm.859745230291198&idorvanity=645790755486725 (advertising a gluthathione injection sourced from Empower).

[7] *See* Ethos Spa, *How Much Do hCG Injections Cost for Men?*, https://myethosspa.com/cost-of-hcg-injections-for-men/ (last visited Mar. 21, 2025) (listing pricing for hCG injections "offered by Empower Pharmacy"); Ethos Spa, *Tirzepatide for Weight Loss: A Comprehensive Guide*, https://myethosspa.com/tirzepatide-for-weight-loss/ (last visited Mar. 21, 2025) (marketing tirzepatide).

rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("cGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

19. Lilly develops and manufactures its medicines in compliance with FDA oversight, the international gold standard for pharmaceuticals. It includes rigorous pre-approval testing for safety and effectiveness under specific conditions for use, routine FDA inspections of manufacturing facilities, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings, which themselves are approved by FDA.

B. The Clinical Trial Process Necessary to Safely Bring Medicines to Market

20. Before a new prescription medication can be brought to market, it must be clinically tested through a rigorous series of studies designed to determine whether the medication is safe and effective for people to use and to receive FDA approval.[8]

[8] FDA, *The Drug Development Process - Step 3: Clinical Research* (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process; *see* 21 U.S.C. § 355(a).

21. FDA approval is famously hard to earn. More than 90% of drug candidates ultimately fail.[9] It is also an enormously costly and time-intensive process. "On average, it takes 10–15 years and costs $2.6 billion to develop one new medicine."[10]

22. To begin, drug sponsors first subject the drug candidate to preclinical testing to determine if the product is reasonably safe for initial use in humans and if the drug candidate exhibits pharmacological activity that justifies commercial development. Based on the data derived from preclinical testing, the drug sponsor is permitted to move the drug candidate into the clinical trial stage, in which it is tested in human subjects through a series of increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials.

23. Phase I clinical trials typically evaluate the drug candidate's safety and generate data that will inform a range of doses that are safe for use in further clinical testing. This determination typically culls a large portion of drug candidates—for example, averaging across diseases, only 52% of drug candidates that make it through Phase I testing will progress to Phase II.[11]

24. Phase II trials are typically designed to preliminarily establish the effectiveness in addition to further confirming safety of the drug for a particular indication over a range of doses and to develop additional data on its safety. Another swath of drug candidates is eliminated in Phase II; drug candidates for various diseases that make it through Phase II only progress to Phase III at rates between 15% and 48.1% depending on disease type.[12] Phase III trials are

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[9] Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020* at 3 (Feb. 2021), https://tinyurl.com/bp5mb3xy (hereinafter "BIO 2021").

[10] PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

[11] BIO 2021 at 7.

[12] *Id*.

designed to confirm the safety and effectiveness of a dose identified in Phase II trials in a much larger patient population as well as to monitor side effects.

25. Based on the data assembled during development in Phase I, Phase II, and Phase III clinical trials, a sponsor company can then submit a marketing application to FDA called a New Drug Application, wherein the sponsor requests that FDA approve the drug candidate for sale and marketing in the United States. The sponsor must detail every ingredient and component in its application to FDA.

26. Once approved for manufacture and distribution, FDA conducts inspections to monitor compliance with cGMP and reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings, and contraindications. FDA also requires manufacturers to track and trace each finished product, to promptly report all adverse events, and to conduct further post-approval studies. All of this is to ensure that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[13]

C. MOUNJARO® and ZEPBOUND®

27. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, which was the culmination of the lengthy and expensive clinical trial process described above that is designed to develop, study, and bring safe medicines to patients.

28. MOUNJARO® and ZEPBOUND® were approved after nearly a decade of development and have undergone testing in 37 clinical trials. They are two groundbreaking medicines consisting of a macromolecule Lilly discovered called tirzepatide. Tirzepatide targets patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic

[13] FDA, *Development & Approval Process* (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs.

polypeptide) receptors. Tirzepatide activates both receptors to improve blood sugar control and reduce appetite and food intake.

29. Both medicines meet critical patient needs. MOUNJARO® is FDA-approved to treat type 2 diabetes, and ZEPBOUND® is approved to treat chronic weight management and obstructive sleep apnea in certain adults. Today, Lilly manufactures, markets, and sells MOUNJARO® and ZEPBOUND® throughout the United States, among other places.

30. MOUNJARO® and ZEPBOUND® are the only FDA-approved medicines containing tirzepatide in the United States. Lilly's tirzepatide medicines are injectables; they are administered via under-the-skin injections. FDA has not approved, and Lilly does not sell, any tirzepatide product in oral form or with additives like niacinamide.

II. DRUG COMPOUNDING

31. Compounding is a "practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[14] For example, if an individual patient is allergic to an ingredient in an FDA-approved medicine, a compounding pharmacy could produce a version of that medication that does not contain the allergen.

32. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[15] This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, many compounded

[14] FDA, *Human Drug Compounding* (Dec. 18, 2024), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

[15] FDA, *Compounding and the FDA: Questions and Answers* (Nov. 15, 2024), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

drugs are not clinically tested and are not reviewed or approved by FDA for safety and effectiveness. Further, many compounders are not subject to labeling requirements and need not comply with Current Good Manufacturing Practice regulations. Additionally, their facilities are not subject to inspections by regulatory authorities, and they have no reporting requirements for adverse events.

33. For these reasons, FDA has warned that "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs . . . exposes patients to potentially serious health risks."[16] Indeed, FDA recently reiterated that compounded drugs that purport to contain tirzepatide "have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and finding of manufacturing quality that is part of the drug approval process."[17]

34. Moreover, compounded drugs prepared at state-licensed pharmacies "are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality."[18]

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

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[16] FDA, *Compounding and the FDA: Questions and Answers* (June 29, 2022), https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

[17] Letter from Center for Drug Evaluation and Research, at 10 (Dec. 19, 2024), https://www.fda.gov/media/184606/download.

[18] *Id*.

tirzepatide."[19] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[20]

36. Leading organizations, state governments, and foreign governments have also expressed concern. Thirty-eight state and territory Attorneys General and State Drug Task Forces have all warned the public about the dangers of these unsafe and unapproved products, including compounders using "non-sterile ingredients" and taking "no steps to sterilize them."[21] The Obesity Society, Obesity Action Coalition, and Obesity Medicine Association issued a joint statement regarding compounded GLP-1 medications, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[22] The Pediatric Endocrine Society has also advised that "[c]linicians and patients [] should exercise caution when exploring options for non-brand name medications, particularly avoiding the use of non-FDA approved medications and those that come from non-FDA-approved compounding pharmacies."[23] Similarly, the JAMA Health Forum published a study that most websites selling compounded anti-obesity medications exclude

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[19] Letter from Shannon Glueck, Branch Chief, FDA Compounding Branch 4, to Philip Dickison, CEO, Nat'l Council of State Boards of Nursing (July 16, 2024), https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf.

[20] FDA, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (Mar. 17, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

[21] Nat'l Ass'n of Attorneys General, *State and Territory Attorneys General Urge FDA to Take Action Against Counterfeit and Illegally Sold GLP-1 Drugs*, (Feb. 19, 2025), https://www.naag.org/policy-letter/state-and-territory-attorneys-general-urge-fda-to-take-action-against-counterfeit-and-illegally-sold-glp-1-drugs/; FDA, *FDA warns patients and health care professionals not to use compounded drugs from Fullerton Wellness* (Nov. 1, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[22] Obesity Medicine Ass'n, *Leading Obesity Expert Organizations Release Statement to Patients on Compounded GLP-1 Alternatives* (Jan. 8, 2024), https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/.

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

important safety information and mislead consumers about the safety and effectiveness of their products.[24] Other patient and consumer groups have issued similar warnings, including the National Consumers League and the American Diabetes Association, which recommended that patients avoid compounded products "due to uncertainty about their content, safety, quality, and effectiveness."[25]

37. 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 due to "increasing community concern" and "increasing reports of patients coming to harm from" compounded weight loss drugs.[26] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[27] 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."[28] Likewise, the South African government has proposed to prohibit the development of compounded GLP-1s. South Africa's regulatory authority has "noted with concern the number of compounded, substandard, and/or falsified versions" of tirzepatide products being sold to the public since "[t]he complexity of compounding GLP1

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[24] Ashwin Chetty, et al., *Online Advertising of Compounded Glucagon-Like Peptide-1 Receptor Agonists*, JAMA HEALTH FORUM, Jan 17, 2025, available at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2829225.

[25] Nat'l Consumers League, *NCL urges the public to heed warnings about unregulated versions of GLP-1 weight loss drugs* (Feb. 4, 2025), https://nclnet.org/the-national-consumers-league-urges-the-public-to-heed-warnings-about-unregulated-versions-of-glp-1-weight-loss-drugs/; American Diabetes Ass'n, *The American Diabetes Association Announces Statement on Compounded Incretin Products* (Dec. 2, 2024), https://diabetes.org/sites/default/files/2024-12/24.11.8%20compounding%20statement%20press%20release_FINAL.pdf.

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

[27] *Id.*

[28] *Id.*

agonists, which are sterile medicines containing complex active substances[,] poses a public health and safety risk."[29]

III. EMPOWER'S DECEPTIVE PRACTICES AND FALSE CLAIMS

38. Empower is no "mom and pop" shop. Despite claiming to be a "pharmacy," it is a large-scale manufacturing operation with a nationwide presence. Empower boasts over 380,000 square feet across three facilities in Texas and New Jersey. Its massive footprint includes Empower's recently acquired 170,000-square foot 503A/503B East Windsor Facility. Empower boasts that its 503A compounding pharmacy is "the largest and most advanced 503A compounding pharmacy in the nation—and the world."[30]

39. Empower engages in a nationwide scheme to sell its untested products by misleading consumers about their safety and efficacy. Empower purports to offer "personalized"

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

"Weight Management" "products for specific patients,"[31] including tirzepatide/niacinamide injections and Tirzepatide ODT, to healthcare providers, telehealth companies, medical spas, pharmacies, and patients. But its products are not personalized and Empower has no evidence to show that they even work.

40. Specifically, Empower has made and continues to make numerous false and deceptive statements about—and engaged in deceptive trade practices regarding—its tirzepatide products, including: (1) that its untested, unapproved Tirzepatide ODT and tirzepatide/niacinamide products are safe and effective alternatives to FDA-approved injectable tirzepatide products, when they are not; (2) that its Tirzepatide ODT and tirzepatide/niacinamide injection combination products are custom-made, "personalized" products, when they are not; and (3) that Empower adheres to regulatory requirements and maintains high-quality standards, when it does not.

41. These statements necessarily deceive consumers as to the nature and quality of Empower's products. They have the tendency to lure the unassuming public away from using safe, clinically tested medicines like those made by Lilly.

A. Empower Deceptively Promotes Knockoff Tirzepatide Drugs as Safe and Effective

42. Empower promotes its Tirzepatide ODT and tirzepatide/niacinamide combination drugs to consumers as a GLP-1 medications for "Weight Management."[32] To convince consumers of its products' safety and effectiveness, Empower expressly cites to articles that rely upon a series of clinical trials. Those clinical trials are ***Lilly's*** clinical trials of ***Lilly's injectable*** tirzepatide.[33]

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[31] Empower Pharmacy, *What Is a Compounding Pharmacy? 503A vs 503B*, https://www.empowerpharmacy.com/compound-medication/news/what-is-a-compounding-pharmacy/ (last visited Mar. 21, 2025).

[32] Empower Pharmacy, *Products,* https://www.empowerpharmacy.com/compounding-pharmacy/ (last visited Mar. 21, 2025).

[33] https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 21, 2025) (citing https://pmc.ncbi.nlm.nih.gov/articles/PMC7843845/;

This makes Empower's promotion of both its Tirzepatide ODT and tirzepatide/niacinamide combination drugs deceptive.

43. ***First***, Empower deceptively cites these trials in its marketing of Tirzepatide ODT. There are material differences in bioavailability between an oral product and a subcutaneous injection. The results of Lilly's clinical trials on its injectable products say nothing about how Empower's untested oral product may work. Empower has no basis to claim that its compounded tablets will have any impact on insulin production or glucagon secretion, since Empower has no evidence that any of the tirzepatide in its tablets will reach the bloodstream.

44. In addition to Empower's explicit (and deceptive) citation to Lilly's clinical trials, Empower makes a series of false claims about its oral tirzepatide, necessarily communicating it has been tested and proven safe and effective. For example, Empower tells consumers that its oral tirzepatide tablets "play a role in blood sugar regulation," "contribute to a decreased appetite," "support the body's natural metabolic process" and even "influence fat metabolism."[34] But Empower has no basis to claim *any* of that. Without any clinical trials of oral tirzepatide, or any bioavailability analysis of any of Empower's products, Empower has no evidence that its oral tirzepatide plays any role in these processes. Rather, these statements—paired with Empower's explicit citation to Lilly's clinical studies—are designed to falsely communicate that Empower's oral tablets have been tested and proven to function as advertised and provide the advertised health benefits.

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https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8826179/; https://www.ncbi.nlm.nih.gov/books/NBK585056/; https://pubmed.ncbi.nlm.nih.gov/33325008/).

[34] Empower Pharmacy Tirzepatide ODT Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-odt/ (last visited Mar. 21, 2025).

45. Empower trades on Lilly's reputation as a trusted manufacturer of safe and effective, FDA-approved medicines by promoting its Tirzepatide ODT as an equivalent, or better, alternative to injectable tirzepatide medicines like MOUNJARO® and ZEPBOUND®. Empower draws that comparison to deceive consumers into believing that Tirzepatide ODT is at least as safe and effective as Lilly's medicines when it is not.

46. Empower also tells consumers that its Tirzepatide ODT is better than Lilly's injectable products, stating that its oral tablet is more convenient and easier to use than Lilly's FDA-approved medicines—all while falsely suggesting equivalent safety and effectiveness to Lilly's injectable tirzepatide medicines. For example, on its website, Empower claims that its Tirzepatide ODT offers the benefit of "[n]o needles, no refrigeration, no preparation" and "[j]ust an easy, consistent routine."[35] This statement explicitly and necessarily communicates to patients that they can receive the same health benefits in a more convenient format.

47. Similarly, on its social media channels, Empower tells consumers they can "[s]kip the needle and get customized weight management support with the new Tirzepatide ODT,"[36] suggesting to consumers that they can receive the benefits of an injectable medicine without any of the alleged drawbacks.

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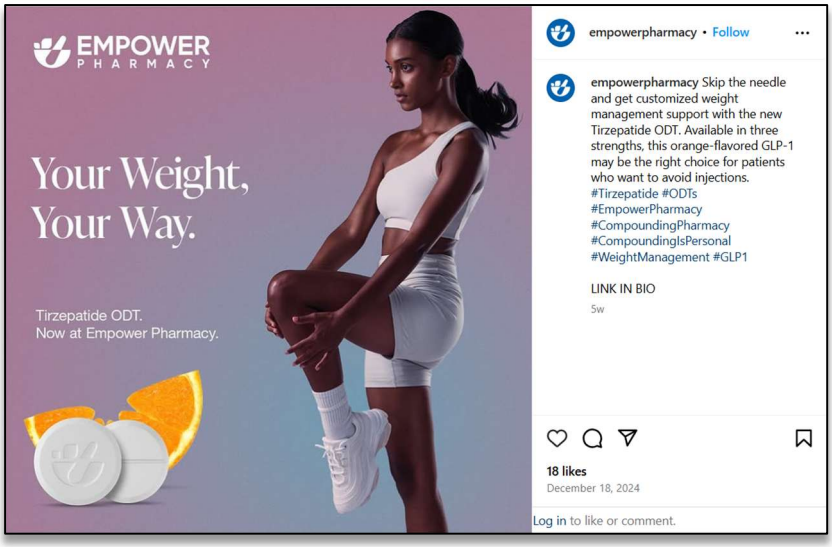
35 *Id.*

36 Empower Pharmacy (empowerpharmacy), *Your Weight, Your Way*, INSTAGRAM (Dec. 18, 2024), https://www.instagram.com/empowerpharmacy/p/DDu35cbxfFv/?locale=es_US%3FICID%3DBLOG_MBF_ES.



48. Empower's advertising therefore promotes Tirzepatide ODT as better (*i.e.*, more convenient and less painful) yet just as safe and effective as Lilly's FDA-approved and clinically tested medicines. But again, the only FDA-approved and clinically tested route of administration for tirzepatide is via subcutaneous injection.

49. ***Second***, Empower also deceptively cites Lilly clinical trials in its marketing of its tirzepatide/niacinamide combination drug. For instance, in its "Product Overview" for its tirzepatide/niacinamide injections, Empower claims that "[a]ccording to recent *clinical studies*, tirzepatide decreases hemoglobin A1C levels more effectively than a placebo."[37] Empower goes on to state the "SURPASS-5 clinical trial revealed a -2.11% drop in hemoglobin A1C levels at per 5mg per week dose."[38] Empower states "[t]his was *proven* during a 40-week period."[39] Empower also states "[t]irzepatide has been *demonstrated* to function similarly to GLP-1 medicines but more

[37] Empower Pharmacy Tirzepatide/Niacinamide Injection Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 20, 2025).

[38] *Id.*

[39] *Id.*

effectively."[40] But applied to Empower's tirzepatide/niacinamide injection, these statements about "clinical trials," "demonstrated function," and "proven results" are false.

50. Lilly's clinical study provides data on the safety and effectiveness of ***Lilly's*** injectable tirzepatide, administered at ***Lilly's*** approved dosages—it says nothing about whether tirzepatide combined with niacinamide is safe and effective for any indicated use in humans.

51. As it does for its Tirzepatide ODT, Empower pairs its deceptive citation to Lilly's clinical trials with a series of false claims about its tirzepatide/niacinamide combination drug, necessarily communicating it has been tested and proven safe and effective. For example, Empower tells consumers that its tirzepatide/niacinamide combination drug can be "implemented as a second-line defense against type 2 diabetes for glycemic control," "significantly reduce[] body weight," and "help people with non-alcoholic fatty liver disease."[41] These statements alongside its deceptive citation—like those made for its Tirzepatide ODT—have been designed to falsely communicate that Empower's tirzepatide/niacinamide combination drug has been tested and proven to function as advertised—and to provide the advertised health benefits.

52. Empower's references to "clinical trials," "demonstrated function," and "proven results" are clear establishment claims. An establishment claim (*i.e.*, a "tests prove" type of claim) must be supported by the kind of testing described in the advertisement. If the seller lacks the testing discussed in its statement, its claims are false. Here, Empower's website expressly and repeatedly references testing and clinical trials in discussing the safety and effectiveness of its tirzepatide/niacinamide injection. Thus, Empower must have clinical studies proving that its

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[40] *Id.*

[41] Empower Pharmacy Tirzepatide/Niacinamide Injection Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 20, 2025).

unapproved combination drug is safe and effective in facilitating weight loss and decreasing A1C levels. But Empower does not have any clinical data assessing the safety or effectiveness of its manipulated tirzepatide/niacinamide injection. Lilly's clinical trials have no bearing on, and cannot substantiate claims about, either of Empower's knockoff tirzepatide drugs.

53. Not only do Empower's falsehoods and omissions cause Lilly monetary damage, but they also cause irreparable harm to Lilly's brand and customer goodwill. Consumers will associate Tirzepatide ODT and tirzepatide/niacinamide injections' failure to produce results with Lilly's clinically proven MOUNJARO® and ZEPBOUND® due to their purportedly shared active ingredient—tirzepatide.

B. Empower Deceptively Promotes Mass-Produced Tirzepatide Drugs as "Personalized" Products

54. Empower also falsely promotes that it offers "personalized" "Weight Management" "products for specific patients," including Empower's combination Tirzepatide ODT and tirzepatide/niacinamide injection.[42] But Empower is not selling custom-made or "personalized" products; in fact, Empower is mass-manufacturing, one-size-fits-all compounded drugs. Again, Empower's deception lures the unassuming public away from using clinically tested and FDA-approved medicines like Lilly's under the false impression that Empower's medicines are "customized."

55. The foundation for this deception is Empower's boast that it is "at the forefront of personalized healthcare," "tailoring medications to meet [patients'] unique needs."[43]

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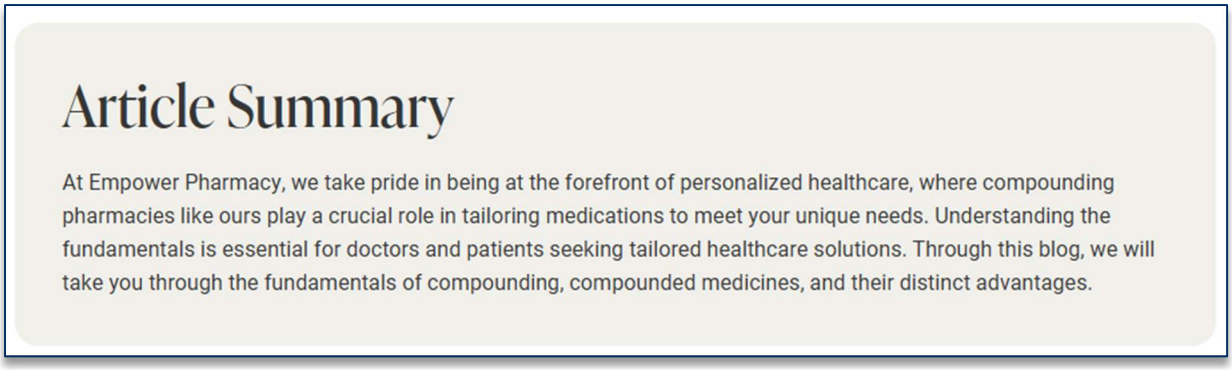
[42] Empower Pharmacy, *What Is a Compounding Pharmacy? 503A vs 503B*, https://www.empowerpharmacy.com/compound-medication/news/what-is-a-compounding-pharmacy/ (last visited Mar. 21, 2025).

[43] Empower Pharmacy. Compounding Pharmacies' Vital Role in Patient Care, https://www.empowerpharmacy.com/compound-medication/news/compounding-empowers-patient-care/ (last visited Mar. 21, 2025).



56. Empower extends this claim to its "weight management" offerings, which it claims are "custom, high-quality prescriptions."[44]

57. It asserts that it utilizes "patient-specific prescriptions,"[45] "utiliz[ing] the latest pharmaceutical technology-driven processes to produce compounded drugs tailored to fit individual patients."[46]

58. But, in reality, there is nothing "personalized" about Empower's compounded Tirzepatide ODT or its tirzepatide/niacinamide combination. Empower produces the same Tirzepatide ODT and tirzepatide/niacinamide combination in predetermined dosages. Upon information and belief and online consumer reviews, Empower does not tailor its products to meet unique patient needs; rather, it makes standard tirzepatide products.

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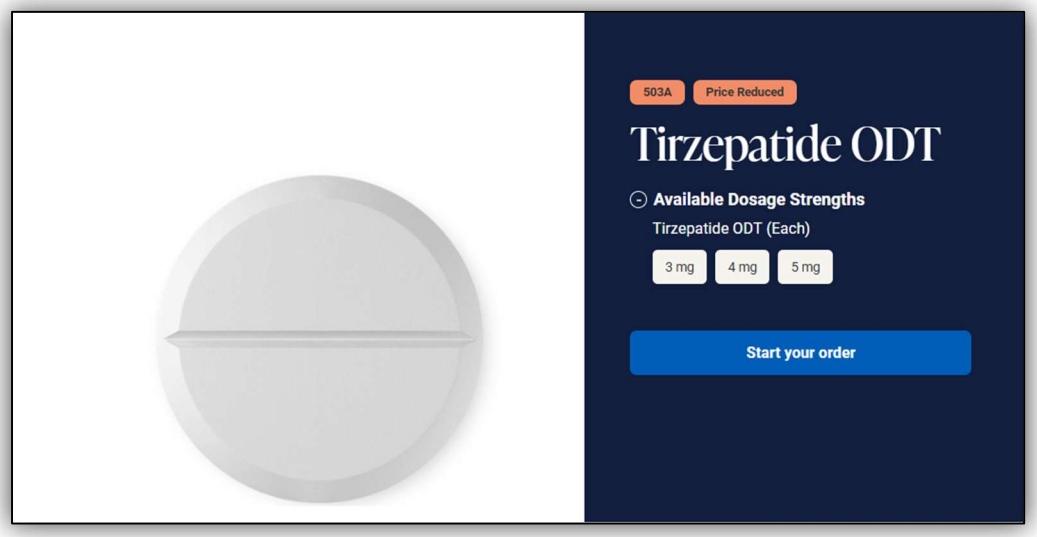
[44] Empower Pharmacy, *Weight Management Medications*, https://www.empowerpharmacy.com/compound-medication/weight-management/ (last viewed Mar. 21, 2025).

[45] *Id.*

[46] Empower Pharmacy, *Our 503A Facility,* https://www.empowerpharmacy.com/about/technology-innovation/facilities/503a/ (last accessed Mar. 21, 2025).

59. On its website, Empower sells a single Tirzepatide ODT product at fixed dosages.[47] Contrary to its claims of personalization, Empower's website does not offer any opportunity to select additives or adjust dosage to fit a patient's specific needs.



60. Similarly, Empower offers a single combination of tirzepatide and niacinamide at fixed dosages.[48] Again, Empower's website offers no opportunity to select a different additive or adjust dosage to fit a patient's specific needs.

[47] Empower Pharmacy Tirzepatide ODT Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-odt/ (last visited Mar. 21, 2025).

[48] Empower Pharmacy Tirzepatide/Niacinamide Injection Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 20, 2025).

61. Online consumer posts confirm that Empower's tirzepatide/niacinamide product is not personalized. On Reddit, consumers discuss the need to change pharmacies to obtain tirzepatide without niacinamide, because the niacinamide was causing them skin-related issues.[49] If Empower were "personalizing" its tirzepatide/niacinamide injection, consumers would not need to change pharmacies; they would be able to simply request a different combination. In other words, on information and belief, the *only* injectable tirzepatide product Empower produces contains niacinamide, and there is no personalized, tailored, or customized product for those patients.

62. Nor is Empower individually manufacturing its products for specific patients. Instead, it is mass manufacturing tirzepatide products in large-scale manufacturing facilities. Indeed, Empower's compounding pharmacy facilities are specifically designed for mass production—not for personalization. Empower brags that in 2023 Empower "fill[ed] 15,000

[49] Maleficent_Time5917, *Niacinimide in Empower Compound* (May 2024), https://www.reddit.com/r/tirzepatidecompound/comments/1cy85pw/niacinamide_in_empower_compound/.

custom-compounded prescriptions daily," and that its East Windsor Facility can produce 50 million vials per year.[50] It also elsewhere describes itself as providing "commercial-scale production."[51] Thus, Empower's practice of selling its Tirzepatide ODT and combination tirzepatide injectable as "personalized" products is deceptive, because in fact, Empower is mass-manufacturing, one-size-fits-all drugs.

C. Empower's Falsely Advertises Regulatory Compliance.

63. Empower falsely advertises to consumers that it is in compliance with regulatory requirements. On its website, Empower states to consumers that it "adheres to stringent regulations set by State Boards of Pharmacy, the FDA, and USP standards, and even voluntary quality testing."[52] Elsewhere on its website, Empower again advertises its "multi-pronged quality process adheres to stringent regulatory standards across every step—from ingredient sourcing to fulfilment [*sic*]—so the medications [it] send[s] out are of the highest caliber every time."[53] These advertising statements are literally false.

64. In fact, over the course of a decade, FDA and multiple State Boards of Pharmacy have observed persistent safety and quality issues and documented significant regulatory and USP violations. Empower's spotty record over the course of a decade reveals an unmistakable pattern of Empower favoring growth and profits at the expense of patient safety. To be clear, Lilly's

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[50] Empower Pharmacy, *Who We Are*, https://www.empowerpharmacy.com/about/our-story/ (last visited Mar. 21, 2025).

[51] PR Newswire, *Empower Pharma to Purchase Eugia Manufacturing Facility in New Jersey for Large Scale Expansion of Personalized Compounded Medicine* (Feb. 5, 2024), https://www.prnewswire.com/news-releases/empower-pharma-to-purchase-eugia-manufacturing-facility-in-new-jersey-for-large-scale-expansion-of-personalized-compounded-medicine-302053371.html.

[52] Empower Pharmacy, *Compounding Personalized Healthcare: Shaun Noorian Interviews with Mark Bishop*. https://www.empowerpharmacy.com/compound-medication/news/empower-pharmacy-compounding-personalized-healthcare/ (last visited Mar. 21, 2025).

[53] Empower Pharmacy, *Technology & Innovation,* https://www.empowerpharmacy.com/about/technology-innovation/ (last visited Mar. 21, 2025).

allegations are that Empower's ***statements*** regarding compliance are unlawful. It challenges Empower's claims about its pharmaceutical practice, not the pharmaceutical practice itself.

65. While FDA does not evaluate compounded drugs for their safety, effectiveness, or quality, FDA does occasionally inspect compounding and outsourcing facilities for compliance with Sections 503A or 503B, respectively, including for insanitary conditions. FDA inspections of Empower facilities have regularly uncovered numerous safety issues—which have resulted in non-sterile, contaminated, or adulterated drugs. For example:

66. In 2015, FDA observed that an injectable medication lot was contaminated with bacteria. Despite test results showing contamination, Empower had no records that it investigated the issue. Further, FDA observed that "[p]rocedures designed to prevent microbiological contamination in drug products purporting to be sterile [did] not include adequate validation of the sterilization process." FDA observed Empower's "aseptic processing areas [were] deficient." FDA also determined Empower had "no written testing program designed to assess the stability characteristics of drug products," meaning Empower had no basis for the Beyond Use Dates it applied to its compounded medications.[54]

67. In 2017, FDA issued a Warning Letter to Empower reiterating significant regulatory violations observed during its 2015 inspection. According to FDA, "[Empower] did not receive valid prescriptions for individually identified patients for a portion of the drug products [it] produced." FDA also "noted serious deficiencies in [Empower's] practices for producing sterile drug products, which put patients at risk." As a result, Empower's compounded drugs were misbranded and lacked the required approvals. FDA reiterated its concerns "that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions."

[54] FDA Form 483 to Empower Clinic Services, LLC (Nov. 25, 2015), https://www.fda.gov/media/95350/download.

Further, FDA emphasized that certain observations constituted "significant CGMP violations at [Empower's] facility," including Empower's failure to "establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile"; failure to "establish an adequate system for monitoring environmental conditions in [an] aseptic processing area"; as well as its failure to "establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic condition." In addition to these violations, FDA noted that it "[could not] fully evaluate whether the corrective actions" Empower claimed it took in response to its 2015 inspection "were sufficient because [Empower] did not include the supporting documentation." [55]

68. In 2019, FDA observed that Empower was using 18 ineligible bulk drug substances in sterile compounding, meaning Empower's compounded drugs were misbranded and lacked required approvals. FDA also observed labeling that "fail[ed] to bear adequate directions for their intended uses." FDA warned Empower that its response to FDA's prior request that Empower stop producing drugs using ineligible bulk drug substances was "inadequate." According to FDA, Empower had "declin[ed] to discontinue serving its patients and customers with these . . . drug products compounded using bulk substances." [56]

69. In 2020, FDA observed deficient aseptic processing, including failures to "document the differential pressure, relative humidity, and temperature before and during drug production"; and failures to maintain "adequate environmental controls during sterile drug

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[55] Letter from Monica Maxwell, Acting Program Division Director, FDA Office of Pharmaceutical Quality Operations Division II, to Arta Shaun Noorian, Owner, Empower Pharmacy, (May 25, 2017), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-services-llc-516718-05252017.

[56] Letter from Monica Maxwell, Program Division Director, FDA Office of Pharmaceutical Quality Operations Division II, to Arta Shaun Noorian, CEO, Empower Pharmacy, (July 22, 2019), https://www.fda.gov/media/130590/download.

production." FDA also observed Empower's failure to "establish validated hold-times for sterilized bulk drug products to mitigate the risk of contamination of finished drug products"; failure to "adequately write and fully follow [] procedures applicable to [Empower's] quality unit"; failures to include instructions in labels to facilitate report by consumers of adverse events to FDA; and failure to submit adverse event reports to FDA.[57]

70. In 2021, FDA issued another Warning Letter, this time for Empower's failures to properly label its products to facilitate adverse event reporting; failure to "submit a complete report to FDA in December 2019" identifying all drug products compounded in the prior six-month period; and failure to submit adverse event reports to FDA. FDA also noted Empower's "procedures for reporting adverse events [were] inadequate" and lacked any "requirement to promptly investigate and submit a follow-up report regarding a serious, unexpected adverse event within 15 calendar days." FDA again observed that Empower's "corrective actions appear[ed] deficient," noting Empower had not addressed FDA's prior concern that Empower lacked adequate procedures for adverse event reporting.[58]

71. In 2022, FDA observed failures to monitor "critical sites . . . where drug products are aseptically filled," including the build-up of "rust and/or discoloration" on carts and tables where aseptic drugs products were filled. FDA also observed failures to investigate complaints "regarding drug products that were received without labels"; failure to maintain "procedures designed to prevent microbiological contamination of drug products purporting to be sterile"; failure to maintain "documentation to show that all active pharmaceutical ingredients (API) and

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[57] FDA Form 483 to Empower Clinic Services LLC, at 2 (Mar. 6, 2020), https://www.fda.gov/media/137544/download.

[58] Letter from Tamala Bogan, Acting Program Division Director, FDA Office of Pharmaceutical Quality Operations Division II, to Arta Shaun Noorian, Owner, Empower Pharmacy, at 2 (Oct. 15, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-services-llc-dba-empower-pharmacy-613792-10152021.

excipients [were] suitable for use in drug products, including control for endotoxins"; failure to "thoroughly investigate complaints, deviations/non-conformances, and out of specification results (OOS) in a timely manner"; failure to "report adverse events"; failure to follow Empower's own policies and procedures; and failure to sterilize drug product containers and closures. Additionally, FDA yet again observed Empower's "[f]ailure to implement Corrective and Preventive Actions identified by [Empower]."[59]

72. In 2023, FDA observed "poor aseptic techniques." For example, FDA inspectors observed "a [s]terile compounding technician . . . reaching over opened finished drug vials while filling empty vials"; that "[p]ersonnel infrequently changed and sanitized gloves to prevent contamination;" and Empower's "[f]ailure to appropriately and regularly clean and disinfect or sterilize equipment." FDA also observed Empower's inappropriate use of "non-pharmaceutical grade components."[60]

73. In 2024, FDA observed Empower's failure to maintain "[p]rocedures designed to prevent microbiological contamination of drug products purporting to be sterile." For example, FDA inspectors observed an Empower technician "picking up a pair of scissors off the ISO - 7 floor," wiping them, and "plac[ing] the scissors back into ISO - 5 hood." FDA observed Empower "release[] a batch of a sterile product even though positive microbial growth was detected during environmental monitoring [] within the ISO 5 production area." FDA also observed Empower's failures to "perform proper aseptic techniques while performing sterile operations"; failure to investigate "approximately 20 complaints for lack of efficacy of compounded drug products since

[59] FDA Form 483 to Empower Clinic Services LLC, at 1–12 (Aug. 5, 2022), https://www.fda.gov/media/162155/download..

[60] FDA Form 483 to Empower Clinical Services, LLC (Dec. 1, 2023), https://www.fda.gov/media/176194/download.

August, 2022"; failure to maintain adequate environment monitoring, cleaning and disinfecting procedures for aseptic conditions; and failure to adequately investigate a report of "fungi" in a batch of medication. FDA observed Empower's continued failure to report adverse reactions to FDA within the required timeframe and include the required "[i]nformation to facilitate adverse event reporting" on its drug products. [61]

74. Multiple states have also raised concerns with Empower's practices. For example, in September 2022, Empower entered a Stipulated Settlement and Disciplinary Order with the California Board of Pharmacy after having been charged with adulterated preparations, unlawful compounding of commercially available products, failure to obtain active ingredients from suppliers registered with FDA, dispensing a compounded product "when the product was not justified by a specific medical need," dispensing prescriptions without prescriber's approval, misbranding, and failure to report adverse effects and complaints. In the Stipulated Settlement and Disciplinary Order, Empower conceded the California Board of Pharmacy would have a factual basis for the charges at a hearing.[62]

75. In September 2021, the Colorado Board of Pharmacy cited Empower for violating other states' regulatory requirements.[63] Then again, in August 2023, the Colorado Board of Pharmacy fined Empower for violating other states' regulatory requirements.[64]

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[61] FDA Form 483 to Empower Pharmacy (Aug. 28, 2024), https://www.fda.gov/media/182593/download.

[62] Corrected Decision and Order, *In the Matter of the Accusation Against, Empower Clinic Services, LLC, DBA Empower Pharmacy, Arta Shuan Noorian*, Board of Pharmacy Department of Consumer Affairs State of California (Jan. 18, 2023), at 15:11-12, 21:16-18, 25:6-7, and 13-57, https://www.pharmacy.ca.gov/enforcement/fy2021/ac207117.

[63] Letter from Colorado Dep't of Regulatory Agencies to Empower Pharmacy (Sept. 17, 2019), https://apps2.colorado.gov/dora/licensing/Lookup/PrintLicenseDetails.aspx?cred=931134&contact=992231.

[64] Stipulation and Final Agency Order, *In the Matter of Disciplinary Proceedings Regarding the Non-Resident Prescription Drug Outlet Registration in the State of Colorado of Empower Pharmacy*, Registration No. PDO OSP.0006131, (Aug. 8, 2023), https://apps2.colorado.gov/dora/licensing/Lookup/PrintLicenseDetails.aspx?cred=931134&contact=992231.

76. Empower has also received fines or notices of noncompliance from the Boards of Pharmacy for Alabama, Florida, and Pennsylvania.[65]

77. In addition, Empower has conducted two recalls of its compounded drugs due to mislabeling in May 2023[66] and lack of sterility in September 2024.[67]

78. Empower also recently acquired its East Windsor Facility, which was operating under a different company and had a concerning history. In December 2023—mere weeks before Empower's acquisition[68]—FDA observed: failures "to adequately investigate and close quality documentation in a reasonable timeline"; a failure to "provide documentation supporting validation of cleaning, sanitization and disinfection procedures"; "[a]septic processing areas [that were] deficient regarding the system for monitoring environmental conditions"; and "[e]quipment used in the manufacture, processing, packing or holding of drug products [was] not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use."[69] In short, its staff were ill-trained and the facility was breaking down. Only weeks later, on February

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[65] *In the Matter of Empower Pharmacy Non-Resident Pharmacy Permit Number: 114339*, No: 20-L-0040, Alabama State Board of Pharmacy, (July 28, 2022), https://albop.blob.core.windows.net/prod/albopdocuments/2022/7/b2c457218dc341bea0b524427e01b6487292022.pdf?sv=2024-05-04&spr=https&se=2025-03-21T22%3A45%3A23Z&sr=b&sp=r&sig=rwd97aSDTwaLUTN%2Flal3kbl9CGCI8eGIBIYIAPDRLSQ%3D; Administrative Complaint, *State of Florida Dep't. of Health v. Empower Clinic Services, LLC*, No. 2023-03021, (June 22, 2023), https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders/LicenseVerification?LicInd=442&ProCde=2210&dba=Empower%20Pharmacy&org=EMPOWER%20CLINIC%20SERVICES%2C%20LLC; Order, *Commonwealth of Pennsylvania Bureau of Professionals and Occupational Affairs v. Empower Pharmacy Registration No. NP000041*, No. 20-54-000737, (Mar. 19, 2024), https://www.pa.gov/content/dam/copapwp-pagov/en/dos/alerts-and-notices/bpoa-disciplinary-actions/2024/2024-March.pdf.

[66] National Drug Codes, *Recall Enforcement Report D-0865-2023* (June 14, 2023). https://ndclist.com/recalls/92367.

[67] National Drug Codes, *Recall Enforcement Report D-0630-2024* (Aug. 14, 2024), https://ndclist.com/recalls/95079.

[68] Kevin Dunleavy, *Empower bolsters compounded drug manufacturing capacity with purchase of Eugia site in New Jersey* (Feb. 5, 2024), https://www.fiercepharma.com/manufacturing/empower-pharma-bolsters-its-capacity-manufacture-compounded-drugs-buyout-eugia.

[69] FDA Form 483 Report to Eugia US Manufacturing LLC (Dec. 22, 2023), https://www.fda.gov/media/175809/download.

5, 2024, Empower announced its acquisition of the entire site—and "the facility's workforce"—from Eugia Pharma Specialties Limited, describing it as a "state-of-the-art facility" that would enable it to produce "50 million vials, or $1.5B in revenue per year."[70] Empower apparently continued business as usual at the East Windsor Facility in its haste to "bring the highest levels of capacity and supply chain resilience to both [its] 503A and 503B business lines."[71]

79. Regulators are not the only ones that have observed noncompliance. Empower's former Director of Supply Chain, Samuel Pray, has alleged that when he began at Empower in May 2022, Empower was "failing to comply with a multitude of FDA regulations," including "us[e] of adulterated and contaminated products when compounding for consumer use (including injectable medications)"; "fail[ures] to properly sterilize equipment"; lack of "written policies and processes for storing ingredients, disposing of adulterated products, packaging products, and cleaning equipment"; "fail[ure] to conduct sample checks to ensure quality of products"; "fail[ure] to investigate complaints received regarding drugs that lacked quality"; and "fail[ure] to report adverse events."[72] He also has alleged Empower "instruct[s] employees to order [active pharmaceutical ingredients] from surreptitious Gmail and Yahoo accounts" rather than "from verifiable or reputable entities."[73]

80. According to Mr. Pray, these violations are intentional: Mr. Pray has alleged Empower's leadership "[a]ctively creat[es] and enforc[es] a culture of disguise . . . including

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[70] PR Newswire, *Empower Pharma to Purchase Eugia Manufacturing Facility in New Jersey for Large Scale Expansion of Personalized Compounded Medicine* (Feb. 5, 2024), https://www.prnewswire.com/news-releases/empower-pharma-to-purchase-eugia-manufacturing-facility-in-new-jersey-for-large-scale-expansion-of-personalized-compounded-medicine-302053371.html.

[71] *Id*.

[72] Defendant Sam Pray's Original Answer, Verified Denials, Affirmative Defenses, and Counterclaims at ¶ 3 (Jan. 27, 2025), *Empower Clinic Services, L.L.C. d/b/a Empower Pharmacy v. Samuel Pray, Revive Rx, LLC, PSW Group LLC, and Striker Pharmacy LLC*, D. Ct. Harris County Tx., No. 2024-85045.

[73] *Id.* at ¶¶ 7, 8, 79.

directives . . . to not keep records."[74] Mr. Pray has further alleged "Empower's CEO instructed employees to order food or animal grade—not pharmaceutical grade—[active pharmaceutical ingredients]" and "explained that the best time to purchase and use these illegal products is right after the FDA inspects Empower because the FDA is not likely to inspect Empower's facility again any time soon" after.[75] Finally, Mr. Pray has alleged that Empower conceals its regulatory violations through intimidation tactics that prevent employees from speaking out.

81. In summary, Empower advertises to consumers that it complies with state and federal regulatory standards. This is false based on its history of past violations *already established*.

IV. EMPOWER'S HARMS TO CONSUMERS AND LILLY

82. Empower's false and deceptive promotion and sale of untested and unapproved Tirzepatide ODT and tirzepatide/niacinamide injections have harmed Lilly and consumers. That harm will continue if left unchecked.

83. ***First***, Empower's false and deceptive practices lure consumers away from obtaining safe and effective treatment with MOUNJARO® and ZEPBOUND® on the false promises that (i) untested and unapproved Empower oral disintegrating tablets and tirzepatide/niacinamide injections are safe and effective in treating diabetes and addressing chronic weight management, (ii) Empower's untested and unapproved compounded tirzepatide/niacinamide injections and tirzepatide oral disintegrating tablets fit patients' unique needs, when, in truth, Empower is marketing and selling the same tirzepatide/niacinamide

[74] *Id.* at ¶ 73(r).

[75] *Id.* at ¶ 6.

injections and tirzepatide oral disintegrating tablets to every consumer, and/or (iii) Empower is in compliance with regulatory requirements.

84. ***Second***, Empower's false and deceptive practices cause irreparable harm to Lilly's brand and customer goodwill by promising results that consumers will not obtain from Empower's products. Empower promotes its Tirzepatide ODT and tirzepatide/niacinamide injections by trading on the credibility—earned through decades of safe and effective pharmaceutical manufacturing and years of clinical research and testing on tirzepatide specifically—of Lilly and its FDA-approved MOUNJARO® and ZEPBOUND®. When consumers fail to achieve desired results from Empower's Tirzepatide ODT and combination injection, consumers may conclude that tirzepatide is ineffective in general—an outcome made more likely given Empower's reliance on Lilly's clinical studies. Worse still, if consumers are harmed using compounded tirzepatide products from a pharmacy like Empower that has a long record of safety lapses, consumers may even draw unwarranted conclusions about the safety and efficacy of Lilly's FDA-approved tirzepatide medicines.

FIRST CAUSE OF ACTION
Deceptive Practices: Safety and Effectiveness in Violation of the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-2; 56:8-19

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

86. The New Jersey Consumer Fraud Act prohibits use or employment of any commercial practice that is unconscionable or abusive, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale or advertisement of any merchandise.

87. The deceptive and false business practices and material omissions that Empower employs to promote and sell its Tirzepatide ODT and tirzepatide/niacinamide injections constitute violations of the New Jersey Consumer Fraud Act.

88. Empower deceives consumers by marketing and selling its oral disintegrating tirzepatide tablets and tirzepatide/niacinamide injections to treat weight issues while misciting inapplicable clinical trials and materially omitting that no data exists to support its use for any purpose. In doing so, Empower purports that its disintegrating tirzepatide tablets and tirzepatide/niacinamide injections are safe and effective prescription medications. Empower's sales practices are deceptive in a material way by, among other things, steering patients with serious diseases like diabetes and obesity away from obtaining safe, effective, and FDA-approved treatments. Empower's unlawful conduct is putting health, safety, and lives at risk.

89. In connection with that sale, Empower states that its Tirzepatide ODT can "play a role in blood sugar regulation," "contribute to a decreased appetite," "support the body's natural metabolic process," and even "influence fat metabolism."[76] Empower also states that its tirzepatide niacinamide injections can be "implemented as a second-line defense against type 2 diabetes for glycemic control," "significantly reduce[] body weight," and "help people lose weight. . . help people with non-alcoholic fatty liver disease."[77] Thus, Empower is falsely and necessarily implying that its products are proven safe and effective.

90. Empower's consumer-oriented conduct actually or has likely deceived consumers and is likely to continue to deceive them.

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[76] Empower Pharmacy Tirzepatide ODT Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-odt/ (last visited Mar. 21, 2025).

[77] Empower Pharmacy Tirzepatide/Niacinamide Injection Product Page, https://www.empowerpharmacy.com/compounding-pharmacy/tirzepatide-niacinamide-injection/ (last visited Mar. 20, 2025)

91. Empower's deceptive and unlawful conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Empower's false and deceptive campaign, Lilly is suffering immediate and continuing, competitive, irreparable injury for which there is no adequate remedy at law.

92. As a direct and proximate result of Empower's false and deceptive practices, Empower has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.

93. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by the New Jersey Consumer Fraud Act, including Empower's profits, treble damages, punitive damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION
Deceptive Practices: Personalization
in Violation of the New Jersey Consumer Fraud Act,
N.J.S.A. §§ 56:8-2; 56:8-19

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

95. Empower deceives consumers by marketing and selling its Tirzepatide ODT and tirzepatide/niacinamide injections as unique, personalized, compounded medicine, when, in fact, Empower does not tailor its unapproved and untested drugs to patients' needs at all. In connection with that sale, Empower falsely states that its tirzepatide/niacinamide injections are "custom, high-quality prescriptions," "patient-specific prescriptions," and "tailored to fit individual patients." Empower's improper consumer-oriented conduct is deceptive in a material way by, among other things, steering patients with serious diseases like diabetes and obesity away from obtaining safe,

effective, and FDA-approved treatments. Empower's unlawful conduct is putting health, safety, and lives at risk.

96. Empower's consumer-oriented conduct actually or has likely deceived consumers and is likely to continue to deceive them.

97. Empower's deceptive and unlawful conduct is interfering with Lilly's ability to conduct its business. As a direct and proximate result of Empower's false and deceptive campaign, Lilly is suffering immediate and continuing, competitive, irreparable injury for which there is no adequate remedy at law.

98. As a direct and proximate result of Empower's false and deceptive practices, Empower has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines. Lilly has suffered and will continue to suffer monetary damages that can be measured and quantified as well as discernible competitive injury by the loss of goodwill.

99. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by the New Jersey Consumer Fraud Act, including Empower's profits, treble damages, punitive damages, reasonable attorneys' fees, costs, and prejudgment interest.

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

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

101. Empower'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). Empower deceptively promotes its tirzepatide products as "safe" and "effective" based on Lilly studies, deceptively promotes its tirzepatide products as "personalized" when they are mass-

manufactured, and falsely advertises that it complies with regulations, despite the fact that regulatory authorities have concluded otherwise on multiple occasions.

102. Empower has made materially false statements to sell its Tirzepatide ODT and its tirzepatide/niacinamide injection. These statements have influenced and are likely to continue to influence consumers' purchasing decisions—specifically, decisions to purchase Empower's Tirzepatide ODT and tirzepatide/niacinamide products instead of Lilly's FDA-approved medicines. Empower is steering patients with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. Empower's unlawful conduct is putting health, safety, and lives at risk.

103. Empower's advertisements and business practices actually deceive or have the tendency to deceive consumers.

104. Empower has caused its false statements to enter interstate trade or commerce.

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

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

107. Given Empower's conduct, this is an exceptional case under 15 U.S.C. § 1117.

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

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in Lilly's favor on Lilly's claims and award Lilly relief including:

1. An Order declaring that Empower:

   i. Engaged in false and deceptive acts, in violation of 15 U.S.C. § 1125(a)(1)(B); and

   ii. Engaged in deceptive trade practices in violation of the New Jersey Consumer Fraud Act.

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

   i. Marketing, distributing, dispensing, selling, or otherwise making available to consumers Empower's Tirzepatide ODT for weight management;

   ii. Marketing, distributing, dispensing, selling, or otherwise making available to consumers Empower's tirzepatide/niacinamide injection;

   iii. Claiming or representing that Empower's tirzepatide products are custom-made for a patient's specific needs;

   iv. Citing Lilly's clinical testing to support the safety and efficacy of Empower's unapproved Tirzepatide ODT or tirzepatide/niacinamide injections;

   v. Claiming or representing that Empower adheres to or exceeds regulatory standards; and/or

   vi. Engaging in any deceptive acts.

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

i. Empower's Tirzepatide ODT and tirzepatide/niacinamide products have never been demonstrated to be safe or effective;

ii. Empower's Tirzepatide ODT and tirzepatide/niacinamide products have never been studied in clinical trials;

iii. Empower's Tirzepatide ODT and tirzepatide/niacinamide products do not have any proven therapeutic effect;

iv. Empower's Tirzepatide ODT product is not comparable or equivalent to any injectable tirzepatide drug product;

v. Empower's Tirzepatide ODT is not superior to any injectable tirzepatide drug product;

vi. Lilly's clinical testing regarding Lilly's FDA-approved injectable tirzepatide medicines provide no support for the safety, efficacy, or quality of Empower's Tirzepatide ODT or tirzepatide/niacinamide injections;

vii. Empower's products were not custom-made, tailor-made, or personalized for an individual patient's specific needs as determined by a prescriber;

viii. Empower does not provide individualized tirzepatide products; and

ix. Empower's drugs do not adhere to or exceed regulatory standards.

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

5. An Order requiring Empower to account for and pay to Lilly any and all profits arising from the foregoing acts of deceptive trade practices and false advertising pursuant to 15 U.S.C. § 1117.

6. An Order requiring Empower to pay Lilly compensatory damages in an amount as yet undetermined caused by the deceptive business practices and false advertising and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117, the New Jersey Consumer Fraud Act, and other applicable laws.

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

8. A finding that Empower's actions are exceptional under 15 U.S.C. § 1117.

9. An Order requiring Empower to pay Lilly's costs and attorneys' fees in this action pursuant to 15 U.S.C. § 1117 and the New Jersey Consumer Fraud Act and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

Dated: April 1, 2025

Respectfully submitted,

/s/ *Liza M. Walsh*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding.

Dated: April 1, 2025

Respectfully submitted,

/s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: April 1, 2025

Respectfully submitted,

/s/ *Liza M. Walsh*

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