

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ELI LILLY AND COMPANY,)	
)	
Plaintiff,)	
)	
v.)	Case No.
)	
STRIVE PHARMACY LLC d/b/a STRIVE)	JURY TRIAL DEMANDED
COMPOUNDING PHARMACY,)	
)	
Defendant.)	

COMPLAINT

1. Strive Pharmacy LLC is a compounding pharmacy that deceives consumers about its untested, unapproved drugs—risking patient safety and diverting unsuspecting consumers from safe and effective medicines to its unapproved drugs.

2. Strive’s scheme centers on products containing tirzepatide. Tirzepatide is the active ingredient found in Plaintiff Eli Lilly and Company’s (“Lilly”) 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.

3. Strive is deceiving consumers in multiple ways. *First*, Strive sells tirzepatide combined with glycine and vitamin B12 (the “tirzepatide combination drug”), claiming it is a custom-made, purportedly “personalized” product. But Strive does not sell “personalized” or patient-unique tirzepatide at all. Instead, Strive mass produces a single, standardized tirzepatide combination drug under the false premise that it is tailor-made for each patient.

4. *Second*, Strive makes claims that necessarily imply that its product is proven superior to FDA-approved medicines. But Strive’s tirzepatide combination drug has not even been

studied in clinical trials. Lilly's FDA-approved tirzepatide medicines do not contain glycine, vitamin B12, or other additives. No clinical study demonstrates that tirzepatide combined with glycine and vitamin B12 is safe and effective for human use, much less superior to Lilly's FDA-approved tirzepatide medicines. Strive is experimenting on consumers with an untested and unproven product.

5. *Third*, Strive falsely states its drugs adhere to state and federal regulations and that it goes above and beyond to ensure safety and quality. In reality, Strive's mass-production of unapproved drugs does not comply with regulations, and Strive has historically failed to observe sterility and sanitization standards in its facilities.

6. Strive's false marketing claims and deceptive business practices create dangerous patient safety risks. Strive's practices lure consumers away from Lilly's safe and effective FDA-approved medicines in favor of Strive's untested and unapproved products. To protect patient safety and stop Strive's deception, Lilly brings this action under Delaware state law and the Lanham Act.

THE PARTIES

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

8. Defendant Strive Pharmacy LLC is a limited liability company organized under the laws of Arizona with its principal place of business located at 1275 E. Baseline Road, Suite 104, Gilbert, AZ 85233. Strive is a registered foreign limited liability company in the state of Delaware, with a registered agent in the state of Delaware. Strive operates and conducts business in Delaware, including by promoting and selling its tirzepatide product here.

JURISDICTION AND VENUE

9. 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 pleaded herein pursuant to 28 U.S.C. § 1367(a). Alternatively, and, in addition, the Court has subject matter jurisdiction over the state law cause of action pleaded herein 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.

10. Strive is subject to personal jurisdiction in Delaware because it has purposefully availed itself of the privilege of conducting activities in Delaware and sought the protection and benefits of its laws. Strive is licensed to conduct business in the state of Delaware and has a registered agent in the state. Strive operates and conducts business in Delaware, including by promoting and selling its tirzepatide product here.

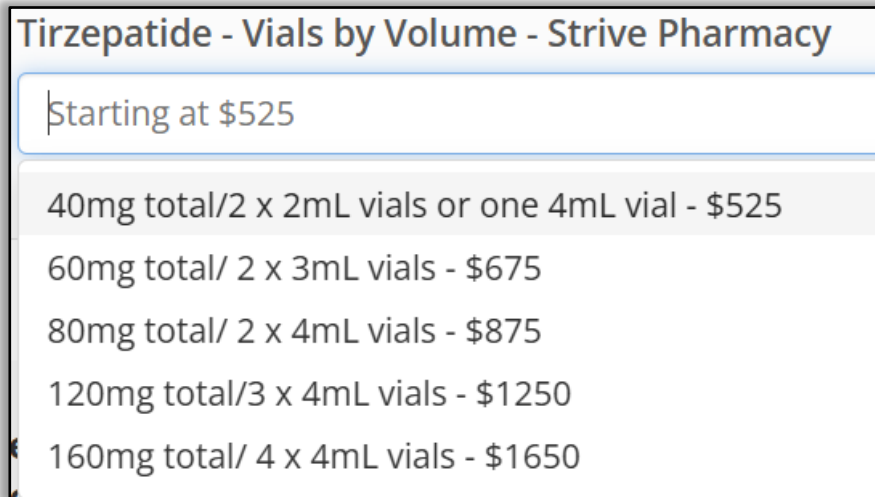
11. Strive does this through partnerships with telehealth providers and Delaware-based healthcare providers, as well as through its website, which allows Delaware consumers to find a provider near them that offers Strive products. For example, at the bottom of its website's home page, Strive offers a "Provider Lookup Tool" that allows Delaware residents to "find a Strive Provider and start enhancing your biology with personalized medications[.]"¹

12. When a user selects the Provider Lookup Tool, they are prompted to input their location to find a Strive provider. Strive-affiliated providers, such as Ianua Health² and Seaside

¹ Strive Pharmacy, *Find a Strive Provider*, https://www.strivepharmacy.com/find-a-strive-provider?utm_source=marketing&utm_medium=website&utm_campaign=become-a-strive-provider-cta&utm_content=button (last visited Mar. 20, 2025); Strive Pharmacy, *Locations*, <https://www.strivepharmacy.com/locations> (last visited Mar. 20, 2025).

² Ianua Health Weight Loss Page, <https://www.ianuahealth.com/weight-loss> (last visited Mar. 6, 2025); Ianua Health Intake Form, <https://intakeq.com/new/inn6kl> (last visited Mar. 23, 2025).

Wellness,³ are located in Delaware and prescribe Strive’s tirzepatide product in Delaware. Ianua Health, for instance, allows consumers to select “Tirzepatide – Vials by Volume” which are manufactured by “Strive Pharmacy.”⁴

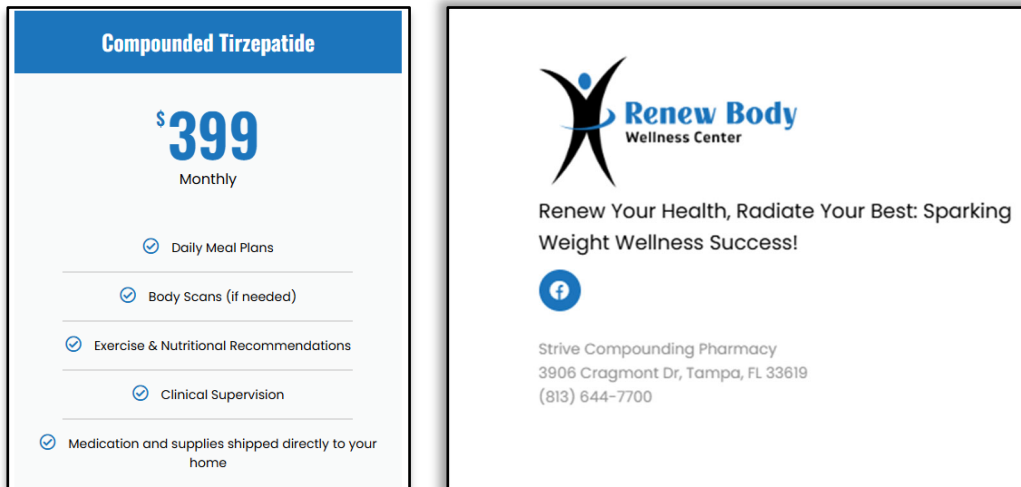


Tirzepatide - Vials by Volume - Strive Pharmacy

Starting at \$525

40mg total/ 2 x 2mL vials or one 4mL vial	- \$525
60mg total/ 2 x 3mL vials	- \$675
80mg total/ 2 x 4mL vials	- \$875
120mg total/ 3 x 4mL vials	- \$1250
160mg total/ 4 x 4mL vials	- \$1650

13. Renew Body Wellness Center, a provider in Newark, Delaware, also offers tirzepatide that it obtains from Strive.




Compounded Tirzepatide

\$399
Monthly

- ✓ Daily Meal Plans
- ✓ Body Scans (if needed)
- ✓ Exercise & Nutritional Recommendations
- ✓ Clinical Supervision
- ✓ Medication and supplies shipped directly to your home

Renew Body
Wellness Center

Renew Your Health, Radiate Your Best: Sparking Weight Wellness Success!



Strive Compounding Pharmacy
3906 Cragmont Dr, Tampa, FL 33619
(813) 644-7700

³ Seaside Wellness Product Page, <https://seaside-wellness.helcim.app/quick-order> (last visited Mar. 6, 2025); Seaside Wellness, *FAQ*, <https://seasidewellnessllc.com/faq> (last visited Mar. 6, 2025).

⁴ *Supra* note 2.

14. According to Strive, other providers in Delaware that source from Strive include Lavish Wellness & Aesthetics and SlimPhoria.

15. Strive also allows consumers to refill prescriptions online and select the Strive facility from which they will receive their shipment.⁵ At this point, consumers can directly engage with Strive, as opposed to their provider. On information and belief, Strive also instructs providers to give purported “personalized” Strive tirzepatide prescriptions by indicating (without any actual patient-specific need) that its products are being uniquely prescribed.

16. Venue is proper in Delaware pursuant to 28 U.S.C. § 1391 because, among other reasons, the events giving rise to these claims substantially occurred here, including because Strive works with several Delaware healthcare providers to deceptively market and sell its tirzepatide product.

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 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

⁵ JennLnz, *First Order From Strive*, (June 2024), https://www.reddit.com/r/tirzepatidecompound/comments/1dizyxl/first_order_from_strive/#lightbox

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.

21. FDA approval is famously hard to earn. More than 90% of drug candidates ultimately fail.⁶ 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.”⁷

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

⁶ Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020* at 3 (Feb. 2021), <https://tinyurl.com/bp5mb3xy> (hereinafter “BIO 2021”).

⁷ PhRMA, *Research and Development Policy Framework* (Sept. 2024), <https://tinyurl.com/5eecdtm9>.

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.⁸

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.⁹ Phase III trials are designed to confirm the safety and efficacy 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.

⁸ BIO 2021 at 7.

⁹ BIO 2021 at 7.

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.”¹⁰

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 insulintropic 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.

¹⁰ FDA, *Development & Approval Process* (Aug. 8, 2022), <https://www.fda.gov/drugs/development-approval-process-drugs>.

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 with additives like glycine or vitamin B12.

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

II. DRUG COMPOUNDING

32. 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.”¹¹ 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.

33. As FDA itself makes clear, “[c]ompounded drugs are not FDA-approved.”¹² This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, many compounded drugs are not clinically tested and are not reviewed or approved by FDA for safety and efficacy. 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.

¹¹ FDA, *Human Drug Compounding* (Dec. 18, 2024), <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

¹² 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>.

34. 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.”¹³ 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.”¹⁴ 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.”

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 . . . tirzepatide.”¹⁵ Further, an October 2024 FDA statement warned of “multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors.”¹⁶

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

¹³ FDA, *Compounding and the FDA: Questions and Answers* (June 29, 2022), <https://web.archive.org/web/20220702213650/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>.

¹⁴ Letter from Center for Drug Evaluation and Research, at 10 (Dec. 19, 2024), <https://www.fda.gov/media/184606/download>.

¹⁵ 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>.

¹⁶ 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>.

compounders using “non-sterile ingredients” and taking “no steps to sterilize them.”¹⁷ 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.”¹⁸ 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.”¹⁹ Similarly, the JAMA Health Forum published a study finding that most websites selling compounded anti-obesity medications exclude important safety information and mislead consumers about the safety and effectiveness of their products.²⁰ 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.”²¹

¹⁷ 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..>

¹⁸ 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/>.

¹⁹ 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/>.

²⁰ 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>.

²¹ National 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),

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.”²² The ban—effective October 2024—targets compounded drugs that are “being misrepresented and sold as replica [Mounjaro®].”²³ 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.”²⁴ 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 agonists, which are sterile medicines containing complex active substances[,] poses a public health and safety risk.”²⁵

<https://diabetes.org/newsroom/press-releases/american-diabetes-association-announces-statement-compounded-incretin#:~:text=The%20statement%20recommends%20against%20using,safety%2C%20quality%2C%20and%20effectiveness.>

²² 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>.

²³ *Id.*

²⁴ *Id.*

²⁵ 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-ghp1-and-gip-ghp1-products-that-are-compounded-substandard-and-falsified/>.

III. STRIVE'S DECEPTIVE TRADE PRACTICES AND FALSE CLAIMS

38. Strive is a compounding pharmacy that purports to offer “weight management” drugs “tailored specially to you,”²⁶ including tirzepatide with glycine and vitamin B12.²⁷ Strive is a large-scale operation with a nationwide presence, offering bulk discounts to providers. According to Strive, its nine locations across the country enable it to guarantee fast turnaround times for customers who order its products.²⁸

39. Strive has made and continues to make numerous explicitly and implicitly false and deceptive statements about—and engaged in deceptive trade practices regarding—its tirzepatide combination drug, including that: (1) its tirzepatide combination drug is a custom-made, “personalized” product, when it is not; (2) its tirzepatide combination drug is found to be superior to Lilly’s medicines, when it is not; and (3) it adheres to regulations, when it does not.

40. These statements are false and deceive consumers as to the nature and quality of Strive’s product, and they have the tendency to lure the unassuming public away from using safe, clinically tested, FDA-approved medicines like those made by Lilly.

A. Strive Falsely Claims Its Tirzepatide Combination Drug Is Custom Made

41. Strive claims that its products are “personalized” for specific patients, which is untrue. Strive actually offers a cookie-cutter tirzepatide product.

²⁶ Strive Pharmacy, *Services*, <https://www.strivepharmacy.com/services> (last accessed Mar. 6, 2025).

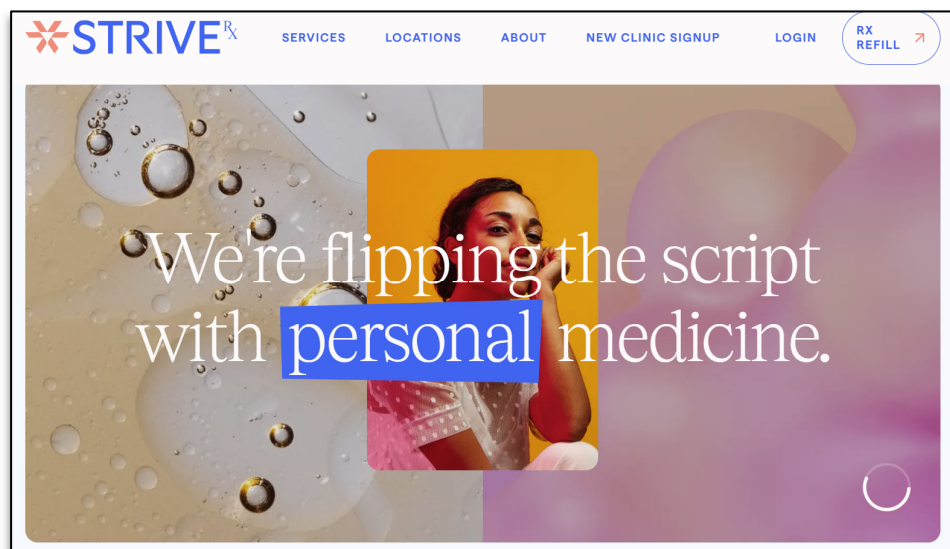
²⁷ Among its other contentions, Strive claims “[w]e source our Tirzepatide Base Powder from a domestic API manufacturer.” See Strive Pharmacy, *Tirzepatide/Glycine/B12 FAQs* (May 15, 2024), <https://lifechoicesmedical.com/wp-content/uploads/2024/05/Tirzepatide-FAQ.pdf>. However, the vast majority—if not all—of compounded tirzepatide in the United States uses API from foreign sources, most of which are not inspected by FDA.

²⁸ Strive Compounding Pharmacy, *Meet the Future of Personal Healthcare | Strive Compounding Pharmacy*, YOUTUBE (Jan. 24, 2025), <https://www.youtube.com/watch?v=ILu4kP3018A>.

1. Strive’s “Personalization” Statements

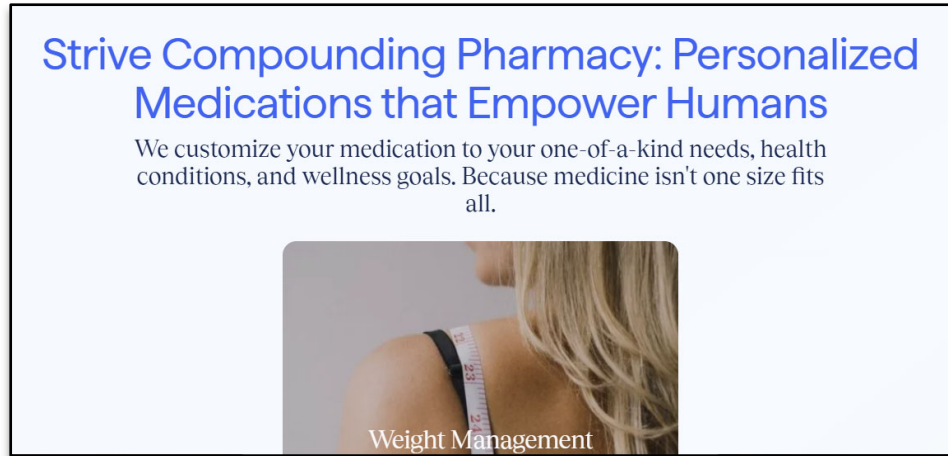
42. Strive repeatedly makes the false claim that its tirzepatide product is personalized based on the needs of the patient.

43. The first thing a visitor to Strive’s website sees is the bolded claim that Strive is “flipping the script with **personal** medicine,”²⁹ with “personal” highlighted in blue by Strive. Strive’s advertising falsely and necessarily implied that its drugs are specifically customized to meet each specific patient’s needs but that other company’s products are mass produced.

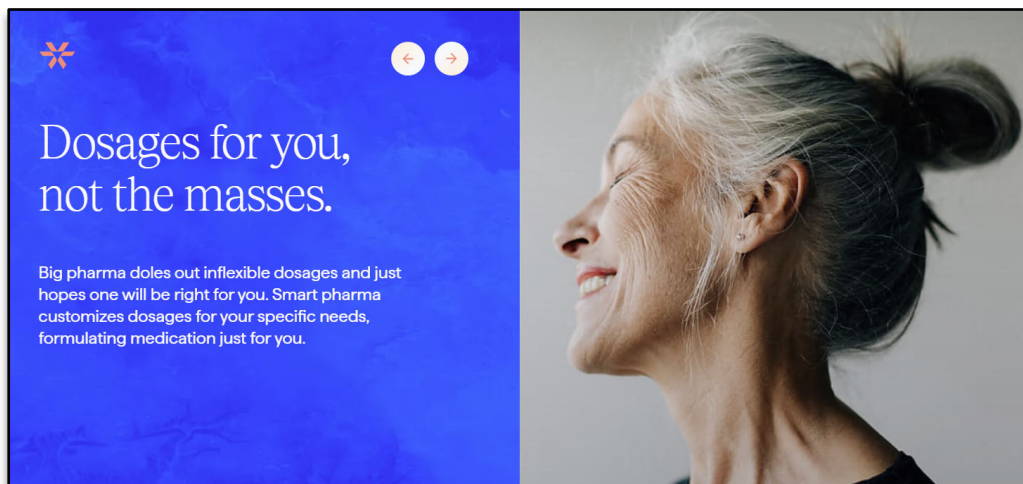


44. On that same home page, Strive explicitly claims to offer “Personalized Medications that Empower Humans.” Strive promises: “We customize your medication to your one-of-a-kind needs, health conditions, and wellness goals. Because medicine isn’t one size fits all.”

²⁹ Strive Pharmacy, <https://www.strivepharmacy.com/> (emphasis in original) (last viewed Mar. 20, 2025).



45. As consumers scroll down the same home page, Strive further promises that it provides “[d]osages for you, not the masses,” reiterating yet again that it offers custom dosages and drugs for each specific patient. Purporting to draw a contrast, Strive says “Big pharma doles out inflexible dosages and just hopes one will be right for you,” while “[s]mart pharma customizes dosages for your specific needs, formulating medication just for you.”



46. Strive doubles down on its “About” page. There, Strive states that it “approach[es] compounding from the conviction that life isn’t one-size-fits-all, and neither is medicine.”³⁰

³⁰ Strive Pharmacy, *About*, <https://www.strivepharmacy.com/about> (last visited Mar. 20, 2025).

“We approach compounding from the conviction that life isn’t one-size-fits-all, and neither is medicine.”

47. Elsewhere, Strive claims it “use[s] a doctor’s prescription to create a medication that fits the individual needs of one person”³¹ and that compounded products are “specifically designed by a pharmacist, with the consent and input of a doctor, that cater[] to the needs of one particular person.”³²

What Is Compound Medicine?

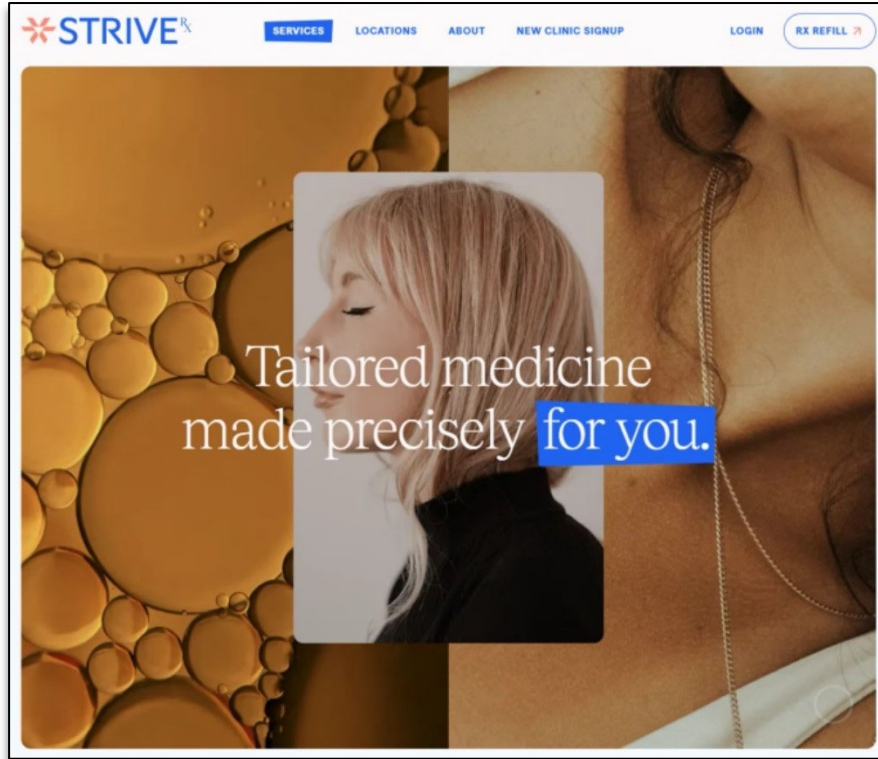
Compound medicine is a medication specifically designed by a pharmacist, with the consent and input of a doctor, that caters to the needs of one particular person. Compounding pharmacies consider a person’s health restrictions, goals, and allergies when tailoring prescriptions.

48. Similarly, under the “Services” tab on Strive’s website, potential customers are enticed by the claim: “Tailored medicine made precisely **for you**,”³³ with “for you” highlighted in blue.

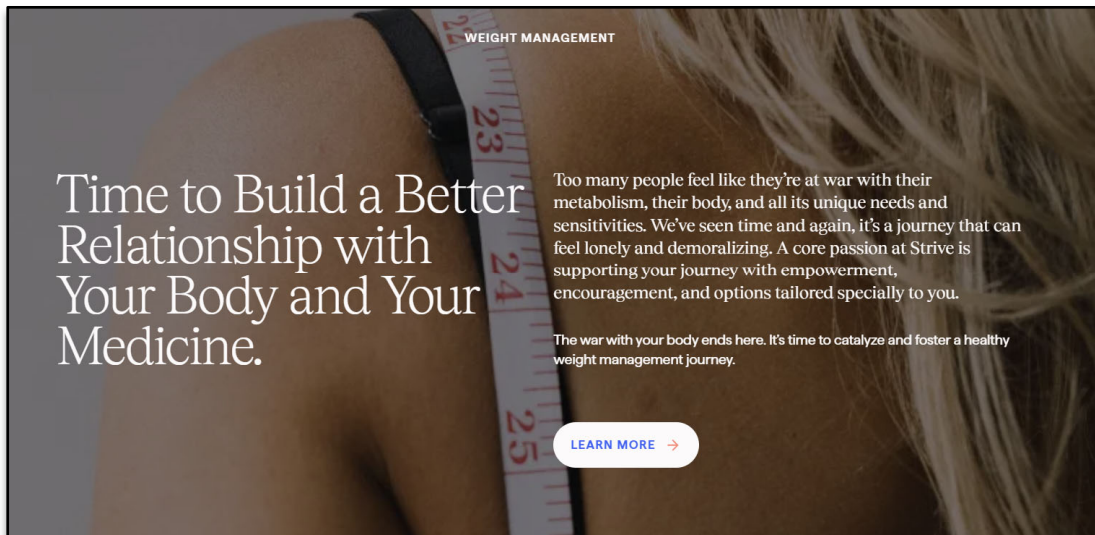
³¹ Strive Pharmacy La Jolla Location, <https://www.strivepharmacy.com/locations/california/la-jolla-92037> (last visited Mar. 20, 2025).

³² Strive Pharmacy Utah Location, <https://www.strivepharmacy.com/locations/utah/sandy-84070> (last visited Mar. 20, 2025).

³³ Strive Pharmacy, *Services*, <https://www.strivepharmacy.com/services> (last visited Mar. 20, 2025) (emphasis in original).



49. Specifically referring to weight management treatments, Strive says: “A core passion at Strive is supporting your journey with empowerment, encouragement, and options tailored specially to you.”³⁴



³⁴ *Id.*

50. On the same page, Strive claims, “we customize your medication’s ingredients and dosage form (pills, lozenges, troches, injections, ointments, oral, topical, etc.) distinctively for you.” Strive promises that it will “work with you and/or your provider to unearth your needs and best options, and then formulate and compound your one-of-a-kind treatment.”

51. Strive then reiterates that it “recognizes that each of us has unique needs and concerns that require varied treatment solutions. With this in mind, we use our compounding expertise and technology to provide personalized compounded weight loss medications that meet you where you are.”³⁵ These compounded weight loss drugs include “tirzepatide” combined with glycine and vitamin B12.

52. In short, throughout its advertising, Strive explicitly and necessarily tells consumers that medicine should not be one-size-fits-all, and that it offers personalized drugs to meet specific individual needs. But as shown below, Strive does no such thing and its repeated claims that its drugs are “personalized” are false.

2. The Truth About Strive’s “Personalized” Tirzepatide Combination Drug

53. In reality, there is nothing “personalized” about Strive’s compounded tirzepatide product. Strive mass produces its tirzepatide combination drug in predetermined dosages.

54. Strive’s 2024 Drug Catalog—available to providers—believes that there is any customization. Strive lists only *one* form of tirzepatide for patients or providers to choose. That’s all. No custom offering. No personalized choice.³⁶


³⁵ Strive Pharmacy Weight Management Page, <https://www.strivepharmacy.com/services/weight-management> (last visited Mar. 20, 2025).

³⁶ Decl. of Bret Phillips in Support of Defendants’ Opposition to Motion for Preliminary Injunction at 23, *Skin Medicinals LLC v. Optio Rx, LLC, et al.*, No. 24-50079 (Bankr. D. Del. July 2, 2024), ECF No. 50. Available at <https://cases.stretto.com/public/x335/12885/PLEADINGS/128850703248000000007.pdf>.

MEDICATION	STRENGTH	FORM	CATEGORY	ROUTE	QUANTITY	PATIENT \$ PRICE	DOCTOR \$ PRICE
Semaglutide/B12	5mg/1mg/mL	Injection	Weight Loss	Injection	0.5mL	\$150	\$100
					1mL	\$220	\$150
					2mL	\$250	\$175
Semaglutide/B12/Chromium Pic/Pyridoxine	500mcg/100mcg 500mcg/12.5mg	Mini Troche	Weight Loss	Oral	Per Troche	\$5/Troche	\$4/Troche
Semaglutide/B12/Chromium Pic/Pyridoxine	1000mcg/100mcg 500mcg/12.5mg	Mini Troche	Weight Loss	Oral	Per Troche	\$6/Troche	\$5.50/Troche
Semaglutide/B12/Chromium Pic/Pyridoxine	1500mcg/100mcg 500mcg/12.5mg	Mini Troche	Weight Loss	Oral	Per Troche	\$8/Troche	\$7/Troche
Semaglutide/B12/Chromium Pic/Pyridoxine	2000mcg/100mcg 500mcg/12.5mg	Mini Troche	Weight Loss	Oral	Per Troche	\$9/Troche	\$8.50/Troche
Super MIC (Methionine/ Inositol/Choline/B12/L-Carnitine/Thiamine/Pyridoxine)	12.4/25/25/1/ 125/50/2 mg/mL	Injection	Weight Loss	Injection	10mL 30mL	\$70 \$70	\$60 \$60
Tirzepatide/B12	10mg/500mcg/mL	Injection	Weight Loss	Injection	2mL	\$225	\$185
					4mL-10mL	\$200/vial	\$175/vial

55. Further demonstrating the lack of customization, on its “New Telehealth & Telemedicine Clinic Registration” webpage, Strive offers “volume-based pricing” for its partner clinics. In other words, Strive’s own statements reveal that Strive is mass-manufacturing drugs to ship to patients and providers.

56. Rather than making “custom” products tailored specifically to individual patient needs and patient-specific prescriptions where the changes result in a clinical difference for that patient, Strive is mass producing its tirzepatide combination drug. Strive tried to cover its tracks with a flyer that Strive distributed to its affiliated providers in October 2024. That flyer confirmed, despite Strive’s promises to the contrary, the *lack* of customization. The flyer was designed to create cover and the illusion of patient-specific prescriptions, when Strive was in fact making the same drug for all patients, despite its claims and purported business practices to the contrary. In the flyer, Strive fed its providers stock language for them to include in prescriptions to make it appear as if the prescription is individually based. Strive emphasized: “[p]lease ensure that you follow this guidance for every tirzepatide prescription.”



1275 E BASELINE RD, STE 104
GILBERT, AZ 85233

Prescribing and Documentation for Tirzepatide

Although tirzepatide is no longer listed on the FDA's drug shortage list, it remains on the ASHP's drug shortage list. Due to ongoing supply constraints, we are limited by our wholesale distributors to 22 prescriptions worth of brand-name tirzepatide per day. This is far below what is necessary to meet our daily patient demand.

To ensure compliance and continuity of care, we must adhere to the following procedures when handling tirzepatide prescriptions:

1. Reason for Compounded Medication:
 - Primary**
 - The prescriber has determined that a dose, which is not available via the brand name pens, is medically necessary for the patient. *(Ex. 9mg or 12mg of Tirzepatide)*
 - If a prescriber deems the commercial strengths are ok we will recommend they convert their patient to semaglutide
 - Secondary**
 - Prescribers must include a clear reason on the prescription for why the compounded version of tirzepatide is being used.
 - Examples:
 - w/b12 for nausea
 - w/glycine to prevent muscle degradation
 - If this information is not provided by the prescriber, the pharmacy staff must contact the prescriber to obtain the reason for using the compounded version and ensure that it is documented on the prescription.
2. Shortage Notation:
 - Each prescription must include the following notation:
 - "The brand name medication is not commercially available as the market cannot meet patient demand."
3. Documentation:
 - Ensure that all communications regarding the shortage, including any follow-up with prescribers, are documented accurately in the patient's prescription file for future reference.

The above steps are crucial in ensuring that we are compliant with regulatory standards while addressing patient needs during this shortage. Please ensure that you follow this guidance for every tirzepatide prescription.

If there are any questions or concerns, please reach out to your direct supervisor for further clarification.

Thank you,

Strive Leadership
10/03/2024

57. Strive has recently told its patients that it requires “proper documentation on the prescription about the provider’s clinically significant reasoning”³⁷ for its combination GLP-1 drugs. But when considered alongside Strive’s other statements and conduct—including the

³⁷ roguex99, *Email from Strive regarding compounding* (Mar. 18, 2025), https://www.reddit.com/r/tirzepatidecompound/comments/1jed7hy/email_from_strive_regarding_compounding/#lightbox.

distribution of the above flier—it is evident that Strive’s “significant difference” prescription requirement is pretextual.

Therefore, Strive will **continue compounding** GLP-1s that aren’t commercially available and/or those determined to provide a **clinically significant difference by the provider.**

Moving forward, **proper documentation on the prescription** about the provider’s **clinically significant reasoning** will be **required** for Strive to accept and fill GLP-1 prescriptions. We will continue to monitor the everchanging landscape of GLP-1 receptor agonist compounding, aiming to adhere to FDA law and guidance, while adjusting to any ongoing litigation.

58. Instructing doctors to pretend that there is a patient-specific need for tirzepatide with B12 reveals that Strive’s “personalization” decisions are driven solely by profit motivations, and not by any unique clinical need.

59. Online consumer posts confirm that Strive’s product is not “personalized” or customized as well. On Reddit, one user reported that a patient who was “sensitive to B vitamins”

could not use Strive’s product.³⁸ Another Reddit user also stated that its “regular Strive option is out for me” because they did not want tirzepatide with additives.³⁹

60. In addition, Strive does not even “personalize” the “dosages” as it claims to do. Another Reddit user reported that Strive gets “crazy expensive” at “higher doses,” because “[y]ou have to end up getting multiple vials as all the vials are the same strength.”⁴⁰ Put differently, Strive simply sells consumers more vials of the same standardized dosage. So despite its claims to the contrary, Strive provides a one-size-fits-all drug—*not* customizable, tailored, or “personalized” products.

61. At bottom, despite all its promises in its promotion of its tirzepatide combination drug, Strive is simply engaged in mass-manufacturing of its standardized, unapproved drug and is asking providers to run cover so the deception can continue.

B. Strive Falsely Suggests Its Tirzepatide Combination Drug Is Proven Superior to Lilly’s FDA-Approved Medicines

62. Strive also presents its “customized” drugs as alternatives that are proven superior to FDA-approved medicines. Strive pitches itself as “Smart Pharma”: A company that supposedly puts individual needs first to deliver superior healthcare outcomes. Strive contrasts “Smart Pharma” with “Big Pharma” (*i.e.*, presumably Lilly and other manufacturers of FDA-approved medicines that are rigorously regulated for safety and quality). On this basis, Strive claims its products are comparatively superior to those made by “Big Pharma,” because they are more

³⁸ Feisty-Feline-1, Comment to *Strive pharmacy crazy pricing?*, <https://www.reddit.com/r/tirzepatidecompound/comments/1hsztop/comment/m9chg87/> (last viewed Mar. 20, 2025).

³⁹ Rhannonshae, Comment to *Strive*, <https://www.reddit.com/r/tirzepatidecompound/comments/1icjri8/strive/> (last viewed Mar. 20, 2025).

⁴⁰ Top-Manufacturer-855, Comment to *Online provider that uses Strive pharmacy?*, https://www.reddit.com/r/tirzepatidecompound/comments/1d0piiz/online_provider_that_uses_strive_pharmacy/ (last viewed Mar. 20, 2025).

personalized than FDA-approved medicines (which is untrue) and that consumers can experience better results with Strive’s “Smart Pharma” medicines (which would be measured by comparative research, but that research does not exist).

1. Strive’s Comparative Personalization Claims

63. Strive not only represents that its products are “customized” when they are not, but it also claims that its allegedly “customized” drugs are *better* than medicines made by legitimate pharmaceutical companies like Lilly, necessarily suggesting that its treatments will offer better, “customized” outcomes than Lilly’s safe and effective medicines. Its website and social media accounts are replete with examples of Strive’s false superiority claims.

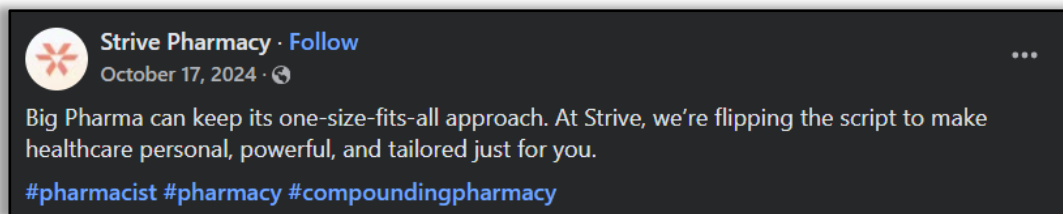
64. For instance, on its website’s “About” page discussed previously, Strive states that “Big pharma doles out inflexible dosages and just hopes one will be right for you. Smart pharma customizes dosages for your specific needs, formulating medication just for you.”⁴¹

65. Strive makes similar claims on social media. In a May 2024 video posted on both X and Instagram, Strive’s Vice President of Marketing tells consumers that Strive’s approach is “more personalized” than “Big Pharma’s one size fits all approach.”⁴² And, in an October 2024 Facebook post, Strive states that “Big Pharma can keep its one-size-fits-all approach. At Strive, we’re flipping the script to make healthcare personal, powerful, and tailored just for you.”⁴³

⁴¹ See *Supra* at III.A.1.

⁴² Strive Pharmacy (@strivepharmacy), *We are driven by a mission...*, X (May 28, 2024, 11:56 AM), <https://x.com/strivepharmacy/status/1795484405882052807>; Strive Pharmacy (strivepharmacy), *We are driven by a mission*, INSTAGRAM (May 28, 2024), https://www.instagram.com/strivepharmacy/reel/C7hHglDR_hj/.

⁴³ Strive Pharmacy, *Big Pharma can keep its one-size-fits-all approach. At Strive, we’re flipping the script to make healthcare personal, powerful, and tailored just for you*, FACEBOOK (Oct. 17, 2024) <https://www.facebook.com/share/v/1A9KmUMg8n/>.



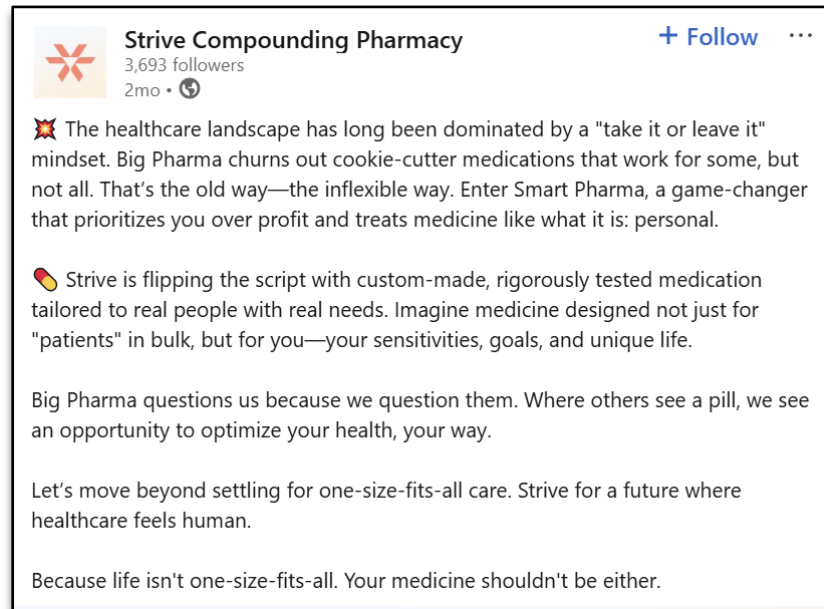
66. Similarly, in a February 2025 Facebook reel, a Strive spokesperson tells consumers that his “big pharma ick” is “[m]edicine that’s one-size-fits-all!”⁴⁴



67. And on LinkedIn, Strive further tells consumers that “Big Pharma churns out cookie-cutter medications that work for some, but not all,” and that “Big Pharma questions us because we question them. Where others see a pill, we see an opportunity to optimize your health, your way. Let’s move beyond settling for one-size-fits-all care. Strive for a future where

⁴⁴ Strive Pharmacy, *Joey's big pharma ick? Medicine that's one-size-fits-all!*, FACEBOOK (Feb. 6, 2025), <https://www.facebook.com/share/r/16JjAWhAw1/>.

healthcare feels human.”⁴⁵ Strive also invites consumers to “[i]magine medicine designed not just for ‘patients’ in bulk, but for you.”



68. In addition, while Strive claims to personalize “dosages” more than “Big Pharma” and disclaims a one-size-fits-all approach to medicine, Strive actually sells a single untested and unapproved drug. By contrast, Lilly makes a total of 16 different FDA-approved tirzepatide administrations: six dosages of MOUNJARO® in autoinjector pens, six dosages of ZEPBOUND® in autoinjector pens, and four dosages of ZEPBOUND® in single-use sterile vials. These dosages were selected after rigorous testing through years-long clinical trials.

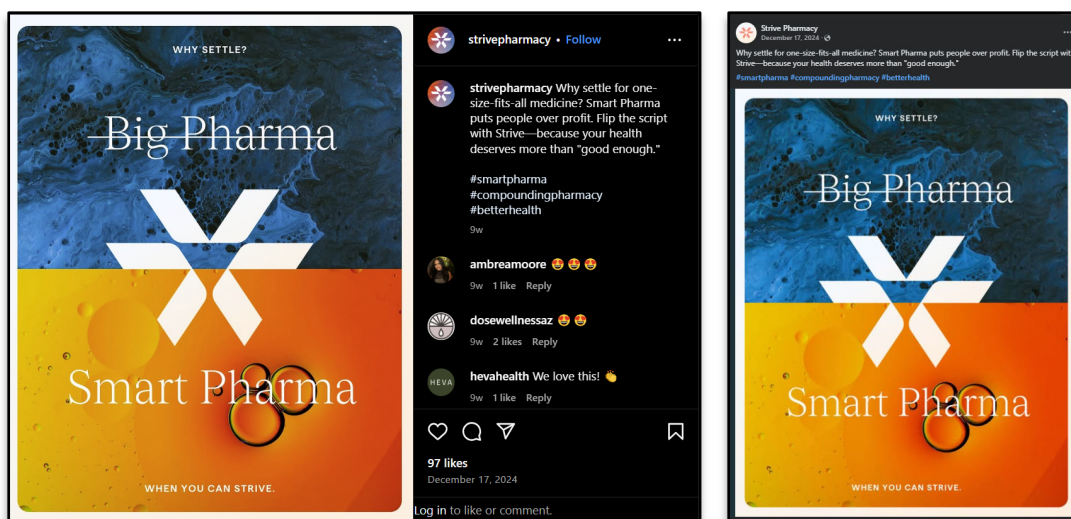
69. Strive’s claims necessarily communicate to consumers that Strive’s products are more customized for an individual consumer than products from its competitors in “Big Pharma,” and that the treatments available from Strive are better suited for the patient and therefore provide better outcomes when neither of those things is true or based on any evidence whatsoever.

⁴⁵ Strive Compounding Pharmacy, *The healthcare landscape has been dominated by a “take it or leave it” mindset*, LINKEDIN (Dec. 2024), https://www.linkedin.com/posts/strivepharmacy_the-healthcare-landscape-has-long-been-activity-7274869058473279490--LRn/.

2. Strive’s Comparative Superiority Claims

70. Strive also goes a step further and claims its products offer superior results to Lilly’s FDA-approved medicines because Strive includes additional active ingredients, including vitamin B12 and glycine. Again, this claim of superiority is false.

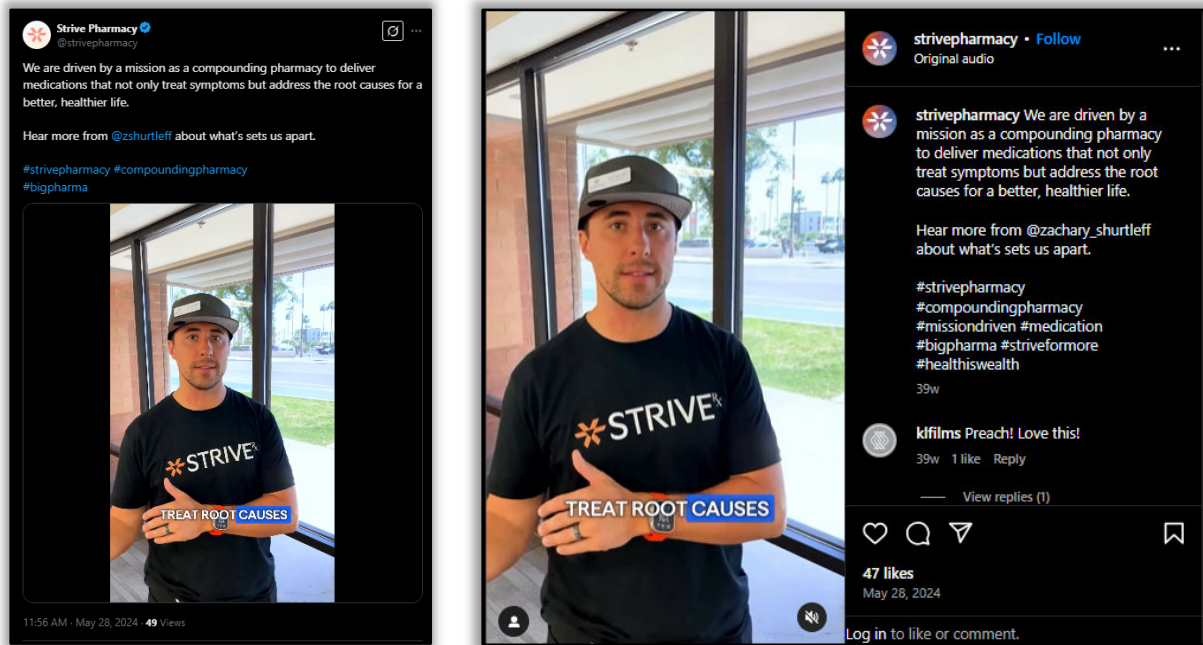
71. For example, across its social media accounts, Strive claims its products provide superior results than FDA-approved medicines. In a December 2024 post made on both Instagram and Facebook, Strive tells consumers Smart Pharma can offer better results, asking consumers to “[f]lip the script with Strive—because your health deserves more than ‘good enough.’”⁴⁶



72. In a May 2024 video posted on both X and Instagram, Strive’s Vice President of Marketing tells consumers that, with Strive’s “medications, they’re not there to just treat symptoms. They’re there to actually treat root causes and add to more healthy, happy years to a

⁴⁶ Strive Pharmacy (strivepharmacy), *Why Settle? When You Can Strive.*, INSTAGRAM (Dec. 17, 2024), https://www.instagram.com/strivepharmacy/p/DDsX_hPJEDq/; Strive Pharmacy, *Why Settle? When You Can Strive.*, FACEBOOK (Dec. 17, 2024), <https://www.facebook.com/share/p/1KvEfdyPVu/>.

person’s life.”⁴⁷ He also explains that Strive medications are “more personalized” than “Big Pharma’s one size fits all approach.”⁴⁸



73. And, in another May 2024 video, Strive tells consumers it is “disrupting Big Pharma,” “flipping the script on personalized medicine,” “treat[ing] root causes rather than just symptoms,” and that it is “on a mission to show the world that **our medications are safer and better for you.**”⁴⁹

⁴⁷ Strive Pharmacy (@strivepharmacy), *We are driven by a mission...*, X (May 28, 2024, 11:56 AM), <https://x.com/strivepharmacy/status/1795484405882052807>; Strive Pharmacy (strivepharmacy), *We are driven by a mission*, INSTAGRAM (May 28, 2024), https://www.instagram.com/strivepharmacy/reel/C7hHglDR_hj/.

⁴⁸ *Id.*

⁴⁹ Strive Compounding Pharmacy, *We’re Strive Compounding Pharmacy, of course, we’re disrupting big pharma.*, YOUTUBE (May 28, 2024), <https://www.youtube.com/watch?v=WqMLc3UJ9tQ> (emphasis added).



74. These statements explicitly and necessarily communicate that Strive’s allegedly “personalized” drugs have been proven *more safe and more effective* than Lilly’s tirzepatide medicines when that is not the case. In fact, no clinical study has been conducted to determine, much less has determined, that tirzepatide combined with glycine and vitamin B12—whether Strive’s product or anyone else’s—is safe and effective for human use. In stark contrast, Lilly engaged in nearly a decade of development and dozens of clinical trials, and FDA evaluated and approved Lilly’s tirzepatide medicines as safe and effective to treat their approved indications.

75. Strive’s products are not “safer” or “better.” Strive is blatantly misrepresenting the nature, characteristics, and qualities of its products without any clinical data underlying its claims.

C. Strive Makes False Statements Regarding Regulatory Compliance⁵⁰

76. Finally, Strive also makes false statements to consumers about its professional practices. Specifically, Strive claims that “[n]ot only do Strive’s medications adhere to state and federal regulations, but we also go far above and beyond regulatory standards to ensure safe, quality medications.”⁵¹ These promises of high safety and quality standards are false.

77. First, Strive’s claim that its drugs adhere to regulations and that Strive itself exceeds regulatory standards is false. Strive is not operating in compliance with state or federal regulations regarding drug manufacturing or drug compounding because it is mass-manufacturing unapproved drugs, not crafting “customized” drugs for individual patients. To be clear, Lilly’s allegations are that Strive’s *statements* regarding compliance are unlawful. It challenges Strive’s claims about its pharmaceutical practice, not the pharmaceutical practice itself.

78. Second, Strive’s claim that it has “an integral and unwavering commitment” to sanitizing its equipment is false. Strive has been cited by regulatory authorities for *failing* to maintain sanitized equipment. For instance, in September 2023, FDA’s Office of Regulatory Affairs issued a Form 483 inspection report to Strive Pharmacy Texas LLC, a Strive affiliate, documenting numerous failures to meet standards for sterile compounding, including Strive personnel performing “aseptic manipulations with exposed hair or skin,” together with a “[f]ailure to “appropriately and regularly clean and disinfect or sterilize equipment” and “inadequate” “cleaning of equipment and glassware.”⁵²

⁵⁰ These allegations apply only to the Third Cause of Action.

⁵¹ Strive Pharmacy, *Services*, <https://www.strivepharmacy.com/services#faq> (last viewed Mar. 20, 2025).

⁵² FDA Form 483 Report to Strive Pharmacy Texas LLC (Sept. 8, 2023), <https://www.fda.gov/media/172930/download>.

79. A Virginia facility that Strive now owns has also been cited by the Virginia Board of Pharmacy for similar violations. In May 2014, the Virginia Board of Pharmacy found that facility, then known as The Compounding Center, had assigned beyond use dates—*i.e.*, the date beyond which a pharmaceutical may not be stored or transported—for high-risk sterile products that were longer than the dates allowed by industry standards.⁵³ These sterile products were then also being used as ingredients in other sterile products which were also assigned longer beyond use dates than allowed. The Compounding Center also maintained incomplete documentation of sterility testing for certain products.

IV. STRIVE'S DECEPTION HARMS CONSUMERS AND LILLY

80. Strive's false, deceptive, and reckless promotion and sale of its tirzepatide product have harmed consumers and Lilly. That harm will continue if left unchecked.

81. First, Strive's practices harm consumers by exposing them to untested, unapproved drug products. As explained above, the use of untested, unapproved drug products unnecessarily risks consumers' safety.

82. Second, Strive's practices lure consumers away from Lilly's safe and effective FDA-approved medicines in favor of Strive's untested and unapproved products based on false assurances that Strive's products are superior to FDA-approved medicines and designed to fit patients' unique needs. In reality, none of that is true. Strive is marketing the same tirzepatide combination drug to every consumer and has no clinical data establishing that its products are safe and effective at all, let alone superior to Lilly's medicines. Diverting customers from Lilly's safe

⁵³ Consent Order, *In re: Leesburg Pharmacy, Inc. a/k/a The Compounding Center* (May 2, 2014). Available at <https://www.dhp.virginia.gov/Notices/Pharmacy/0201001953/0201001953Order05022014.pdf> (last visited Mar. 6, 2025).

and effective, FDA-approved medicines on false pretenses results not only in potential lost sales but, more importantly, risks medical harm to consumers.

83. Strive’s deception harms Lilly. Strive’s statements that medicines from traditional pharmaceutical companies like Lilly—companies Strive dubs “Big Pharma”—are less effective, one-size-fits-all treatments harm Lilly’s reputation. In particular, when Strive deceives patients into believing that its compounded products are made with their unique needs in mind—while contrasting Strive’s practices with the more traditional medicine companies—consumers will necessarily conclude that Lilly’s FDA-approved tirzepatide medicines, which come in 16 different administrations, is a one-size-fits-all medicine that does not effectively address their medical needs. And to the extent Strive’s product is unsafe or ineffective, these statements would cause patients to believe that Lilly’s tirzepatide is unsafe and ineffective (when it is not), undermining Lilly’s brand and customer goodwill.

FIRST CAUSE OF ACTION
Deceptive and Unfair Trade Practices: “Personalization”
in Violation of Delaware Code tit. 6 §§ 2531 *et seq.*

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

85. Under Delaware’s Uniform Deceptive Trade Practices Act (“UDTPA” §§ 2531 *et seq.*), deceptive trade practices are unlawful. A person engages in a deceptive trade practice when, in the course of business, they represent “that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have” or when they represent that “goods are of a particular style or model, if they are another.” Del. Code Ann. tit. 6 § 2532(a)(5); § 2532(a)(7).

86. Strive deceptively advertises and markets its tirzepatide product to consumers in the conduct of trade or commerce.

87. Strive’s improper consumer-oriented conduct is deceptive in a material way by claiming that its tirzepatide combination drug is a custom-made, “personalized” product, when it is not.

88. Strive’s improper consumer-oriented conduct actually or has likely deceived consumers and is likely to continue to deceive them.

89. As a direct and proximate result of Strive’s deceptive trade practices, consumers are led to believe that they are obtaining a more effective customized and tailor-made product when they are not.

90. As a direct and proximate result of Strive’s deceptive trade practices, Lilly has suffered and will continue to suffer monetary damages and discernible competitive injury by the loss of goodwill associated with Lilly’s MOUNJARO[®] and ZEPBOUND[®] tirzepatide medicines.

91. As a direct and proximate result of Strive’s unlawful campaign, Strive has benefitted and profited from sales it made as a result of goodwill associated with Lilly’s MOUNJARO[®] and ZEPBOUND[®] tirzepatide medicines.

92. Strive is liable to Lilly for damages in amounts to be proven at trial, including attorneys’ fees and costs, injunctive relief enjoining Strive from further violating the law, and any other remedies the Court may deem appropriate under Delaware’s UDTPA §§ 2531 *et seq.*, including treble damages.

SECOND CAUSE OF ACTION
Deceptive and Unfair Trade Practices: Superiority Claims
in Violation of Delaware Code tit. 6 §§ 2531 *et seq.*

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

94. Under Delaware’s Uniform Deceptive Trade Practices Act (“UDTPA” §§ 2531 *et seq.*), deceptive trade practices are unlawful. A person engages in a deceptive trade practice

when, in the course of business, they represent “that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have” or when they represent that “goods are of a particular style or model, if they are another.” Del. Code Ann. tit. 6 § 2532(a)(5); § 2532(a)(7).

95. Strive deceptively advertises and markets its tirzepatide product to consumers in the conduct of trade or commerce.

96. Strive’s improper consumer-oriented conduct is deceptive in a material way by claiming that its unapproved tirzepatide combination drug is superior to FDA-approved medicines, when no evidence supports that claim.

97. Strive’s improper consumer-oriented conduct actually or has likely deceived consumers and is likely to continue to deceive them.

98. As a direct and proximate result of Strive’s deceptive trade practices, consumers are led to believe that they are obtaining a more effective customized and tailor-made product when they are not.

99. As a direct and proximate result of Strive’s deceptive trade practices, Lilly has suffered and will continue to suffer monetary damages and discernible competitive injury by the loss of goodwill associated with Lilly’s MOUNJARO[®] and ZEPBOUND[®] tirzepatide medicines.

100. As a direct and proximate result of Strive’s unlawful campaign, Strive has benefitted and profited from sales it made as a result of goodwill associated with Lilly’s MOUNJARO[®] and ZEPBOUND[®] tirzepatide medicines.

101. Strive is liable to Lilly for damages in amounts to be proven at trial, including attorneys’ fees and costs, injunctive relief enjoining Strive from further violating the law, and any

other remedies the Court may deem appropriate under Delaware’s UDTPA §§ 2531 *et seq.*, including treble damages.

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

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

103. Strive’s commercial advertising claims described herein are false or misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

104. Strive has made materially false or misleading descriptions of fact, as well as false or misleading representations of fact to sell its tirzepatide combination product. These representations include but are not limited to: (1) Strive’s tirzepatide combination drug being “personalized,” or “customized” for a specific patient; (2) Strive’s unapproved tirzepatide combination drug being superior to Lilly’s medicines; and (3) Strive’s adherence to regulatory standards. These representations have influenced and are likely to continue influencing purchasing decisions—specifically, decisions to purchase Strive’s tirzepatide product instead of Lilly’s medicines.

105. Strive’s false and deceptive statements and business practices actually deceive or have the tendency to deceive consumers.

106. Strive has caused its false and deceptive statements to enter interstate trade or commerce.

107. As a direct and proximate result of Strive’s false and deceptive statements and practices, Lilly is suffering immediate and continuing irreparable injury for which there is no adequate remedy at law.

108. As a direct and proximate result of Strive's false and deceptive statements and practices, Lilly has suffered and will continue to suffer monetary damages and discernible competitive injury by the loss of goodwill.

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

110. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including 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 its favor on its claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that Strive:
 - a) Engaged in false and deceptive advertising and promotion, in violation of 15 U.S.C. § 1125(a)(1)(B); and
 - b) Engaged in deceptive acts or practices, in violation of Del. Code Ann. tit. 6 §§ 2531 *et seq.*
2. An injunction preliminarily and then permanently enjoining and restraining Strive and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:
 - a) Marketing, promoting, advertising, or otherwise making available to consumers its tirzepatide product in the manner that it is currently marketed or in any way that suggests it is custom-made, tailor-made, personalized, or changed for an individual patient's specific needs as determined by a prescriber;
 - b) Marketing, promoting, advertising, or otherwise making available to consumers its tirzepatide product in the manner that it is currently

marketed or in any way that suggests it is superior to Lilly's tirzepatide medicines;

- c) Falsely stating that Strive's drugs adhere to or exceed regulatory standards; and
- d) Engaging in any deceptive acts.

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

- a) Strive's tirzepatide product is not custom-made, tailor-made, personalized, or changed for an individual patient's specific needs as determined by a prescriber;
- b) Strive does not provide individualized tirzepatide product;
- c) Strive's tirzepatide is not superior to any branded tirzepatide medicines; and
- d) Strive's drugs do not adhere to or exceed regulatory standards.

4. An Order directing Strive 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 Strive to account for and pay to Lilly any and all profits arising from the foregoing acts of deceptive advertising and business practices pursuant to 15 U.S.C. § 1117, Del. Code. tit. 6 § 2533, and other applicable laws.

6. An Order requiring Strive to pay Lilly compensatory damages in an amount as yet undetermined caused by the false or misleading advertising and business practices and trebling in accordance with 15 U.S.C. § 1117, Del. Code tit. 6 § 2533, and other applicable laws.

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

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

9. An Order requiring Strive to pay Lilly's costs and attorneys' fees in this action pursuant to 15 U.S.C. § 1117, Del. Code tit. § 2533, and any other applicable provision of law.

10. Other relief as the Court may deem appropriate.

OF COUNSEL:

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