

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

<p>DARBY DAY, individually and on behalf of all others similarly situated,</p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p>OPENLOOP HEALTH INC., TRIAD RX BUYER LLC and TRIAD RX, INC., Defendants.</p>	<p>Case No.</p> <p>CLASS ACTION COMPLAINT</p> <p>JURY TRIAL DEMAND</p>
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Darby Day (“Plaintiff”), individually and on behalf of all others similarly situated, by and through his undersigned counsel brings this class action complaint against Defendants OpenLoop Health Inc., Triad Rx Buyer LLC and Triad Rx Inc. alleging the following based upon personal knowledge as to his own acts and experiences, and as to all other matters, upon information and belief, including the investigation conducted by Plaintiff’s counsel.

PRELIMINARY STATEMENT

1. Since 2021 the United States weight loss industry has grown into an unprecedented multi-billion dollar industry driven by sales of weight loss drugs, and specifically prescription GLP-1 weight loss drugs.¹

¹ GLP-1 is the acronym for “Glucagon-like peptide-1 receptor agonists” (“GLP-1 drugs”). GLP-1 drugs are peptide-based therapies that mimic a naturally occurring hormone that regulates blood sugar and appetite. In terms of weight loss medications, GLP-1 drugs have been viewed as a game changer. The GLP-1 market has also become one of the most valuable and fastest-growing sectors in modern pharmaceuticals, with analysts projecting global sales of GLP-1–based obesity and diabetes medications to approach or exceed \$100 billion by 2030. *See* Goldman Sachs, *Why the anti-obesity drug market could grow to \$100 billion by 2030* (Oct. 30, 2023) <https://www.goldmansachs.com/insights/articles/anti-obesity-drug-market> (last visited Nov. 18, 2025).

2. Looking to get their piece of this multi-billion dollar pie, OpenLoop Health, Inc. (“OpenLoop”), Triad Rx. Inc., and Triad Rx Buyer LLC (“Triad Rx”), together with their co-conspirators, including networks of marketing companies and telehealth physicians / clinicians, embarked on the manufacturing, distribution, and nationwide sale of a fraudulent, unapproved GLP-1 weight loss drug, specifically, an “oral tirzepatide” weight loss pill.

3. Despite the fact that Defendants and their co-conspirators could never manufacture an oral tirzepatide pill that functions as a legitimate, effective GLP-1 drug for weight loss, they have marketed and continue to market and sell it to thousands of unsuspecting consumers as a safe and effective equivalent and alternative to GLP-1 injectable weight loss medications that are approved by the Federal Drug Administration (“FDA”).²

4. The claims here concern Defendants’ so-called “oral tirzepatide” weight loss pill, a product that has never been approved by the FDA, has no demonstrated mechanism of absorption or efficacy, and functions as modern-day *snake oil*—a mass-produced, pharmacologically inert compound when delivered via a pill, and misrepresented to consumers as a legitimate GLP-1 weight loss therapy.

5. Plaintiff purchased the “oral tirzepatide” from a website called *MEDVi*, which claimed to offer personalized, doctor-supervised weight-loss treatment. In reality, *MEDVi* was

² There are FDA approved injectable tirzepatide weight loss products sold under the brand names *Mounjaro* and *Zepbound*, which are clinically recognized for the treatment of type 2 diabetes and obesity. Compounded injectable formulations of tirzepatide are also sold online and by compounding pharmacies but must comply with FDA rules and regulations. These compounded products are the subject of ongoing challenges by brand-name manufacturers *Eli Lilly & Co.* and *Novo Nordisk A/S* in lawsuits around the country alleging, among other things, that they fail to comply with the FDA’s compounding provisions, 21 U.S.C. §§ 353a–353b. This case, however, does **not** concern *injectable* tirzepatide.

one of dozens of deceptive artifices, *i.e.* nearly identical “telehealth” websites each promoting the same oral tirzepatide pills through nearly identical deceptive language and imagery.

6. These consumer-facing websites or “brands”, like *MEDVi*, conceal their common origin but are part of the same scheme and operation with Open Loop at the hub. The websites bombard customers with ads online and via social media, and also further the scheme and deception by, among other things, creating the false narrative that there is a proliferation of purported “companies” selling an “oral tirzepatide” pill, thereby giving consumers the false impression that the drug is legitimate and widely accepted and prescribed.

7. Through this scheme, Defendants have profited by intentionally deceiving consumers into each paying hundreds of dollars for unapproved, ineffective oral weight loss pills that were (knowingly) never capable of delivering the weight loss results promised.

8. On behalf of himself and those similarly situated persons who purchased “oral tirzepatide” pills that were manufactured, marketed, and/or delivered to them by OpenLoop and/or Triad Rx (“Class”), Plaintiff seeks to hold Defendants liable for: violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.* (“RICO”), the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.* (“NCUDTPA”), the consumer-protection statutes implicated by the Multistate Consumer Protection Subclass; and, for common-law fraud and unjust enrichment. Defendants’ conduct has caused Plaintiff and the Class economic damages, and Plaintiff also seeks to stop Defendants from continuing to deceptively market and sell “oral tirzepatide” pills.

THE PARTIES

9. Plaintiff Darby Day is a resident of Wilmington, North Carolina. As described below, Plaintiff purchased “oral tirzepatide” from Defendants.

10. Defendant OpenLoop Health Inc. is a corporation organized and existing under the laws of the State of Delaware.³ It maintains its corporate headquarters and principal place of business at 317 6th Ave, Suite 400, Des Moines, IA 50309. Per its co-founder and Chief Executive Officer, Jon Lensing, OpenLoop Health Inc. “operates in all 50 states and serves as the operating system of digital health for 100+ organizations nationwide.”⁴ OpenLoop’s co-founder and CEO is, and has been at relevant times, Jon Lensing.

11. Defendant Triad Rx, Inc. is an Alabama corporation with its principal place of business at 26258 Pollard Rd., Daphne, Alabama.⁵ Triad Rx, Inc. is a compounding pharmacy that is “licensed in over 45 States and ship[s] nationwide.”⁶ The company holds active pharmacy⁷ and controlled-substance⁸ licenses with the Delaware Division of Professional Regulation. As alleged below, the bottle of “oral tirzepatide” that Plaintiff and other members of the Class received identified the name “Triad Rx” and the Daphne, Alabama address.

³ DE File No. 6583115.

⁴ *Jon Lensing*, LinkedIn (<https://www.linkedin.com/in/jon-lensing/>).

⁵ AL File No. 000036902.

⁶ *About Us*, Triad Rx, <https://www.triadrx.us/coronavirus/our-pharmacy> (last visited Nov. 14, 2025).

⁷ Delaware Division of Professional Regulation, License No. A9-0013097 (issued Nov. 22, 2024), https://delpros.delaware.gov/oh_verifylicensedetails?pid=a0ecs000001vVWLAA2 (last visited Nov. 14, 2025).

⁸ Delaware Division of Professional Regulation, License No. PH-0025033 (issued Aug. 13, 2025), https://delpros.delaware.gov/oh_verifylicensedetails?pid=a0ecs00000PfdtRAAR (last visited Nov. 14, 2025).

- a. In a filing with the Montana Secretary of State, dated March 5, 2025, all corporate officers for Triad Rx., Inc. were stricken except for one—David Lindsey.⁹ David Lindsey is listed as the officer for Triad Rx, Inc. in the states of Alaska, Arkansas, California, Oregon, Utah, and Vermont.
- b. David Lindsey is also listed as the sole officer of a compounding pharmacy named “Link Pharmacy,” a Texas LLC.¹⁰ In a Texas filing dated May 2, 2025, a Delaware entity sharing Link Pharmacy’s address—LT Pharmacy Buyer, LLC¹¹—formally assumed the trade name “Link Pharmacy.” That filing was signed by OpenLoop’s CEO, Jon Lensing.¹²

12. Defendant Triad Rx Buyer LLC is a Delaware limited liability company, incorporated on December 13, 2024, and subsequently registered to do business in multiple states.¹³ Upon information and belief, Triad Rx Buyer LLC operates as the fulfillment and distribution arm of Triad Rx, Inc., including by dispensing the oral tirzepatide tablets purchased by consumers through Defendants’ associated telehealth storefronts. Plaintiff’s own prescription label identified “Triad Rx Buyer LLC” as the dispensing pharmacy, confirming its operational role in the manufacture, labeling, and shipment of the product at issue. Triad Rx Buyer LLC lists its business address as 26258 Pollard Rd., Daphne, Alabama—the same address used by Triad

⁹ MT File No. F1218307, Doc. No. B1409-6418.

¹⁰ *Link Pharmacy LLC*, TX File No. 805755872. The trade name “Link Pharmacy” was first assumed by Link Pharmacy Corp. in June of 2022. *See* TX File No. 804431274, Doc No. 1154147670004. However, Link Pharmacy Corp. was converted to Link Pharmacy LLC on October 22, 2024, with David Lindsey being the sole owner. *See* TX File No. 804431274, Doc No. 1415939450002.

¹¹ DE File No. 4556803.

¹² TX File No. 0805949098, Doc. No. 1477603290002.

¹³ DE File No. 10036831

Rx, Inc.—and reflects that location in its Alabama filing.^{14 15} In several Triad Rx Buyer LLC secretary of state filings, the agent or officer listed is Jon Lensing, the CEO of OpenLoop.¹⁶

Other state filings list a contact email address JillF@OpenLoopHealth.com.¹⁷ On or around July 25, 2025, Triad Rx, Inc. sold its Daphne, Alabama property to Triad Rx Buyer LLC and OpenLoop.¹⁸

13. Upon information and belief, Triad Rx, Inc., and Triad Rx Buyer LLC (collectively “Triad Rx”) are controlled by OpenLoop.

NON-PARTY ENTITIES ASSOCIATED WITH THE DEFENDANTS

14. The following ¶¶ 15-32 identify persons, properties, entities, and businesses associated with the named Defendants and that are participants in the scheme to market and sell “oral tirzepatide”.

A. The Partner Pharmacies

15. In addition to Defendant Triad Rx, Inc., OpenLoop identifies several other “Partner Pharmacies,” including RedRock Pharmacy, Health Warehouse, and Precision Compounding Pharmacy. Publicly available information confirms that these entities likewise compound and fulfill weight-loss drug prescriptions for telehealth platforms.¹⁹

¹⁴ AL File No. 001182224

¹⁵ Triad Rx Buyer LLC is also associated with the addresses:

- 317 6th Ave, Suite 400, Des Moines, IA 50309 (CT File No. 3198828);
- 2140 Justin Rd, Lewisville, TX 75077 (MA File No. 001905975); and
- 18484 Preston Rd, Suite 300A, Dallas, TX 75252 (TX File No. 0806022399).

¹⁶ See, e.g., ID File No. 0006217093; NC File No. 3106232; WA File No. 605858030.

¹⁷ See, e.g., CT File No. 3198828.

¹⁸ See Deed Record for Baldwin County, Ala., Doc. No. 2025-2201827, <https://baldwin.al.publicsearch.us/doc/265734640> (last visited Nov. 11, 2025).

¹⁹ See RedRock, <https://www.redrockrx.com/orderform> (last visited Nov. 17, 2025); Health Warehouse <https://www.healthwarehouse.com/pharmacy/condition/weight-loss> (last visited Nov. 17, 2025); Precision <https://precisionmeds.com/weight-loss/> (last visited Nov. 17, 2025).

B. Physicians/Clinicians

16. OpenLoop identifies that medical services, such as prescriptions, are delivered by OpenLoop Healthcare Partners, P.C. OpenLoop Healthcare Partners, P.C. is an Iowa professional corporation who identifies Jon Lensing’s father, Dale Lensing, as an officer of the company.²⁰ It is registered to do business in at least forty-three states, including Delaware.²¹ Its headquarters and principal place of business are the same as those of OpenLoop Health Inc.: 317 6th Ave., Suite 400, Des Moines, IA 50309. Jon and Dale Lensing have appeared together as officers on OpenLoop Healthcare Partners, P.C.’s Nebraska Secretary of State filings.²² In the Mississippi Secretary of State filing, the company lists “**JON@OpenLoopHealth.com**” as its contact email.²³ Moreover, Yejoon Chung appears as an officer in at least four state filings and, in the company’s Connecticut Secretary of State filing, lists the email “**YEJOON@OpenLoopHealth.com.**” Jon Lensing and Yejoon Chung also served as officers of a now-inactive entity, Apollo Technologies, Inc.²⁴

17. Upon information and belief, Defendant OpenLoop Health Inc., is responsible for the operation and management of OpenLoop Healthcare Partners, P.C., including, among other things, staffing, payroll, and diagnostic policies and procedures. *See, e.g.,* OpenLoop, *Clinician Job Board*, <https://clinician.openloophealth.com/job-board/> (Job postings for nurses and physicians appear on the OpenLoop Health, Inc. website); OpenLoop, *Remote Nurse Practitioner – Telehealth (Part-Time)*, <https://clinician.openloophealth.com/jobs/remote-nurse-practitioner-telehealth-part-time/> (describing compensation for medical-weight-loss consults,

²⁰ IA File No. 650332.

²¹ DE File No. 6291757.

²² NE File No. 2105196250.

²³ MS File No. 1261367.

²⁴ *See* GA File No. 21256355.

including synchronous and asynchronous visit rates); OpenLoop, *HRT/TRT Telemedicine Provider*, <https://clinician.openloophealth.com/jobs/hrt-trt-telemedicine-provider/> (stating that providers are “responsible for diagnostic and therapeutic decision-making within ... organization policies and procedures.”); OpenLoop, *Telemedicine RN (Full-Time)*, <https://clinician.openloophealth.com/jobs/telemedicine-rn-full-time/> (position responsibilities include meeting “productivity targets and quality standards established by the organization.”).

18. To receive “oral tirzepatide” a customer must get a prescription from a licensed physician or clinician. Thus, entities, including OpenLoop Healthcare Partners, P.C., and their staff, are the means by which such prescriptions are given to Plaintiff and members of the Class, and then are fulfilled by the Participating Pharmacies, including Triad Rx.

C. The Consumer Facing Websites and Brands

19. Each of the following are companies and/or branding that operate as a consumer-facing telehealth storefront that markets and sells oral tirzepatide, and expressly identifies that it is associated with Defendants.

20. **MEDVi, LLC d/b/a MEDVi** was incorporated in Delaware on April 4, 2024.²⁵ Aside from its registered agent address,²⁶ there is no publicly available information regarding its ownership or management. In *Siuksta v. MEDVi, LLC*, No. 25-cv-22185 (S.D. Fla. May 13, 2025), MEDVi was served but failed to appear. The company purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.²⁷ MEDVi has a designated

²⁵ DE File No. 3393894.

²⁶ 131 Continental Dr, Suite 305, Newark, DE 19713.

²⁷ *MEDVi*, <https://medvi.org/> (last visited Nov. 19, 2025).

OpenLoop patient waiting room,²⁸ and a disclaimer at the bottom of its homepage lists OpenLoop as its medical service provider.²⁹

21. **Agile Telehealth Services, LLC d/b/a Agile Telehealth** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.³⁰ Upon information and belief, Agile Telehealth was incorporated in Delaware.³¹ Agile Telehealth has a designated OpenLoop patient waiting room.³² Its website's terms of use identify Triad Rx as a "partner pharmacy,"³³ and its Telehealth Consent Form is, in fact, OpenLoop's own document—bearing OpenLoop's name in the header and referring to OpenLoop throughout.³⁴ Further, an Agile Telehealth consumer publicly identified Triad Rx as the source of their oral tirzepatide.³⁵

22. **Diddly Health LLC d/b/a Diddly Health** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.³⁶ Upon information and belief, Diddly Health was incorporated in Texas.³⁷ Diddly Health has a designated OpenLoop patient waiting

²⁸ <https://openloophealth.doxy.me/medvi>

²⁹ *MEDVi*, <https://medvi.org/> (last visited Nov. 19, 2025).

³⁰ *Weight Loss*, Agile Telehealth, <https://agiletelehealth.com/weight-loss/> (last visited Nov. 12, 2025).

³¹ DE File No. 3103790.

³² <https://openloophealth.doxy.me/agilewm>

³³ *Terms of Use*, Agile Telehealth, <https://agiletelehealth.com/terms-of-use/> (last visited Nov. 12, 2025).

³⁴ *See Telehealth Consent*, Agile Telehealth, <https://agiletelehealth.com/telehealth-consent/> (last visited Nov. 12, 2025).

³⁵ *See* post by *masseffectionate*, Reddit

https://www.reddit.com/r/tirzepatidecompound/comments/1h1gjex/just_fyi_the_sublingual_tirz_works/ (last visited Nov. 12, 2025).

³⁶ *See Tirzepatide*, Diddly Health, <https://diddlyhealth.com/tirzepatide/> (last visited Nov. 12, 2025).

³⁷ TX File No. 0805775812.

room.³⁸ Its website’s terms of use identify Triad Rx as a “partner pharmacy,”³⁹ and mirror OpenLoop’s in all material respects except for their names.⁴⁰

23. [Intentionally omitted].

24. **Thrive Health Group Inc. d/b/a Fridays** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁴⁴ Upon information and belief, Fridays was incorporated in California.⁴⁵ Fridays has a designated OpenLoop patient waiting room.⁴⁶ Its website’s terms of use identify Triad Rx as a “partner pharmacy.”⁴⁷

25. **FuturHealth Inc., d/b/a FuturHealth** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁴⁸ Upon information and belief, FuturHealth was incorporated in Delaware.⁴⁹ FuturHealth has a designated OpenLoop patient waiting room.⁵⁰ Its

³⁸ <https://openloophealth.doxy.me/diddlyhealth>.

³⁹ *Terms of Use*, Diddly Health, <https://diddlyhealth.com/terms-of-use/> (last visited Nov. 12, 2025).

⁴⁰ *See Terms of Use*, OpenLoop <https://openloophealth.com/terms-of-use> (last visited Nov. 12, 2025).

⁴¹ [Intentionally omitted].

⁴² [Intentionally omitted].

⁴³ [Intentionally omitted].

⁴⁴ *Microdose Tirzepatide*, Fridays, <https://www.joinfridays.com/products/sleep-support> (last visited Nov. 17, 2025).

⁴⁵ CA File No. 5498080.

⁴⁶ <https://openloophealth.doxy.me/fridayswm>.

⁴⁷ *Terms of Use*, Friday’s Health, <https://www.joinfridays.com/terms-conditions> (last visited Nov. 12, 2025).

⁴⁸ *Tirzepatide*, FuturHealth, <https://futurhealth.com/medication-tirzepatide/> (last visited Nov. 12, 2025).

⁴⁹ DE File No. 2554469.

⁵⁰ <https://openloophealth.doxy.me/futur>

website's terms of use identify OpenLoop as a partner "Medical Group."⁵¹ Further, a FuturHealth consumer publicly identified Triad Rx as the source of their oral tirzepatide.⁵²

26. **AI Coaching Inc., d/b/a Gala GLP-1** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁵³ Upon information and belief, Gala GLP-1 was incorporated in Delaware.⁵⁴ Gala GLP-1 has a designated OpenLoop patient waiting room.⁵⁵

27. **EverOne Health, Inc. d/b/a Remmy** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁵⁶ Upon information and belief, Remmy was incorporated in Delaware.⁵⁷ Remmy has a designated OpenLoop patient waiting room.⁵⁸

28. **24HrDoc Medical Group, P.A. d/b/a 24HrDoc** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁵⁹ Upon information and belief, 24HrDoc was incorporated in Delaware.⁶⁰ 24HrDoc has a designated OpenLoop patient waiting room.⁶¹

29. **Plus EV Holdings Inc. d/b/a Intimate Rose** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁶² Upon information and belief, Intimate

⁵¹ *Terms of Use*, FuturHealth, <https://landing.fh.co/terms/> (last visited Nov. 12, 2025).

⁵² See post by *Organic-Wear-573*, Reddit https://www.reddit.com/r/glp1/comments/1m01erl/warning_about_futurhealth_and_glp1s/ (last visited Nov. 12, 2025).

⁵³ *Gala GLP-1*, <https://galaglp1.com/> (last visited Nov. 12, 2025).

⁵⁴ DE File No. 2705359.

⁵⁵ <https://openloophealth.doxy.me/galaglp1>

⁵⁶ *Remmy*, <https://www.heyremmy.com/> (last visited Nov. 12, 2025).

⁵⁷ DE File No. 10028484.

⁵⁸ <https://openloophealth.doxy.me/heyremmy>

⁵⁹ *Oral Tirzepatide*, 24HrDoc, <https://www.24hrdoc.com/weight-loss/oral-tirzepatide> (last visited Nov. 11, 2025).

⁶⁰ DE File No. 10247040.

⁶¹ <https://openloophealth.doxy.me/24hrdoc>

⁶² *Weight Loss Treatment*, Intimate Rose, <https://www.intimaterose.com/pages/weight-loss-treatment-online> (last visited Nov. 12, 2025).

Rose was incorporated in Missouri.⁶³ Intimate Rose has a designated OpenLoop patient waiting room.⁶⁴ Its website's terms of use identify Triad Rx as a "partner pharmacy."⁶⁵ Furthermore, on September 9, 2025, Intimate Rose received an FDA Warning Letter concerning the "Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet" regarding its compounded tirzepatide products.⁶⁶

30. **Lovely Meds Inc. d/b/a Lovely Meds** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁶⁷ Upon information and belief, Lovely Meds was incorporated in Delaware.⁶⁸ Lovely Meds has a designated OpenLoop patient waiting room.⁶⁹ Furthermore, on September 9, 2025, Lovely Meds received an FDA Warning Letter concerning the "Unlawful Sale of Unapproved and Misbranded Drugs to United States Consumers Over the Internet" regarding its compounded tirzepatide products.⁷⁰

31. **MyStart Health LLC d/b/a MyStart Health** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁷¹ Upon information and belief, MyStart Health was incorporated in Delaware.⁷² MyStart Health has a designated OpenLoop

⁶³ MO Charter No. 01197211.

⁶⁴ <https://openloophealth.doxy.me/intimaterose>

⁶⁵ *Terms of Use*, Intimate Rose, <https://www.intimaterose.com/pages/useful-information> (last visited Nov. 12, 2025).

⁶⁶ *See Intimate Rose*, FDA Warning Letter (Sept. 9, 2025), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/intimate-rose-09092025> (last visited Nov. 12, 2025).

⁶⁷ *Oral Tirzepatide*, Lovely Meds, <https://www.lovelymeds.com/online-clinic/weight-loss/oral-tirzepatide> (last visited Nov. 11, 2025).

⁶⁸ DE File No. 4849899

⁶⁹ <https://openloophealth.doxy.me/LovelyMeds>

⁷⁰ *See Lovely Meds*, FDA Warning Letter (Sept. 9, 2025), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lovely-meds-inc-dba-lovely-meds-09092025> (last visited Nov. 12, 2025).

⁷¹ *MyStart Health*, <https://www.mystarhealth.com/> (last visited Nov. 12, 2025).

⁷² DE File No. 3722688.

patient waiting room.⁷³ Further, a MyStart Health consumer publicly identified Triad Rx as the source of their oral GLP-1 medication.⁷⁴

32. **Better Life Health, Inc. d/b/a Prime Health d/b/a Remedy Meds LLC d/b/a Remedy Meds** purportedly operates as a consumer-facing telehealth storefront marketing oral tirzepatide.⁷⁵ Upon information and belief, Remedy Meds was incorporated in Delaware.⁷⁶ Remedy Meds has a designated OpenLoop patient waiting room.⁷⁷ Its website's terms of use identify OpenLoop as a partner "Medical Group."⁷⁸ Further, a Remedy Meds consumer publicly identified Triad Rx as the source of their oral tirzepatide.⁷⁹

⁷³ <https://openloophealth.doxy.me/mystarthealth>

⁷⁴ See comment by *Moo58*, Reddit

https://www.reddit.com/r/SemaglutideFreeSpeech/comments/1kewsz/no_weight_loss_after_5_weeks/ (comment deleted as of Nov. 11, 2025). Archived version available at https://www.redddit.com/v/SemaglutideFreeSpeech/comments/1kewsz/no_weight_loss_after_5_weeks/ (last visited Nov. 12, 2025).

⁷⁵ *Compounded Tirzepatide (Oral Tablet)*, Remedy Meds, <https://remedymeds.com/medication/comp-tirz-odt> (last visited Nov. 12, 2025). See also *Prime Health*, <https://joinprimehealth.com/> (last visited Nov. 12, 2025).

⁷⁶ DE File No. 10027804.

⁷⁷ <https://openloophealth.doxy.me/remedymeds>. See also <https://openloophealth.doxy.me/primehealth>.

⁷⁸ *Terms of Use*, Remedy Meds, <https://remedymeds.com/remedymeds/documents/terms-of-service.pdf> (last visited Nov. 12, 2025). See also *Terms of Use*, Prime Health, <https://joinprimehealth.com/primehealth/documents/terms-of-service.pdf> (last visited Nov. 12, 2025).

⁷⁹ See comment by *FitnessPizzaInMyMou*, Reddit

https://www.reddit.com/r/tirzepatidecompound/comments/1h1gjex/just_fyi_the_sublingual_tirz_works/ (last visited Nov. 12, 2025).

JURISDICTION AND VENUE

33. Plaintiff brings this action pursuant to RICO, 18 U.S.C. § 1964(c), which confers jurisdiction upon this Court over the subject matter of this action. The Court also has jurisdiction over the subject matter pursuant to 28 U.S.C. § 1331 in that this action arises under the laws of the United States.

34. The Court has original jurisdiction under 28 U.S.C. § 1332(d)(2) because the matter in controversy, exclusive of interests and costs, exceeds the sum or value of \$5,000,000 and is a class action in which there are in excess of 100 class members, at least one of the class members is a citizen of a state different from at least one of the Defendants. This Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over Plaintiff's state law claims because those claims are so related to the federal claims that they form part of the same case or controversy.

35. This Court may properly exercise personal jurisdiction over Defendants because OpenLoop Health Inc. and Triad Rx Buyer LLC are incorporated in the State of Delaware, Triad Rx Inc. purposefully availed itself of this jurisdiction by obtaining pharmacy licensure with the State of Delaware, and all Defendants conduct substantial, continuous, and systematic business within the state. Defendants also transact business nationwide, including in Delaware, through their operation of telehealth platforms and mail-order prescription services that solicit, process, and fulfill orders from consumers residing in Delaware and throughout the United States. The wrongful conduct alleged herein was directed, in part, from or through Delaware and caused harm to consumers located within this District.

36. Venue is proper in this forum pursuant to U.S.C. § 1391(b) because a substantial part of the events and omissions giving rise to the claims alleged herein occurred in this District

and Defendants transact business within this District and are subject to personal and general jurisdiction within this District.

FACTUAL ALLEGATIONS

A. Defendants' "Oral Tirzepatide" is Snake Oil

1. *Injectable GLP-1 Drugs*

37. Obesity and being overweight are among the fastest growing and most prevalent chronic conditions humans face, affecting approximately 2.5 billion people worldwide and leading to a broad range of severe diseases.

38. Glucagon-like peptide-1 receptor agonists ("GLP-1RAs" or "GLP-1 drugs") manage blood sugar levels to treat obesity and type 2 diabetes. GLP-1 drugs mimic the naturally occurring hormone GLP-1, which enhances insulin secretion, suppresses glucagon release, slows gastric emptying, and increases satiety. These effects promote glucose control and weight loss. GLP-1 drugs are distinct from other therapies for obesity and type 2 diabetes because they act through two complementary mechanisms: metabolic control and appetite suppression. Other drugs generally work by stimulating one or the other. This unique formulation of GLP-1 drugs leads them to have superior efficacy and comparably better side effect profiles than alternatives.

39. GLP-1RAs have traditionally been administered by **subcutaneous injection** due to their chemical composition as large peptide molecules—typically exceeding 4,000 Daltons in molecular weight—which renders them susceptible to enzymatic degradation and poor gastrointestinal absorption when taken orally.

2. *Barriers to Developing Alternatives to Injectable Forms of GLP-1 Drugs*

40. Certainly, people often prefer a pill over an injectable, the former being (or at least being perceived as): less-invasive, more convenient and easy to take, and eliminates issues

for those with needle aversion. Undoubtedly, there would be substantial demand for an oral tirzepatide. Accordingly, since the discovery of GLP-1 Drugs, researchers and drug companies have sought to develop non-injectable alternatives for the delivery of GLP-1 Drugs.

41. However, to date, efforts to develop oral delivery systems for tirzepatide have repeatedly failed. “The oral administration of peptides is not a new concept, and the challenges faced are best illustrated by considering the failure to date to produce a marketable oral formulation of insulin since its discovery in 1921.”⁸⁰ Early oral formulations aimed at buccal absorption were unsuccessful because of “the relatively thick mucosal barrier and continuous flow of saliva.”⁸¹ Attempts to deliver GLP-1 through inhalation achieved rapid plasma concentrations but raised safety and dosing concerns because GLP-1 receptors are “abundantly expressed in pulmonary tissue.”⁸²

42. The barriers to date of developing an effective oral peptide delivery are known and replete:

- a. “[T]here are important differences between oral administration and subcutaneous administrations. As a result of the different ways injectable and oral medications interact with the human body, the rate of absorption and bioavailability of those drugs (especially over time) necessarily varies. This often causes the [active pharmaceutical ingredient] API to behave differently once it enters the body, which can ‘influence drug effectiveness and safety’ as well as ‘the onset, intensity,

⁸⁰ Aroda, Blonde & Pratley, *A New Era for Oral Peptides: SNAC and the Development of Oral Semaglutide*, 23 Rev. Endocr. Metab. Disord. 979, 982 (2022) (<https://pubmed.ncbi.nlm.nih.gov/35838946/>).

⁸¹ Choe HJ, Cho YM. *Peptidyl and Non-Peptidyl Oral Glucagon-Like Peptide-1 Receptor Agonists*. 36 Endocrinol. Metab. 22-29, 23 (2021) (<https://doi.org/10.3803/EnM.2021.102>).

⁸² *Id.*

and sometimes the duration of action.” *Eli Lilly v. Willow Health Services, Inc.*, 25-cv-3570 (C.D. Cal.), Compl. ¶ 97.

- b. The human digestive system is designed to break down proteins into smaller components. Peptides, which are short chains of amino acids, are subject to the same process. When taken orally, peptides are rapidly degraded by digestive enzymes—beginning with those present in saliva—long before they can reach the bloodstream.⁸³
 - c. Oral administration of peptide-based drugs results in “low bioavailability owing to poor absorption coupled with rapid degradation by proteolytic enzymes.”⁸⁴
 - d. “Several barriers must be overcome when developing orally administered peptides with a molecular weight above 1,000 Da.”⁸⁵
 - e. These barriers—enzymatic degradation, low permeability of the GI wall, and variable absorption—have historically prevented oral delivery of peptides such as insulin, despite a century of research.⁸⁶
43. In 2019, the FDA did approve *Rybelsus*, which was an oral *semaglutide*,⁸⁷ the first and only orally administered GLP-1RA approved by the FDA to date. Oral *semaglutide* was developed by co-formulating semaglutide with sodium N-(8-[2-hydroxybenzoyl]amino) caprylate (“SNAC”), an absorption enhancer that enables gastric uptake of the peptide:

⁸³ Jastreboff & Kushner, *New Frontiers in Obesity Treatment: GLP-1 and Nascent Nutrient-Stimulated Hormone-Based Therapeutics*, 74 Ann. Rev. Med. 125, 132 (2023) (<https://pubmed.ncbi.nlm.nih.gov/36706749/>).

⁸⁴ *Id.*

⁸⁵ Aroda, et al., *supra* n. 80.

⁸⁶ *Id.*

⁸⁷ Tirzepatide is a dual GIP/GLP-1 receptor agonist that targets two incretin pathways simultaneously, while semaglutide is a pure GLP-1 receptor agonist that acts on only one.

- a. “Coformulating semaglutide with SNAC facilitates transcellular absorption through the gastric membrane and helps prevent degradation of semaglutide in the stomach.”⁸⁸
 - b. SNAC “acts as a local pH buffer for semaglutide, increasing solubility and protecting the drug from degradation,” while also “increasing lipophilicity and transcellular absorption of semaglutide through the stomach epithelium.”⁸⁹
 - c. Acting locally in the stomach, SNAC buffers gastric acidity, prevents proteolytic degradation, and temporarily increases gastric membrane permeability to allow direct absorption of semaglutide into systemic circulation.⁹⁰
44. “Oral semaglutide must be co-formulated with the absorption enhancer SNAC in order to be absorbed.”⁹¹ Yet, even with SNAC, oral semaglutide’s absolute bioavailability is approximately one percent, requiring administration under tightly controlled conditions, *i.e.* on an empty stomach, with a small amount of water, and no food or drink for at least thirty minutes afterward.⁹²
45. The development of Rybelsus and its use of SNAC underscores the exceptional difficulty of formulating effective oral peptide therapies. Without a comparable absorption enhancer or pH-modifying agent, oral formulations of GLP-1 drugs—including compounded

⁸⁸ Jastreboff & Kushner, *supra* n. 83.

⁸⁹ Choe & Cho, *supra* n. 81.

⁹⁰ Aroda et al., *supra* n. 80.

⁹¹ Andersen, Knop & Vilsbøll, *A Pharmacological and Clinical Overview of Oral Semaglutide for the Treatment of Type 2 Diabetes*, 81 *Drugs* 1003, 1007 (2021) (<https://pubmed.ncbi.nlm.nih.gov/33964002/>).

⁹² See FDA, *Clinical Pharmacology Review for Rybelsus (oral Semaglutide)*, NDA 213051 (2019)

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213051Orig1s000ClinPharmR.pdf.

versions—lack any demonstrated mechanism to prevent degradation or promote gastric absorption.

46. The need for an absorption enhancer is especially significant for tirzepatide. The molecular weight of semaglutide is approximately 4,114 Da, while tirzepatide's molecular weight is approximately 4,813 Da. Moreover, tirzepatide and semaglutide are fundamentally different molecules despite both being used to treat metabolic conditions. Semaglutide is a single-pathway GLP-1 receptor agonist, a modified version of the native GLP-1 hormone designed to activate one incretin receptor and slow gastric emptying, reduce appetite, and improve glycemic control.⁹³ Tirzepatide, by contrast, is a dual-agonist peptide engineered to activate both the GLP-1 and GIP receptors simultaneously, producing a broader and more potent hormonal effect.⁹⁴ Their amino-acid sequences, structural modifications, and receptor-binding profiles differ in ways that meaningfully alter how each drug is absorbed, stabilized, and cleared. Semaglutide's chemistry allowed the development of a specialized oral formulation using the SNAC platform, which was optimized exclusively for semaglutide's stability, solubility, and dose requirements. Tirzepatide does not share these formulation properties, and its dual-receptor potency makes uncontrolled oral absorption both unreliable and potentially unsafe. As a result, the technological pathway that enabled oral semaglutide does not translate to tirzepatide, and no FDA-approved method exists to deliver tirzepatide orally in a safe, effective, or predictable manner.

47. Given these molecular characteristics, the absence of an absorption enhancer comparable to SNAC precludes meaningful gastrointestinal absorption of either molecule. Given

⁹³ *See id.*

⁹⁴ *See FDA, Clinical Pharmacology Review for Tirzepatide (Mounjaro), NDA 215866 (2021)* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215866Orig1s000ClinPharmR.pdf.

tirzepatide’s molecular size, structure, and enzymatic vulnerability, effective oral delivery without a permeation enhancer is pharmacologically impossible.

48. OpenLoop’s ostensible competitors likewise acknowledge—and even openly disclose—that oral tirzepatide is not scientifically feasible. Roman Health Ventures Inc. (“Ro”), a major direct-to-consumer telehealth platform with its own provider and pharmacy network,⁹⁵ published an article titled “*Oral tirzepatide: is there a pill version of Zepbound or Mounjaro?*” The article opens unequivocally with the following statement: “**Currently, oral tirzepatide does not exist.**” It explains that “tirzepatide is a synthetic peptide that is rapidly degraded by digestive enzymes within the gastrointestinal tract,” such that “too little of it would remain in your system to be effective.” The article further notes that “while researchers have found ways for other GLP-1s, such as semaglutide, to be effective in an oral form, they haven’t been able to do the same for tirzepatide,” and concludes that “[u]nlike oral semaglutide, tirzepatide’s larger molecular size and chemical modifications currently pose significant challenges for the development of an effective oral formulation.”⁹⁶

49. **At bottom, no compounded or non-absorption enhancer oral formulation of tirzepatide has yet to be shown in any peer-reviewed study to achieve any measurable systemic bioavailability or therapeutic effect.** *See Eli Lilly & Co. v. Adonis Health, Inc.*, No. 25-cv-03536-JST (N.D. Cal.), Compl. ¶¶ 5, 29 (“No clinical study suggests tirzepatide taken orally is safe and effective.” “FDA has not approved, and Lilly does not sell, any tirzepatide product in oral form.”).

⁹⁵ *See Terms of Use*, Ro, <https://ro.co/terms-of-use/> (last visited Nov. 14, 2025).

⁹⁶ Ro, *Oral tirzepatide: is there a pill version of Zepbound or Mounjaro?*, <https://ro.co/weight-loss/oral-tirzepatide/> (last visited Nov 14, 2025).

3. *Drug Companies' Current Investments to Develop Oral Delivery of GLP-1 Drugs*

50. The ongoing efforts and competition among major pharmaceutical companies to develop a safe and effective oral GLP-1 medication underscores the scientific and technological challenges, as well as the financial investment, in doing so.

51. Metsera, Inc. is as “an early clinical-stage biotechnology company that seeks to develop next-generation injectable and oral solutions for obesity and related conditions. It commenced operations in June 2022, has no approved products for commercial sale, and has not generated product revenue.” *Pfizer Inc. v. Metsera, Inc.*, No. 2025-1259-MTZ, Entry BL-33 (Del. Ch. Nov. 3, 2025). In September 2025, Pfizer entered into a definitive agreement to acquire Metsera for up to \$7.3 billion. Novo Nordisk, however, sought to derail Pfizer’s \$7.3 billion acquisition by making a \$9 billion bid for Metsera. The bidding war between the conglomerates concluded November 13, 2025, with Metsera’s acceptance of Pfizer’s final deal valued up to **\$10 billion**.

52. Metsera’s publicly available materials describe its main pipeline candidates, MET-224o and MET-097o, as ultra-long-acting oral GLP-1 receptor agonist peptides designed to achieve “injectable-like performance.” These compounds use Metsera’s proprietary MOMENTUM oral peptide delivery platform to improve bioavailability and are still in early-stage clinical testing.

53. The fact that two of the world’s largest pharmaceutical companies were engaged in multi-billion-dollar transactions and antitrust litigation over the rights to develop a potentially viable oral GLP-1 medication reflects the extraordinary difficulty of achieving such a formulation. These events also portend that once such an oral delivery agent is ever developed, it will be proprietary and the subject of intellectual property protection, underscoring the complete

absence of efficacy of the snake oil being manufactured and sold by Defendants and their cohorts.

54. Also, Eli Lilly and Co. is developing *Orforglipron*, an investigational, once-daily oral GLP-1RA being studied for type 2 diabetes and obesity. Orforglipron **remains under clinical investigation and is not approved for commercial use**. According to Eli Lilly, the drug “is designed to help lower blood sugar and support weight loss,” and preliminary trial data have been positive, with additional results expected in the first quarter of 2026. **Eli Lilly’s need to develop a new molecule for oral administration confirms what the science already makes clear: if tirzepatide could simply be placed in a pill and taken orally, there would be no reason for Lilly to pursue Orforglipron at all.**

55. The collective efforts of Pfizer, Novo Nordisk, Eli Lilly, and Metsera demonstrate that oral GLP-1 delivery is a frontier problem requiring novel chemistry and specialized delivery systems. Put simply, such a result cannot be achieved merely by placing the active ingredient together with inert supplements and pressing it into tablets—as Defendants did—a fact universally reflected in the scientific literature and in the billions invested by legitimate manufacturers.

56. In addition to lacking any demonstrated efficacy, the safety of Defendants’ oral tirzepatide product is entirely unknown. Defendants’ “oral tirzepatide” has never undergone FDA review, clinical testing, or any evaluation necessary to determine whether ingesting it poses acute or long-term health risks. By manufacturing, marketing, and selling an untested, unapproved peptide compound for ingestion, Defendants—through their reckless and conspiratorial conduct—expose consumers to physiological unknowns. These are precisely the risks that

established regulatory safeguards exist to prevent, and Defendants’ decision to bypass them endangers consumers and underscores the unlawful nature of their scheme.

57. As repeatedly recognized by Eli Lilly and Co., the patent holder for tirzepatide (marketed as Mounjaro and Zepbound), “[n]o clinical study demonstrates that **any** oral formulation of tirzepatide is safe and effective for human use.” *Eli Lilly v. Willow Health Services, Inc.*, 25-cv-3570 (C.D. Cal.), Compl. ¶ 93. *See also Eli Lilly v. AIOS Inc.*, 25-cv-03535 (N.D. Cal.), Compl. ¶¶ 5, 98, 99 (“Lilly’s clinical trials did not evaluate oral tirzepatide.” “Lilly’s studies did not assess the effectiveness of any oral tirzepatide...” “[Defendant] has no basis to claim that its oral tirzepatide will have any impact on ... any weight loss—since [Defendant] has no evidence that **any** of the purported tirzepatide in its tablets will reach the bloodstream.”); *Eli Lilly & Co. v. Adonis Health, Inc.*, No. 25-cv-03536-JST (N.D. Cal.), Compl. ¶¶ 5, 29 (“No clinical study suggests tirzepatide taken orally is safe and effective.” “FDA has not approved, and Lilly does not sell, any tirzepatide product in oral form.”); *Eli Lilly v. Empower Clinic Services, LLC*, 25-cv-02183 (D. N.J.), Compl. ¶ 2 (“Lilly’s tirzepatide medicines are tested and approved for under-the-skin injections only—not in any oral form.”); *Eli Lilly v. Willow Health Services, Inc.*, 25-cv-3570 (C.D. Cal.), Compl. ¶ 98 (“Lilly’s clinical testing ... studies have no relevance to an oral drop.”).

B. Defendants Are Fraudulently Marketing, Producing, and Selling “Oral Tirzepatide”

58. Despite the fact that it is snake oil, Defendants have embarked on a scheme to sell “oral tirzepatide” to thousands of deceived, unsuspecting consumers.

59. OpenLoop is a telehealth service provider. According to its marketing materials, OpenLoop purportedly “partners with leading medical weight loss programs across the U.S.” to

provide provider networks and pharmacy fulfillment for compounded and branded GLP-1 medications.⁹⁷

60. CEO Jon Lensing describes OpenLoop as “a leading operating system for telehealth nationwide.” On LinkedIn, he states that “OpenLoop operates in all 50 states and serves as the operating system of digital health for 100+ organizations nationwide.”⁹⁸

61. In an October 8, 2025, interview with CNBC, titled “OpenLoop Health CEO on AI’s operations in the healthcare industry,” Lensing described the company as “the operating system for next gen health,” explaining:

“People want convenient healthcare, so OpenLoop is focused on taking non-healthcare companies and turning them into healthcare delivery centers overnight. Think about getting sexual and reproductive healthcare through a dating app, or getting urgent care through a grocery store chain or *weight management through a gym*; **OpenLoop enables all of these companies to turn themselves into healthcare companies overnight.**”⁹⁹

62. OpenLoop’s “partners”, “non-healthcare companies” and “100+ organizations nationwide” consist of the Consumer Facing Websites and Brands, like MEDVi and the numerous other GLP-1 marketing websites that offer “oral tirzepatide” identified above.

63. OpenLoop’s own marketing materials confirm that it provides the operational infrastructure and staffing that enables the proliferation of these interchangeable shell-site “brands.” In a white paper published on its website titled *The Guide to Marketing Your*

⁹⁷ *Medical Weight Loss*, OpenLoop Health, <https://openloophealth.com/companies/medical-weight-loss> (last visited Nov. 11, 2025).

⁹⁸ *Jon Lensing*, LinkedIn (<https://www.linkedin.com/in/jon-lensing/>) (last visited Nov. 11, 2025).

⁹⁹ *OpenLoop Health CEO on AI’s operations in the healthcare industry*, CNBC (Oct. 8, 2025), <https://www.cnbc.com/video/2025/10/08/openloop-health-ceo-on-ais-operations-in-the-healthcare-industry.html>.

Telehealth Business,¹⁰⁰ OpenLoop advertises that it supplies the full infrastructure necessary to launch consumer-facing telehealth storefronts. The publication includes suggested landing-page layouts, step-by-step marketing strategies, and a turnkey white-label model designed to allow any entity to present itself as a fully operational telehealth provider. As OpenLoop states: “OpenLoop is more than a digital health solutions provider—we’re a partner...” “[o]ur team has helped launch and scale digital health offerings across 50 states,” and “You Manage Your Brand — OpenLoop Handles All The Operational Headaches.” It further promises that “whether you’re looking to launch a new service, streamline operations, or maximize every marketing dollar, OpenLoop’s proven white-label frameworks, regulatory expertise, and end-to-end support make us the go-to choice for organizations that want to lead—not just compete—in digital health.” OpenLoop concludes by urging would-be “brands” to “picture it—access to nationwide providers and payers with no additional operational lift.”

64. OpenLoop’s accompanying blog materials make the point even more explicitly. In an article titled *How To Start a Telehealth Business*, OpenLoop tells prospective operators: “reach out to OpenLoop, and we can set up and maintain your entire back-end operations ... You bring the patients, we handle everything else.”¹⁰¹

65. Caused by and due to OpenLoop, dozens of websites have appeared online, and have been actively marketing, selling and supplying oral tirzepatide directly to consumers.

¹⁰⁰ OpenLoop, *The Guide to Marketing Your Telehealth Business*, https://assets.ctfassets.net/7b49qn4tvor3/6IbKts7qfpYjK29O6HWIA4/1497b82d038c9c463813c2160e871914/The_Guide_to_Telehealth_Marketing_1_.pdf (last visited Nov. 18, 2025).

¹⁰¹ OpenLoop, *How to Start a Telehealth Business*, Blog (Feb. 20, 2025), https://openloophealth.com/blog/how-to-start-a-telehealth-business?utm_source=whitepaper&utm_medium=pdf&utm_campaign=demand_gen&utm_content=telehealth_marketing_guide&utm_term=openloop (last visited Nov. 18, 2025).

1. The Websites Are Substantially Similar

66. Although operating under different names—such as “MEDVi,”¹⁰² “HeyFeels,”¹⁰³ “24HrDoc,”¹⁰⁴ “Diddly Health,”¹⁰⁵ “Fridays,”¹⁰⁶ “Gala GLP-1,”¹⁰⁷ “Remmy,”¹⁰⁸ “Intimate Rose,”¹⁰⁹ “Lovely Meds,”¹¹⁰ “MyStart Health,”¹¹¹ “Remedy Meds,”¹¹² and “GLIP1,”¹¹³ among others—these sites are substantially similar to one another.

MyStart Health



Gala GLP-1



Fridays



¹⁰² MEDVi, <https://medvi.org/> (last visited Nov. 19, 2025).

¹⁰³ HeyFeels, <https://www.heyfeels.com/> (last visited Nov. 18, 2025).

¹⁰⁴ 24HrDoc, <https://www.24hrdoc.com/weight-loss/oral-tirzepatide> (last visited Nov. 18, 2025).

¹⁰⁵ Diddly Health, <https://diddlyhealth.com/tirzepatide/> (last visited Nov. 18, 2025).

¹⁰⁶ Friday's Health, <https://www.joinfridays.com/products/metabolic-support> (last visited Nov. 18, 2025).

¹⁰⁷ Gala GLP-1, <https://galaglp1.com/> (last visited Nov. 18, 2025).

¹⁰⁸ Remmy, <https://www.heyremmy.com/> (last visited Nov. 18, 2025).

¹⁰⁹ Intimate Rose, <https://www.intimaterose.com/pages/weight-loss-treatment-online> (last visited Nov. 18, 2025).

¹¹⁰ Lovely Meds, <https://www.lovelymeds.com/online-clinic/weight-loss/oral-tirzepatide> (last visited Nov. 18, 2025).

¹¹¹ MyStart Health, <https://www.mystarthealth.com/> (last visited Nov. 18, 2025).

¹¹² Remedy Meds, <https://remedymeds.com/medication/comp-tirz-odt> (last visited Nov. 18, 2025).

¹¹³ GLIP1, <https://www.glip1.com/> (last visited Nov. 18, 2025).

Remedy Meds



Diddly Health



Intimate Rose



Fridays

As seen on **Forbes HEALTH**
As seen on **WebMD**

In-Stock

Daily Oral

Tirzepatide Microdose – Metabolic Support

Oral tablets with GLP-1/GIP (contains Tirzepatide), Inositol

\$198

Buy now

Key Benefits
This microdosed GLP-1/GIP blend with inositol is designed to support blood sugar regulation and overall metabolic health – ideal for those with elevated A1C.

How It Works
Oral GLP-1/GIP – Metabolic Support is a daily capsule that uses microdosing to provide gentle support for appetite regulation and metabolic balance in an easy-to-take form.

Why It's Unique
It offers a non-injectable way to explore microdosing as part of everyday wellness.

The Fridays Difference
Fridays' Microdose line includes oral and injectable GLP-1/GIP blends designed to support focus, energy, sleep, and overall balance. Each option is developed with clinician oversight and delivered with convenience in mind—helping you integrate science-driven wellness into your daily routine without complexity.

FuturaHealth



Good choice! This is the fan favorite. Tirzepatide gets results.

● In-Stock | Last updated: 07/30/2025

✓ GLP-1 + GIP Pill



Starting at \$99/mo+

- On average, people on GLP-1 + GIP Pill medication lose 20% of their weight in a year*
- Free 2-day shipping, if prescribed
- Lab tested for quality to promote patient safety

24HrDoc

Get \$100 off your first month of weight loss!

24DOC All Conditions Sexual Health Weight Loss Refill Prescription More Sign Up



Oral Tirzepatide

You can now access cutting-edge diabetes and weight loss treatment in pill form—without leaving home.

- ⚡ Get your medication refill fast
- 🕒 Professional care available 24/7
- 📄 Prescription within 45 minutes

Get treatment online at just ~~999.99~~ \$239.99

Great ★★★★☆ 11,700 reviews on ★ Trustpilot



Excellent
4.3 out of 5
★ Trustpilot

MyStart Health

MyStart SAVE \$75 + Free Shipping Get started

ON SALE
Compounded Semaglutide
Rx Semaglutide
Generic Ozempic
● Available
Starting at \$297 \$222
Get started

Wegovy
Rx Semaglutide
● Supply Shortage
Starting at \$1600
Get started

Oral Semaglutide
Rx Semaglutide
● Available
Starting at \$297 \$222
Get started

Oral Tirzepatide
Rx Tirzepatide
● Available
Starting at \$449 \$374
Get started

Gala GLP-1

Gala Get Started

Doctor-trusted GLP-1 treatment

Get access to treatment options like custom medication kits and GLP-1s, if a provider determines they're right for you.

Start your free assessment

Ozempic® Limited quantity
Starting at \$1,299/mo
Important safety information
See supply information

Zepbound® Limited quantity
Starting at \$1,399/mo
Important safety information
See supply information

Compounded Semaglutide (Oral) In stock
Starting at \$299.75/mo
Important safety information
Learn more Get started

Compounded Tirzepatide (Oral) In stock
Starting at \$369.25/mo
Important safety information
Learn more Get started

Remmy

 <p><input checked="" type="checkbox"/> Compounded Personalized GLP-1 Tablets</p> <p>One dissolvable tablet per day</p> <p>See if I qualify</p>	 <p><input checked="" type="checkbox"/> FDA-Approved Zepbound®</p> <p>Prefilled injectable pen</p> <p>See if I qualify</p>
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Lovely Meds

Lovely Meds Weight Loss Performance L

What Is Oral Tirzepatide?

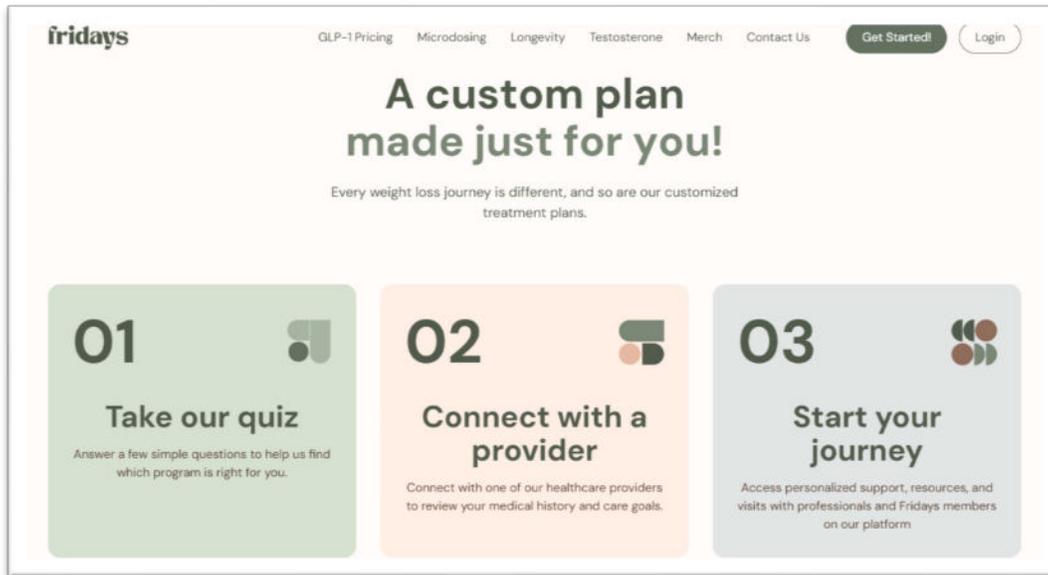
Oral Tirzepatide offers an innovative approach to weight management and metabolic health. As a dual receptor agonist, Tirzepatide targets both GLP-1 and GIP receptors, delivering superior benefits in appetite control, insulin sensitivity, and weight reduction.

Taken orally, it provides a needle-free option for those who prefer a convenient alternative to injections.

67. Each follows a similar layout and marketing script. Each displays (or has displayed) oral tirzepatide on its website. Each claims to offer affordable, science-backed, doctor-supervised GLP-1 weight-loss programs, and each directs consumers through the same three-step process: (1) complete a short questionnaire, (2) “meet” with a provider, and (3) receive medication shipped to their home.

<u>Remedy Meds</u>	<u>Lovely Meds</u>	<u>MEDVi</u>
<p>1 Activate Your Weight Loss Plan Instantly</p> <ul style="list-style-type: none"> ✓ Same-day start available ✓ Takes just 15 minutes 	<p>1 Answer a confidential online consultation in just 2 minutes</p> <p>Our free consultation allows you to provide your medical history conveniently, entirely online, without any hassle. No appointments or waiting rooms—simply answer a few questions about your health, and our licensed medical team will assess your needs quickly and securely.</p>	<p>Get Approved</p> <p>Complete a quick online evaluation to determine if GLP-1 medication is right for you. Our team of licensed professionals will review your information and provide approval in no time.</p> 
<p>2 Clinician Builds Your Program</p> <ul style="list-style-type: none"> ✓ Intake reviewed by a licensed clinician ✓ Personalized treatment plan created 	<p>2 Get a free prescription from a US-licensed clinician</p> <p>Our simple online process connects you with a qualified healthcare professional who will assess your suitability for the treatment and, if appropriate, provide a prescription.</p>	<p>Get Prescribed</p> <p>Once approved, you'll receive personalized care and a prescription to support your weight loss and health goals. Your care plan is designed to help you achieve lasting results safely and effectively.</p> 
<p>3 Medication Delivered Right to your Doorstep</p> <ul style="list-style-type: none"> ✓ Discreet, guaranteed delivery ✓ No pharmacy visits or waiting rooms 	<p>3 Start your journey</p> <p>We send your treatment in discreet packaging within 24-48 hours. Your journey doesn't stop there, enjoy ongoing support with <u>answers to all your queries</u>.</p>	<p>Receive your Rx</p> <p>Your medication will be shipped directly to your door for maximum convenience. With MEDVi, starting your treatment is as simple as opening your package and following our easy-to-use instructions.</p> 

Fridays



68. Many of these entities have no identifiable corporate officers, addresses, or professional licenses. Several appear to share hosting infrastructure, code templates, and stock photography.

2. *MEDVi's Website and Representations*

69. By way of example is the website www.medvi.org, operating under the name MEDVi.



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¹¹⁴ Screenshot posted in review by “Holly,” Buffalo, N.Y. (Aug. 18, 2025), available at https://www.consumeraffairs.com/health/medvi.html?page=3#sort=top_reviews&filter=1 (last visited Nov. 17, 2025).



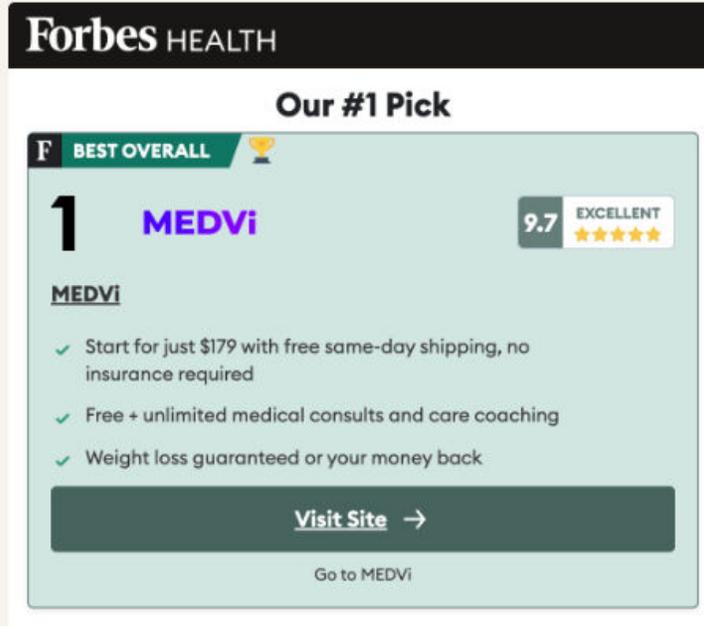
115

70. MEDVi’s homepage invites visitors with the headline: *“Finally serious about weight loss? So are we.”* Beneath it, a button labeled *“Get Started”* initiates the intake process. The page further proclaims:

- a. “Weight loss guaranteed or your money back”
- b. “Trusted by experts, priced for you”
- c. “Find the right GLP-1 medication with the confidence that comes from knowing it is doctor-approved and budget-friendly”
- d. “MEDVi is proud to be ranked #1 on Forbes and WebMD”

¹¹⁵ *Instagram Advertisement for MEDVi Compounded Oral Tirzepatide*, screenshot dated Nov. 19, 2025 (on file with counsel).

MEDVi is proud to be ranked #1 on Forbes and WebMD



Forbes HEALTH

Our #1 Pick

F BEST OVERALL 

1 **MEDVi** **9.7** EXCELLENT 

MEDVi

- ✓ Start for just \$179 with free same-day shipping, no insurance required
- ✓ Free + unlimited medical consults and care coaching
- ✓ Weight loss guaranteed or your money back

[Visit Site →](#)

Go to MEDVi

71. Throughout MEDVi.org, Defendants market their compounded GLP-1 pills, side by side with injectables, as *personalized, life-changing, and doctor-approved*. Images show bottles labeled “MEDVI GLP-1 Medication, Oral Dissolving Tablets” along with accompanying text emphasizing its effectiveness: e.g. “Highly effective and no needles!”, “You have a *very high* chance of success with MEDVi prescribed HLP-1 medication.” Likewise, Defendants market the ease and convenience of tirzepatide being taken as a pill (“Just a simple tablet once per day.”). Further, MEDVi.org states that their program is “Backed by Research From” the Mayo Clinic, Harvard, etc., which falsely represents oral tirzepatide’s safety and efficacy as “backed by research”, when it is not.

Our Recommendation

Based on your intake form, we recommend Tirzepatide dissolvable tablets. Highly effective and no needles! Just a simple tablet once per day.

Note: you can choose whichever medication you prefer, regardless of our recommendation!

You have a **very high** chance of success with MEDVi prescribed GLP-1 medication

94.6%
VERY HIGH

The advertisement features a central image of a clear plastic bottle of MEDVi Compounded Tirzepatide Oral Dissolving Tablets. The text is presented in a clean, sans-serif font on a light beige background. A small icon of the bottle is placed to the left of the success rate text.

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¹¹⁶ Screenshot taken Nov. 17, 2025, from MEDVi “Results” page, <https://medvi.org/results/approval-confirmation.php>.

Weight Loss Guarantee

If you do not lose weight by the end of your complete program, we give you all of your money back. It's that simple!

BACKED BY RESEARCH FROM

MAYO CLINIC Stanford MEDICINE WebMD

HARVARD UNIVERSITY NIH National Institutes of Health

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72. The site further places its oral tirzepatide product directly beside images of *Ozempic*—an FDA-approved injectable GLP-1 medication—creating the false impression that the compounded pills are therapeutically comparable.

Trusted by experts, priced for you.

Find the right GLP-1 medication with the confidence that comes from knowing it is doctor-approved and budget-friendly.

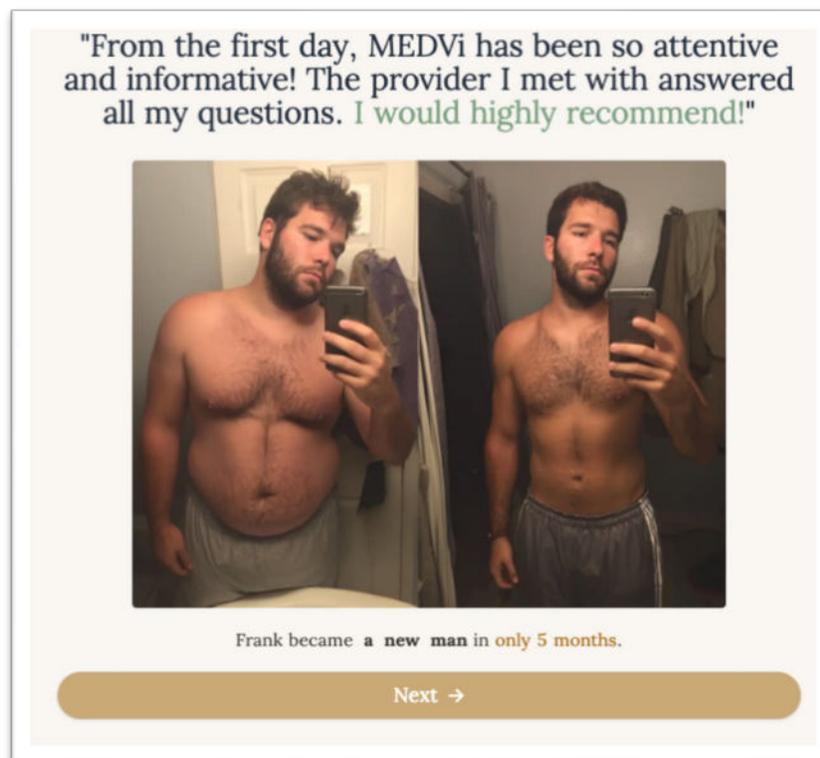
Medication	Starting Price	Dosing	Availability
MEDVi GLP-1 Injections	\$179	One simple injection per week.	Available
MEDVi GLP-1 Tablets	\$249	One dissolvable tablet per day.	Available
Ozempic® Injection	\$1,999/mo	Quantities are limited. Availability is subject to change.	Limited

¹¹⁷ *Id.*

73. The site states that treatment is provided through “personalized care and GLP-1 medication,” highlighting that the process is “Fast” and “Easy to start.”

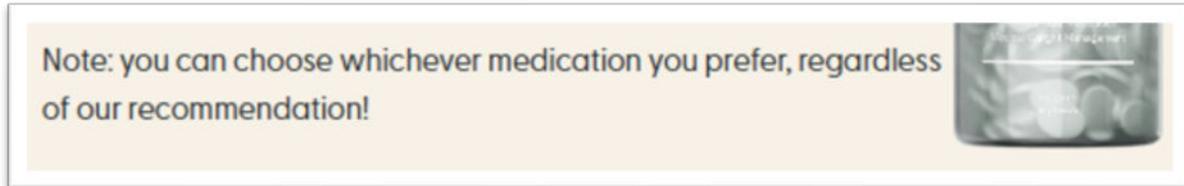
74. The homepage includes testimonial-style claims such as “When nothing else worked, MEDVi did!” together with numerical statements like “9/10 patients call it the most effective treatment to date” and “18% average weight loss,” displayed in large font beside photographs of models.

75. Testimonials purport to show real patients achieving transformative results.

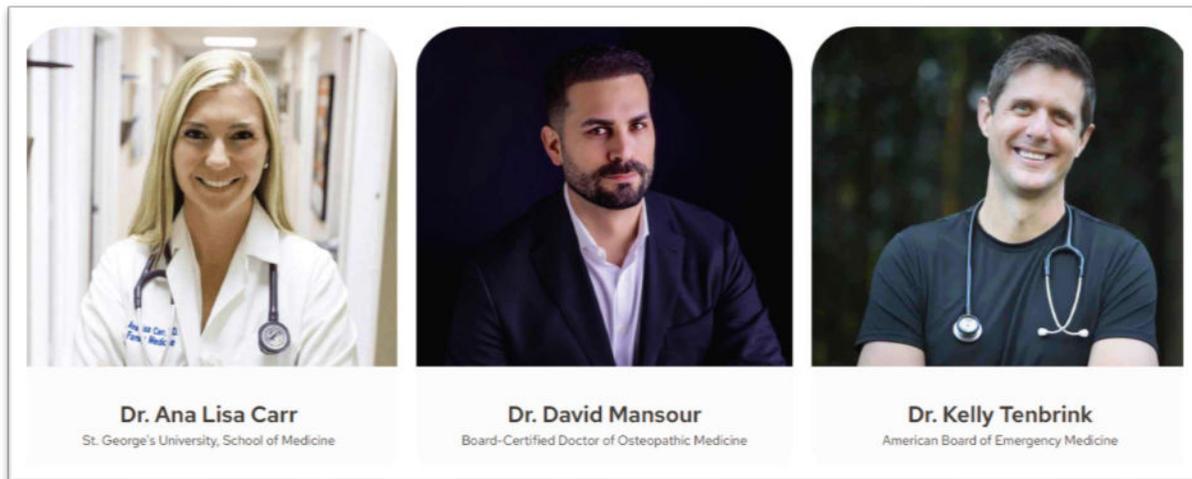


76. The website further assures prospective buyers that medication will be “Prescribed and shipped within 2 days” and “Prescribed by world-class, U.S.-based, board-certified clinicians.”

77. At checkout, the website reiterates that users receive “1:1 physician guidance and 24/7 MEDVi support,” and that they may “**choose whichever medication [they] prefer, regardless of our recommendation!**”



78. To further the scheme, the website’s landing page also contains a section titled “Meet the incredible doctors we’ve partnered with,” featuring photographs and names of Dr. Ana Lisa Carr,¹¹⁸ Dr. David Mansour,¹¹⁹ and Dr. Kelly Tenbrink¹²⁰ as MEDVi’s medical professionals.



79. Publicly available information could not confirm whether these individuals are employees of or affiliated with OpenLoop, are the prescribing physicians or physicians

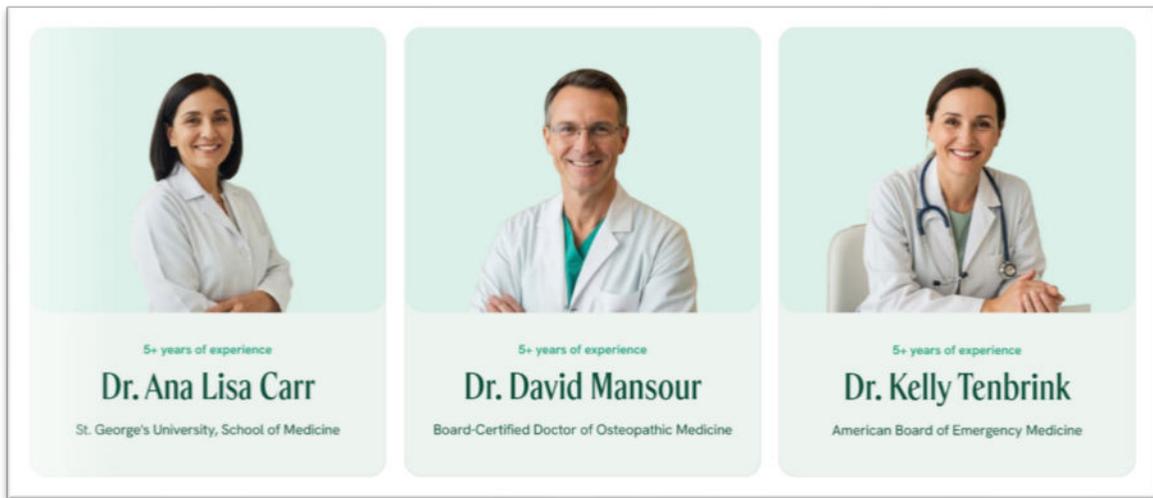
¹¹⁸ Ana Lisa Carr, LinkedIn (<https://www.linkedin.com/in/ana-lisa-carr-md-mba-8b665b2a/>).

¹¹⁹ David Mansour, LinkedIn (<https://www.linkedin.com/in/david-mansour-do-mba-mph/>).

¹²⁰ Kelly Tenbrink, LinkedIn (<https://www.linkedin.com/in/kelly-tenbrink-md-b5b0a9b6/>).

overseeing the medical professionals and clinicians who the customers purportedly meet with and will issue prescriptions, or are otherwise just compensated endorsers.

80. Identical names appear on the nearly **identical website heyfeels.com**,¹²¹ which uses the same heading, “Meet the incredible doctors we’ve partnered with.” However, the accompanying images on HeyFeels depict *completely different people*.



81. The same physician names also appear in other of the OpenLoop websites¹²²—including [glip1.com](https://www.glip1.com).¹²³ GLIP1.com is also nearly identical to MEDVi’s, using the same color scheme, layout, and copy; in fact, it refers to itself as “MEDVi” throughout its landing page.

3. *Plaintiff’s Experience*

82. On or about October 18, 2025, Plaintiff purchased a one-month supply of “oral tirzepatide” tablets from [medvi.org](https://www.medvi.org).

¹²¹ *HeyFeels*, <https://www.heyfeels.com/> (last visited Nov. 18, 2025).

¹²² For example, Dr. Ana Lisa Carr appears on the sites “Healthy Haus” (<https://healthy.haus/>), “Slims” (<https://www.getslims.co/>), and “Kestner Health and Wellness” (<https://thekestners.com/about-us-5594>). Dr. Kelly Tenbrink appears on “Active MD” (<https://myactivemd.com/pages/our-team>).

¹²³ *GLIP1*, <https://www.glip1.com/> (last visited Nov. 18, 2025).

83. Plaintiff paid \$279.99 using his personal Visa card. He was issued Invoice No. GJAH3F4U-0003 and Receipt No. 2977-3583 confirming the transaction.

84. The purchase covered a supply period from approximately October 18 through November 15, 2025.

85. At no point before or after submitting payment did Plaintiff speak with, video-conference, or otherwise consult a licensed medical professional through any affiliated telehealth provider.

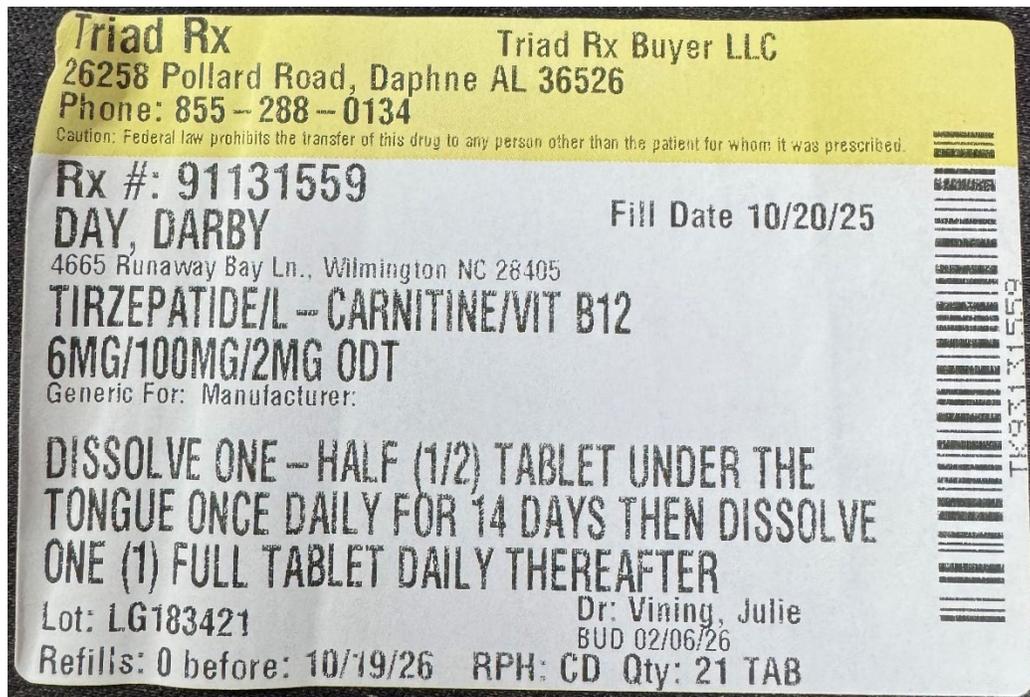
86. As part of the online intake process, Plaintiff was asked only to provide information about his medical history, height, and weight through an online questionnaire.

87. Based on marketing and representations, Plaintiff understood that the product he purchased was a legitimate and clinically effective oral version of tirzepatide, comparable in therapeutic effect to FDA-approved injectable GLP-1 medications.

88. Plaintiff's invoice and receipt bore MEDVi's name and logo, **but listed OpenLoop's headquarters as the billing address**—indicating that Plaintiff's payment was processed or directed to OpenLoop rather than MEDVi.



89. Plaintiff received his medication in packaging from Triad Rx, which also listed Triad Rx Buyer LLC on the pill bottle label.¹²⁴



90. The oral tirzepatide Plaintiff received was nothing more than the active pharmaceutical ingredient (“API”) tirzepatide blended with L-Carnitine and Vitamin B12.

91. Plaintiff took the medication as directed for more than a week but experienced no physiological effects. Having previously used an injectable GLP-1 medication, Plaintiff recognized that the oral formulation was not producing the expected results.

92. Concerned that the medication he received was ineffective and potentially unsafe, Plaintiff immediately stopped taking it and cancelled his subscription to prevent additional charges for future shipments.

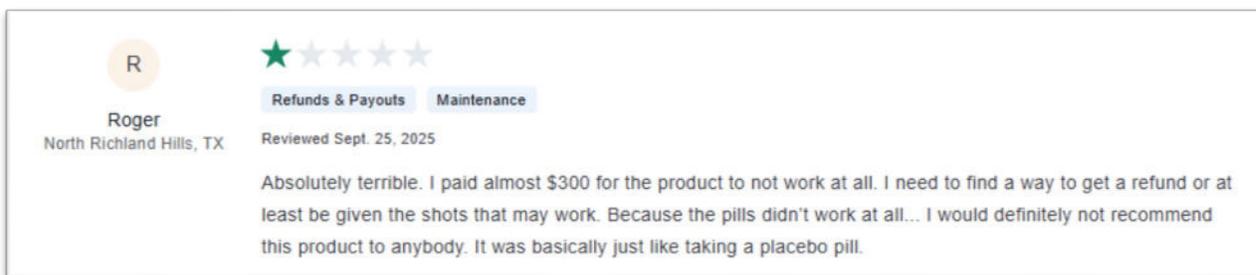
¹²⁴ Rx # 91131559

4. ***Consumers Are Deceived into Purchasing “Oral Tirzepatide” From Defendants***

93. Consumer reviews tell the same story: consumers are being deceived into purchasing so-called “oral tirzepatide” from Defendants.¹²⁵

94. MEDVi alone has amassed roughly 607 reviews on the Consumer Affairs website between March 25, 2025, and November 20, 2025—more than half of which are one-star ratings.¹²⁶

95. These reveal the extent to which consumers are being deceived into buying oral tirzepatide. Those consumers also identify it as ineffective. The consumers’ refund requests were denied, ignored, or met with generic form responses.



¹²⁵ See, e.g., *Consumer Affairs: Remedy Meds*, <https://www.consumeraffairs.com/health/remedy-meds.html?page=1#sort=recent&filter=1> (last visited Nov. 20, 2025) (showing 86 of 96 reviews as 1-star); **Henry Meds** <https://www.consumeraffairs.com/health/henry-meds.html?page=1#sort=recent&filter=1> (last visited Nov. 11, 2025) (showing 44 of 45 reviews as 1-star); **FuturHealth** <https://www.consumeraffairs.com/health/futurhealth.html?page=1#sort=recent&filter=1> (last visited Nov. 11, 2025) (showing 72 of 72 reviews as 1-star). See also *Better Business Bureau: SkinnyRx* <https://www.bbb.org/us/ca/sacramento/profile/pharmacy/skinnyrx-1156-90096184/complaints?page=1> (last visited Nov. 11, 2025); *Trustpilot: SkinnyRx* <https://www.trustpilot.com/review/skinnyrx.com?stars=1> (last visited Nov. 11, 2025).

¹²⁶ See *Consumer Affairs: MEDVi* <https://www.consumeraffairs.com/health/medvi.html> (last visited Nov. 11, 2025).

96. Many consumers attached photographs of the medication they received, revealing that the pills were dispensed by Triad Rx and Triad Rx Buyer LLC. In one image posted August 28, 2025, “Whitney” of Littleton, Colorado, shows a prescription labeled “Triad Rx.”¹²⁷



¹²⁷ *Consumer Affairs: MEDVi* <https://www.consumeraffairs.com/health/medvi.html?#reviews> (last visited Nov. 20, 2025).

97. Another, posted August 25, 2025, by “Nini” of Brooklyn, New York, bears the label “Triad Rx Buyer LLC.”¹²⁸



98. Another review, posted November 12, 2025, by “Suzi” of Oostburg, Wisconsin, describes being approved and charged for oral tirzepatide without any interaction with a physician: “I have ordered oral Tirzepatide ... The next day I got messages that the med was approved and it's processing to be shipped. I called them and requested verbally to cancel the

¹²⁸ *Id.*

order. They told me they would refund less a doctor's fee of 80 dollars because I got approved right away. **Like what? When? I didn't even talk to a doctor ...**”¹²⁹

99. Notably, to the extent there was a positive review of MEDVi, the consumer first stated that they had been sold the oral formulation, which produced no measurable results, and then any subsequent weight loss occurred only after switching to an injectable medication.

100. Numerous reviewers recount nearly identical experiences: they were prescribed and paid for oral tirzepatide, and they yielded no results from the oral medication. For instance, “Faith” of California (Oct. 17, 2025) wrote in their 5-star review, “I have been using Medvi for 6 months now. I started with the sublingual tirzepatide tablets and eventually moved up to the injectable version.” “Alejandro” of San Diego, California (Oct. 15, 2025) stated their 5-star review, “I began on the pill for the first 2 months... I definitely felt the effect of appetite suppression once I switched to the injection and have experienced more consistent weight loss since.” “Kay” of Midland, Virginia (Oct. 22, 2025) wrote, “Prescribed oral **, followed strict regime of diet, exercise and pill. No weight loss 5 weeks. Opted to change to injectable after 6 weeks....”¹³⁰

101. Others described following the program precisely as directed but seeing no physiological effect. “Ramona” of Tucson, Arizona (July 4, 2025) wrote: “I’m taking tablet form tirzepatide/L-carnitine/Vit B12... Everything went great. No side effects at all. I lost no weight in the first 4 weeks. My meeting with the nurse consultant... let me know that my body was getting used to the meds.”¹³¹

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

102. Taken together, these consumer accounts corroborate Plaintiff's experience and reveal a uniform pattern: consumers were induced to purchase oral tirzepatide based on representations of safety and effectiveness, received compounded pills manufactured by Triad Rx, observed no therapeutic effect, and were then encouraged to switch to injectable formulations. The volume and consistency of these reports underscore that the deception was not isolated or inadvertent but systemic—arising from the uniform marketing and distribution of an unapproved and pharmacologically ineffective product.

5. *Defendants are Manufacturing Oral Tirzepatide*

103. Triad Rx manufactured and distributed oral tirzepatide tablets through a coordinated network operated by OpenLoop, which supplies the telehealth “provider” infrastructure for the GLP-1 marketing websites discussed above. This scheme and operation resulted in OpenLoop and Triad Rx's selling oral tirzepatide to thousands of consumers nationwide.

104. The domain openloophealth.doxy.me¹³² hosts virtual waiting rooms used by 100+ GLP-1 marketing sites. Each portal displays the same pool of available telehealth providers. For example, MEDVi's waiting room showed over 250 providers, many of whom appeared identically across portals branded as *Fridays*,¹³³ *FuturHealth*,¹³⁴ *Lovely Meds*,¹³⁵ and *Remedy Meds*,¹³⁶ demonstrating that these platforms share a common provider network created, operated, and controlled by OpenLoop.

¹³² <https://openloophealth.doxy.me/>.

¹³³ <https://openloophealth.doxy.me/fridayswm>.

¹³⁴ <https://openloophealth.doxy.me/futur>.

¹³⁵ <https://openloophealth.doxy.me/lovelymeds>.

¹³⁶ <https://openloophealth.doxy.me/remedymeds>.

105. Upon information and belief, the oral tirzepatide tablets marketed through websites such as MEDVi were not conceived or created by those nominal “brands.” Rather, the products were already being manufactured in bulk by Triad Rx under the direction or control of OpenLoop and its related entities.

106. These consumer-facing websites serve primarily as lead-generation and payment-processing portals. They exist to drive orders to the compounding and distribution network operated by OpenLoop and Triad Rx, which are the entities actually producing, packaging, and shipping the medication to consumers.

107. The marketing companies themselves do not maintain any inventory, pharmacy licensure, or clinical infrastructure. Their ability to “offer” oral tirzepatide presupposes that the product already exists in quantity—manufactured, labeled, and ready for distribution—by the OpenLoop-Triad network.

108. In practice, the consumer’s purchase from a site such as MEDVi functions as an order routed through OpenLoop’s telehealth system and fulfilled by Triad Rx. The marketing site is merely a façade designed to give the appearance of a distinct, independent medical provider.

109. The existence of identical products, shared provider networks, and uniform pricing across dozens of such sites confirms that the manufacturing and decision-making authority resides with OpenLoop and Triad Rx, not the shell entities presenting themselves as personalized GLP-1 brands.

110. It is OpenLoop, after all, that “enables all of these companies to turn themselves into healthcare companies overnight.”¹³⁷

¹³⁷ *OpenLoop Health CEO on AI’s operations in the healthcare industry*, CNBC (Oct. 8, 2025), *supra*, n. 97.

111. Upon information and belief, OpenLoop and Triad Rx have used this network of interchangeable websites to mass-market and distribute unapproved compounded “oral tirzepatide” formulations nationwide under different names while concealing the identity of the true manufacturer and seller.

CLASS ACTION ALLEGATIONS

112. Plaintiff brings this action and seeks to certify and maintain it as a class action under Fed. R. Civ. P. 23, individually and on behalf of the following classes as defined below:

A. Nationwide Class

113. The Nationwide Class is defined as:

All consumers domiciled in the United States who purchased “oral tirzepatide” that was marketed, manufactured, distributed, fulfilled or delivered to them by OpenLoop and/or Triad Rx, or any affiliated entity.

B. North Carolina Subclass

114. As an alternative or in addition to the Nationwide Class, Plaintiff also brings this action and seeks to certify and maintain it as a class action under Fed. R. Civ. P. 23, individually and on behalf of the following class (“North Carolina Subclass”):

All consumers domiciled in North Carolina who purchased “oral tirzepatide” that was marketed, manufactured, distributed, fulfilled or delivered to them by OpenLoop and/or Triad Rx, or any affiliated entity.

C. Multistate Consumer Protection Subclass

115. As an alternative or in addition to the Nationwide Class, Plaintiff also brings this action and seeks to certify and maintain it as a class action under Fed. R. Civ. P. 23, individually and on behalf of the following class (“Multistate Consumer Protection Subclass”):

All persons domiciled in California, Colorado, Connecticut, Florida, Illinois, Michigan, Missouri, New Jersey, New Mexico, New York, North Carolina, South Carolina, Tennessee, and, Washington, who purchased “oral tirzepatide” that was

marketed, manufactured, distributed, fulfilled or delivered to them by OpenLoop and/or Triad Rx or any affiliated entity.

116. Excluded from the Classes are: (a) Defendants and any entities in which Defendants have a controlling interest; (b) any entities in which Defendants' officers, directors, or employees are employed and any of the legal representatives, heirs, successors, or assigns of Defendants; (c) all current employees of Defendants; (d) all governmental entities; and (e) anyone who makes a timely election to be excluded from the Class.

117. Plaintiff reserves the right to modify or amend the definitions of any proposed Class, and/or to add subclasses (collectively, "the Class" as used herein), if necessary before the Court determine whether certification is appropriate and as the Court may otherwise allow.

118. This case is properly brought as a class action under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3), and all requirements therein are met for the reasons set forth herein.

119. The claims of all Class members derive directly from a single course of conduct by Defendants. Defendants have engaged and continue to engage in uniform and standardized conduct toward the Class members. Defendants do not differentiate, in degree of care or candor, in their actions or inactions, or the content of their statements or omissions, among individual Class members. Accordingly, Plaintiff brings this lawsuit as a class action on Plaintiff's own behalf and on behalf of all "oral tirzepatide" purchasers similarly situated pursuant to Fed. R. Civ. P. 23. This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of these provisions.

120. Certification of Plaintiff's claims are appropriate because they can prove the elements of their claims on a Class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

121. **Numerosity.** The Class is so numerous that joinder of all members is impracticable. Defendants marketed, sold, and delivered compounded oral tirzepatide products nationwide through dozens of consumer-facing websites, including MEDVi, FuturHealth, Fridays, Remedy Meds, and others, reaching thousands of consumers. The precise number of Class Members is unknown to Plaintiff at this time, but the Class is readily ascertainable from Defendants' own records and/or by Plaintiff and Class Members themselves. Defendants' prescription, dispensing, telehealth intake, and payment processing records identify every consumer who was provided or billed for oral tirzepatide.

122. **Typicality.** Plaintiff's claims are typical of the claims of the Class. The claims of Plaintiff and the Class Members are based on the same legal theories and arise from the same unlawful and willful conduct of Defendants, resulting in the same injury to the Plaintiff and the respective Class. Plaintiff and Class Members are similarly affected by Defendants' wrongful conduct and were damaged in the same way as set forth in this Complaint. Plaintiff, like all Class Members, purchased Defendants' oral tirzepatide products in reliance on uniform representations of safety, legitimacy, and efficacy, and suffered the same type of injury—payment for snake oil—an unapproved and ineffective drug that was misrepresented as legitimate GLP-1 therapy. Plaintiff's interests coincide with, and are not antagonistic to, those of the other Class Members.

123. **Commonality and Predominance.** Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

- a. Whether Defendants, individually and collectively, engaged in a coordinated scheme to market, sell, and distribute unapproved “oral tirzepatide” products nationwide;
- b. Whether Defendants’ representations that their oral tirzepatide products were safe, effective, and equivalent to FDA-approved GLP-1 medications were false, misleading, or deceptive;
- c. Whether Defendants misrepresented or concealed material facts regarding the regulatory status, pharmacologic properties, or clinical efficacy of their oral tirzepatide products;
- d. Whether Defendants operated and controlled a network of consumer-facing websites designed to conceal the common origin of the products and to mislead consumers into believing they were purchasing legitimate telehealth services;
- e. The nature of the relationships between and among OpenLoop, Triad Rx, and the various consumer-facing “brands” identified herein;
- f. Whether Defendants violated the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962(c)–(d), through their role and participation in the manufacture, sale, and distribution of oral tirzepatide;
- g. Whether Defendants are engaged in an “enterprise,” as that term is used by 18 U.S.C. § 1961(4);
- h. Whether Defendants committed racketeering predicate acts of mail fraud in violation of in violation of 18 U.S. C. § 1341;
- i. Whether Defendants committed racketeering predicate acts of wire fraud in violation of in violation of 18 U.S. C. § 1343;

- j. Whether Defendants otherwise engaged in unfair, unlawful, fraudulent, unethical, unconscionable, and/or deceptive trade practices;
- k. Whether Defendants' conduct violated the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1, and similar consumer-protection statutes;
- l. Whether Defendants' sale and delivery of "oral tirzepatide" violated N.C. Gen. Stat. §§ 106-122(4) and 106-135, rendering such sales *per se* unfair or deceptive under § 75-1.1;
- m. Whether Defendants' sale and delivery of "oral tirzepatide" is a *per se* unfair, deceptive, or unconscionable act or practice under the Multistate Class consumer protection statutes.
- n. Whether Defendants' misrepresentations and omissions constitute common law fraud;
- o. Whether Defendants knew or should have known that their oral tirzepatide products lacked FDA approval and pharmacologic plausibility;
- p. Whether Defendants financially benefited from their conduct
- q. Whether Defendants were unjustly enriched by violations of the applicable statutes and common law herein;
- r. The appropriate nature and scope of class-wide equitable relief, including restitution, disgorgement, and injunctive relief;
- s. The appropriate measure of compensatory and statutory damages;
- t. Whether Defendants' conduct was willful, wanton, or reckless so as to warrant punitive damages;

- u. Whether Plaintiff and the Class are entitled to an award of attorneys' fees and costs.

124. These and other questions of law or fact which are common to Plaintiff and Class Members predominate over any questions affecting only individual members of the Class.

125. **Adequacy.** Plaintiff is an adequate Class representative because he has retained counsel competent and experienced in complex class action litigation. Neither Plaintiff nor his counsel have any interests adverse to those of the other members of the Class. Plaintiff is knowledgeable about the subject matter of this action and will assist counsel to vigorously prosecute this litigation. The interests of the Class Members will be fairly and adequately protected by Plaintiff and his counsel.

126. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this matter. The injury suffered by each member of the Class, while meaningful on an individual basis, is not of such magnitude as to make the prosecution of individual actions against Defendants economically feasible. Even if members of the Class themselves could afford such individualized litigation, the court system could not. In addition to the burden and expense of managing many actions, individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation increases the delay and expense to all parties and the court system presented by the legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

CAUSES OF ACTION

A. Causes of Action Brought on Behalf of the Nationwide Class

COUNT I

Violation of the Racketeer Influenced and Corrupt Organizations Act (“RICO”) 18 U.S.C. § 1962(c) (Against All Defendants On Behalf of the Nationwide Class)

127. Plaintiff realleges and incorporates by reference all of the allegations contained in each preceding paragraph as if fully set forth herein.

128. This claim is brought by Plaintiff against all Defendants on behalf of himself and the Nationwide Class under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1962(c).

129. The federal Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1962, 1964, provides a private right of action for a plaintiff to recover against defendants who harm them by conducting an enterprise through a pattern of racketeering activity, as well as defendants who conspire to do so.

130. This claim is brought by Plaintiff for himself and for the members of the Nationwide Class against all Defendants for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1962(c).

131. Section 1962(c) makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity” 18 U.S.C. § 1962(c).

132. Plaintiff is a “person,” as that term is defined in 18 U.S.C. § 1961(3), and have standing to sue under 18 U.S.C. § 1964(c) as he was and is injured in his property “by reason of” RICO violations described herein.

133. At all relevant times, each Defendant is a “person” within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding “a legal or beneficial interest in property.”

134. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c), as described herein.

1) Defendants are Engaged in, or Their Activities Affect, Interstate or Foreign Commerce

135. Section 1961(4) defines an enterprise as “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).

136. Defendant OpenLoop Health, Inc. (“OpenLoop”) is a corporation organized and existing under the laws of the state of Delaware, has an office and principal place of business in the state of Iowa, and conducts business throughout all 50 states of the United States. Upon information and belief, OpenLoop controls and deploys OpenLoop Healthcare Partners, P.C. as the provider network across various GLP-1 marketing websites. Although each website displays a different roster of purported “providers,” the identities vary inexplicably from site to site, calling into question who these individuals actually are and whether they possess valid credentials. Plaintiff’s own experience—receiving a prescription without any meaningful interaction with a licensed clinician—further underscores the sham nature of this process. Accordingly, OpenLoop Healthcare Partners, P.C. operates as an instrumentality through which OpenLoop advances its fraudulent prescription scheme in interstate commerce for its own financial benefit.

137. Defendant Triad Rx Buyer, LLC (“Triad Buyer”) is a Delaware limited liability company and an affiliate of OpenLoop. Defendant Triad Rx, Inc., is an Alabama Corporation and an affiliate of OpenLoop. Upon information and belief, OpenLoop exercises ownership and operational control over Triad Buyer and Triad Rx, Inc.

138. Together with a network of nominal “GLP-1 marketing” entities—including MEDVi and similar websites—Defendants formed an association-in-fact enterprise (the “Enterprise”) within the meaning of § 1961(4). The Enterprise functions as a continuing unit with a common purpose: to

market, distribute, and profit from the nationwide sale of unapproved and pharmacologically ineffective “oral tirzepatide” products.

139. Defendants control and direct the resources, personnel, and instrumentalities of the Enterprise. OpenLoop supplies the telehealth infrastructure and “provider” network; Triad Rx and Triad Buyer manufacture, compound, and distribute the products; and the GLP-1 marketing fronts serve as the consumer-facing vehicles through which the scheme is carried out.

140. Defendants devised, implemented, and maintained a scheme to defraud consumers by representing that the oral tirzepatide formulations offered through these marketing fronts were legitimate, safe, and effective medical treatments, when in fact they were not. The scheme relied on a bogus medical qualification process (¶¶ 85-86, 98), fabricated telehealth “consultations,” and misleading representations of doctor oversight to create the false appearance of legitimate medical care. (¶¶ 66-81).

141. The fraudulent acts were executed through the use of interstate mail and wire communications, including email, web-based forms, electronic payments, and online advertising, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

142. The Enterprise is engaged in, and its activities affect, interstate commerce because it markets, sells, and ships purported GLP-1 medications to consumers throughout the United States. Through this scheme, Defendants have obtained millions of dollars in payments from consumers across state lines.

2) “Conduct or Participate, Directly or Indirectly, in the Conduct of Such Enterprise’s Affairs”

143. “[T]o conduct or participate, directly or indirectly, in the conduct” of such an enterprise, “one must participate in the operation or management of the enterprise itself.” *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993).

144. As described herein, each RICO Defendant participated in the operation and management of the Enterprise by directing, coordinating, and executing the scheme to market, prescribe, and distribute unapproved and ineffective “oral tirzepatide” formulations. OpenLoop and OpenLoop Healthcare Partners P.C. provided the infrastructure and personnel necessary to make the scheme appear legitimate (¶¶ 58-65); Triad Rx and Triad Buyer manufactured, packaged, and shipped the product (¶¶ 84-90, 96-97); and the GLP-1 marketing fronts, including MEDVi, served as the consumer-facing channels through which the fraudulent sales were made (¶¶ 66-81).

3) Mail and Wire Fraud Predicate Offenses

145. Defendants knowingly and intentionally participated in a scheme to defraud Plaintiff and the Class by inducing them to purchase purported “oral tirzepatide” medications represented to have the same therapeutic benefits as FDA-approved GLP-1 drugs, despite knowing that such products were pharmacologically ineffective. The object of the scheme was to obtain money from consumers through false representations of safety, efficacy, and physician oversight.

146. In furtherance of this scheme, Defendants caused materials and products to be placed in, and delivered through, the United States mail and private carriers, including the shipment of the “oral tirzepatide” medications, in violation of 18 U.S.C. § 1341.

147. In furtherance of this scheme, Defendants also caused interstate wire communications—including website transactions, email communications, electronic payments, and online advertisements—to be transmitted in furtherance of the scheme, in violation of 18 U.S.C. § 1343. These transmissions included representations made on websites such as *medvi.org* and affiliated domains, telehealth communications through the OpenLoop platform, and electronic payment processing for purchases and recurring subscription charges.

148. Each fraudulent transaction involved multiple acts of mail and wire fraud, including but not limited to:

- a. **Misleading Product Representations:** Defendants published and maintained online listings and advertisements for “oral tirzepatide,” knowing that these claims of safety, efficacy, and equivalence to FDA-approved drugs were (literally) false and misleading. ¶¶ 66-81, 91-92; *see also* ¶¶ 63-64.
- b. **Fraudulent Prescriptions:** Defendants caused affiliated or contracted physicians to issue and transmit electronic prescriptions for “oral tirzepatide” despite knowing that the products were unapproved and medically ineffective. ¶¶ 82-88, 98-102.
- c. **Fraudulent Fulfillment:** Defendants caused Triad Rx to mail or ship the oral tirzepatide to consumers across state lines, thereby using the mails in furtherance of the fraudulent scheme. ¶¶ 89-90, 96-97.
- d. **Ongoing Electronic Communications:** Defendants used telehealth portals, email, and customer messaging centers to perpetuate the false impression that the treatments were physician-supervised and medically legitimate. ¶¶ 83, 98, 101, 103-104.

149. These mailings and wirings occurred repeatedly and continuously as part of a coordinated course of conduct spanning all fifty states, constituting a “pattern of racketeering activity” within the meaning of 18 U.S.C. § 1961(5).

150. Defendants voluntarily and intentionally committed, and aided and abetted, numerous predicate acts of mail and wire fraud in furtherance of their scheme.

151. Defendants intended that Plaintiff and Class Members rely upon their express and implied representations that the oral tirzepatide was safe, effective, and medically supervised.

Plaintiff and Class Members did in fact rely upon these representations when purchasing the products, suffering monetary losses as a result.

152. The use of interstate mail and wire communications was integral and foreseeable to the scheme: Defendants marketed their products online, processed payments electronically, issued electronic prescriptions, and shipped products nationwide through the mail.

4) Pattern of Racketeering Activity

153. Defendants willfully and knowingly conducted or participated, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5), and 1962(c), employing the use of mail and wire communications in violation of 18 U.S.C. §§ 1341 and 1343.

154. Specifically, Defendants—individually and collectively—committed, conspired to commit, and/or aided and abetted in the commission of numerous predicate acts of racketeering activity, including repeated violations of the federal mail and wire fraud statutes, within the past ten years and continuing to the present.

155. The predicate acts described herein are related and continuous. They share a common purpose (to market and sell unapproved, pharmacologically ineffective oral tirzepatide formulations), common participants (OpenLoop, Triad Rx, Triad Buyer, and their network of front-end marketing entities), and a common method of execution (deceptive online advertising, telehealth communications, and fulfillment via interstate shipment). Collectively, they constitute a “pattern of racketeering activity” within the meaning of 18 U.S.C. § 1961(5).

156. Defendants used, directed, and caused to be used hundreds of thousands of interstate mail and wire communications—including digital advertisements, payment processing,

electronic prescriptions, and shipment tracking—in furtherance of the Enterprise’s objectives through uniform misrepresentations, concealments, and material omissions.

157. As set forth above, Defendants devised and executed a continuing scheme to defraud consumers nationwide by:

- a. Transmitting false and misleading representations via internet advertisements and intake portals claiming that “oral tirzepatide” was effective, and medically supervised (¶¶ 62-81, 98-102);
- b. Causing affiliated or contracted physicians to issue fraudulent prescriptions transmitted electronically through OpenLoop’s telehealth system (¶¶ 82-90, 104; *see also* ¶¶ 63-64);
- c. Causing Triad Rx and Triad Rx Buyer to ship these unapproved and ineffective medications to consumers across state lines (¶¶ 82-90, 96-97); and
- d. Collecting recurring electronic payments from consumers under the false pretense that they were receiving legitimate, FDA-comparable GLP-1 therapy (¶¶ 88, 98-101).

158. Defendants either directly approved these fraudulent representations or orchestrated and maintained a system that made such misrepresentations inevitable (*see* ¶¶ 63-64). Each mailing and wiring was made in furtherance of Defendants’ overarching plan to profit from the deceptive sale and distribution of unapproved oral GLP-1 products.

159. Defendants committed these racketeering acts intentionally and knowingly, with the specific intent to defraud and to personally or directly profit from these actions.

160. Defendants intended for Plaintiff and Class Members to rely upon their false representations, and the scheme was designed and calculated to deceive reasonable consumers into believing they were purchasing legitimate, medically effective treatments.

161. Many of the precise dates and instances of the fraudulent use of the U.S. mail and interstate wire facilities cannot be alleged without access to Defendants' internal records. Plaintiff has, however, detailed the types of predicate acts of mail and wire fraud and the specific categories of misrepresentations made through the websites, telehealth platforms, and shipping channels operated or controlled by Defendants.

162. These were not isolated incidents. Defendants engaged in a continuous and ongoing pattern of racketeering activity since at least February 2024,¹³⁸ and continuing through the present, involving thousands of deceptive transactions across all fifty states. There exists a continuing threat that such racketeering conduct will persist so long as Defendants are permitted to market and distribute unapproved oral tirzepatide formulations under new or rebranded consumer-facing websites.

5) Harm to Plaintiff

163. On information and belief, Defendants have been, and continue to be, unjustly enriched through their scheme to market, prescribe, and sell unapproved and pharmacologically ineffective oral tirzepatide formulations. Through this scheme, Defendants obtained millions of dollars in payments from consumers, including Plaintiff and Class Members, in exchange for

¹³⁸ This date is based on the earliest archived capture of OpenLoop's website showing a dedicated "Weight Loss" marketing page. See OpenLoop Health, *Website Snapshot*, <https://web.archive.org/web/20240223204041/https://openloophealth.com/> (archived Feb. 23, 2024) (last visited Nov. 18, 2025).

products that lacked **any** therapeutic value and were misrepresented as safe and effective GLP-1 medications.

164. Defendants' unlawful actions directly, illegally, and proximately caused injury to the business and property of Plaintiff and Class Members. As a result of Defendants' fraudulent acts and misrepresentations, Plaintiff and Class Members paid substantial sums for products that had no medical efficacy, received nothing of the value promised, and in some cases incurred additional costs to cancel subscriptions or replace the ineffective medication with legitimate treatment. But for Defendants' fraudulent acts, representations and omissions, Plaintiff and Class Members would not have purchased the products, and the resulting harm was reasonably foreseeable to Defendants.

165. Pursuant to the civil remedy provisions of 18 U.S.C. § 1964(c), Plaintiff and the Class are entitled to recover treble damages, the costs of suit, and reasonable attorneys' fees, together with such other and further relief as the Court may deem just and proper.

COUNT II
Violation of the Racketeer Influenced and Corrupt Organizations Act (RICO)
18 U.S.C. § 1962(d)
(Against All Defendants on Behalf of the Nationwide Class)

166. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein.

167. This claim is brought under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1962(d) on behalf of Plaintiff and the Nationwide Class.

168. Defendants have undertaken the fraudulent acts described above as part of a common scheme. Defendants willfully, knowingly, and unlawfully conspired, confederated, and agreed together and with others to violate 18 U.S.C. § 1962(c). Each Defendant was aware of the essential nature and scope of the enterprise and agreed that others would commit at least two

predicate acts of racketeering—including mail and wire fraud—in furtherance of the shared scheme to market and sell unapproved oral tirzepatide formulations. Defendants intentionally concealed their fraudulent conduct to prevent Plaintiff and Class Members from discovering the scheme despite reasonable diligence.

169. OpenLoop, Triad Buyer and Triad Rx jointly orchestrated and supplied the infrastructure that made the scheme possible. OpenLoop recruited and operated the telehealth network through which fraudulent prescriptions were issued and processed, while Triad Buyer and Triad Rx manufactured, filled, and shipped the unapproved drugs. The consumer-facing GLP-1 marketing fronts, including MEDVi, executed the deception by advertising the products as safe, effective, and physician-supervised. Each Defendant knowingly participated in, facilitated, and benefited from this common plan.

170. Defendants collectively directed and caused one another to engage in racketeering activity, coordinating the content of online advertisements, the flow of payments, and the issuance and transmission of prescriptions and shipments across state lines.

171. Each Defendant understood that it was committing, or aiding and abetting the commission of, numerous predicate acts. Their coordinated conduct included: (a) disseminating false and misleading representations via interstate wires through websites, electronic communications, and payment systems (¶¶ 62-81, 98-102); (b) transmitting or causing the transmission of fraudulent prescriptions electronically (¶¶ 82-90, 104); and (c) mailing or shipping unapproved and ineffective oral tirzepatide products nationwide (¶¶ 82-90, 96-97). Defendants knowingly profited from and furthered the enterprise by concealing the true source, composition, and ineffectiveness of the products sold.

172. The participation and agreement of each Defendant were necessary to the success of the enterprise. Defendants knew or should have known that their acts were part of a pattern of racketeering activity and agreed, either expressly or tacitly, to the commission of those acts to further the enterprise's ongoing fraudulent purpose. Evidence of the full extent of this agreement lies largely within Defendants' possession and control.

173. As a direct and proximate result of Defendants' conspiracy and violations of 18 U.S.C. § 1962(d), Plaintiff and the Class have been injured in their property and are entitled to treble damages, attorneys' fees, costs of suit, and such other relief as the Court deems just and proper.

B. Causes of Action Brought on Behalf of the State Classes

i. North Carolina

COUNT III

Violation of the North Carolina Unfair & Deceptive Trade Practices Act

(N.C. Gen. Stat. §§ 75-1.1, *et seq.*)

(Against All Defendants On Behalf of Plaintiff and the North Carolina Class)

174. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein.

175. This claim is brought by Plaintiff against all Defendants on behalf of himself and the North Carolina Class.

176. N.C. Gen. Stat. § 75-1.1(a) makes unlawful “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.”

177. “Commerce” includes “all business activities, however denominated.” N.C. Gen. Stat. § 75-1.1(b).

178. Defendants engaged in unfair and deceptive acts or practices in and affecting commerce by marketing, prescribing, manufacturing, and selling unapproved oral tirzepatide formulations to consumers, including Plaintiff and the North Carolina Class, through misleading online representations that such products were safe, effective, and medically supervised treatments for weight loss and diabetes management.

179. Defendants' conduct included, but was not limited to:

- a. Representing that their compounded oral tirzepatide products were clinically effective and comparable to FDA-approved injectable GLP-1 medications (¶¶ 66-81, 90-92);
- b. Advertising that such products were prescribed by "world-class, U.S.-based, board-certified clinicians," when in fact no meaningful individualized physician evaluation occurred (¶¶ 63-64, 66-81, 85-86, 98);
- c. Misrepresenting or concealing that no oral formulation of tirzepatide has been approved by the U.S. Food and Drug Administration, and that no scientific evidence supports the safety or efficacy of the compounded oral tirzepatide formulation (¶¶ 66-77; *see also* ¶¶ 40-49);
- d. Failing to disclose that the products were mass-produced by Triad Rx rather than compounded individually for any particular patient (¶¶ 90, 96-97, 101); and
- e. Using deceptive endorsements, fabricated testimonials, and fictitious medical affiliations to induce consumer purchases (¶¶ 61, 66-81, 87, 93-102).

180. These representations and omissions were material because they would affect the purchase decisions of a reasonable consumer. Plaintiff and Class Members reasonably believed

they were purchasing a legitimate and medically effective GLP-1 medication, specifically “oral tirzepatide,” under physician supervision.

181. In truth, Defendants’ oral tirzepatide product was pharmacologically ineffective, unapproved, and unsafe for human consumption. The advertising and representations described above were false and misleading and had the capacity to deceive consumers.

182. Defendants’ acts and omissions occurred in and affected commerce within the meaning of N.C. Gen. Stat. § 75-1.1 because they involved the marketing, sale, and delivery of pharmaceutical products to consumers in North Carolina and throughout the United States.

183. Defendants owed Plaintiff and Class Members a duty to disclose the true nature of their products and operations because such facts were known exclusively to Defendants, were material to consumers’ purchasing decisions, and were actively concealed through coordinated misrepresentations on their websites and marketing platforms.

184. Plaintiff and Class Members reasonably relied on Defendants’ misrepresentations and omissions when purchasing oral tirzepatide. But for these deceptive statements, they would not have purchased the products or paid the inflated prices demanded.

185. As a direct and proximate result of Defendants’ unfair and deceptive acts and omissions, Plaintiff and Class Members suffered ascertainable losses, including the purchase price of the ineffective medication and additional costs related to cancelling subscriptions or replacing the products with legitimate treatment.

186. Defendants’ conduct also constitutes a *per se* violation of N.C.G.S. § 75-1.1. Under N.C.G.S. § 106-122(4) and § 106-135, it is unlawful to “sell, deliver for sale, hold for sale, or offer for sale” any *new drug* for which no approved application exists under § 505 of the federal Food, Drug, and Cosmetic Act (“FDCA”).

- a. The oral tirzepatide products are drugs within the meaning of section 201(g) of the FDCA (21 U.S.C. § 321(g)) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body.
- b. These drugs are also *new drugs* as defined by section 201(p) of the FDCA (21 U.S.C. § 321(p)), because they are not generally recognized as safe and effective for their labeled uses.
- c. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FDCA (21 U.S.C. § 355(a)).
- d. No approved applications pursuant to section 505 of the FDCA are in effect for these oral tirzepatide products. Accordingly, their introduction or delivery for introduction into interstate commerce violates FDCA sections 505(a) and 301(d) (21 U.S.C. § 331(d)).

187. Defendants’ manufacture, marketing, and sale of compounded oral tirzepatide—an unapproved “new drug” under § 106-135(a)(1)—squarely violates these provisions. Because the statute is intended to protect consumers from unsafe and ineffective drugs, such violations constitute *per se* unfair or deceptive trade practices under N.C.G.S. § 75-1.1.

188. Moreover, Defendants cannot invoke the Section 503A compounding exemption of the federal FDCA, 21 U.S.C. § 353a. That safe harbor applies only where compounded medications are prepared pursuant to a valid prescription for an *identified individual patient* and tailored to that patient’s specific medical needs. The oral tirzepatide products at issue here were

mass-produced by Triad Rx at the direction of OpenLoop for distribution through numerous GLP-1 marketing websites, not compounded in response to any individualized prescription. As such, Defendants' conduct falls outside the 503A exemption and squarely within the North Carolina prohibition on the sale of unapproved new drugs.

189. Pursuant to N.C. Gen. Stat. § 75-16, Plaintiff and the North Carolina Class seek treble damages, attorneys' fees, injunctive relief prohibiting further deceptive marketing and sales of unapproved oral GLP-1 products, and such other relief as the Court deems just and proper.

COUNT IV
Common Law Fraud
(Against All Defendants on Behalf of Plaintiff and the North Carolina Class)

190. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein.

191. This claim is brought by Plaintiff against all Defendants on behalf of himself and the North Carolina Class.

192. Defendants knowingly and intentionally misrepresented material facts and omitted material information in connection with the marketing, sale, and distribution of "oral tirzepatide" medications through websites such as medvi.org and related GLP-1 marketing platforms.

193. Specifically, Defendants falsely represented that their oral tirzepatide products were safe, effective, and clinically comparable to FDA-approved injectable GLP-1 medications; that they were prescribed by licensed, board-certified medical professionals following individualized evaluation; and that the products were compounded in compliance with applicable law and medical standards.

194. In reality, Defendants' oral tirzepatide products were not approved by the U.S. Food and Drug Administration, were pharmacologically ineffective when administered orally, and were mass-produced by Triad Rx for distribution through OpenLoop's network of consumer-facing marketing sites. Defendants concealed these material facts from consumers.

195. Defendants also created and disseminated fabricated testimonials, deceptive "medical partner" profiles, and misleading comparative imagery suggesting "oral tirzepatide's" equivalence to brand-name Ozempic and Mounjaro products. These representations were designed to induce consumers, including Plaintiff, to purchase an unapproved and ineffective compound under the guise of legitimate medical treatment.

196. Defendants owed Plaintiff and Class Members a duty to disclose these material facts because they possessed exclusive knowledge of them, actively concealed them, and knew that reasonable consumers would rely on their representations concerning safety, efficacy, and medical legitimacy when deciding whether to purchase the products.

197. Plaintiff and Class Members reasonably and justifiably relied on Defendants' misrepresentations and omissions. In reliance upon those statements, Plaintiff purchased and ingested the oral tirzepatide believing it to be a legitimate, effective GLP-1 medication.

198. Defendants knew that their statements were false or acted with reckless disregard for their truth or falsity. Their misrepresentations and omissions were made willfully, wantonly, and with the intent to deceive and defraud Plaintiff and Class Members to induce payment for an ineffective product.

199. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiff and Class Members suffered damages including, but not limited to, the amounts paid for the ineffective oral tirzepatide, the costs of replacement treatment, and other consequential damages.

200. Plaintiff and the North Carolina Class seek compensatory damages, punitive damages, attorneys' fees, costs of suit, and such further relief as the Court deems just and proper.

COUNT V
UNJUST ENRICHMENT
(Against All Defendants on Behalf of Plaintiff and the North Carolina Class)

201. Plaintiff realleges and incorporates by reference all preceding paragraphs as though fully set forth herein.

202. This claim is brought by Plaintiff against all Defendants on behalf of himself and the North Carolina Class.

203. Plaintiff and Class Members conferred monetary and other benefits upon Defendants by purchasing "oral tirzepatide" medications through Defendants' GLP-1 marketing websites, including medvi.org, in reasonable reliance on Defendants' representations regarding safety, efficacy, and medical supervision.

204. Defendants have been unjustly enriched in retaining the revenues derived from the sale and distribution of these unapproved and ineffective drug products. Retention of those monies under these circumstances is unjust and inequitable because Defendants obtained such payments through material misrepresentations and omissions concerning the nature, quality, and legality of the products sold.

205. Specifically, Defendants received and retained payments from consumers for compounded oral tirzepatide that:

- a. was falsely represented as a safe and effective GLP-1 medication comparable to FDA-approved injectables;
- b. was mass-produced by Triad Rx without a valid prescription for any individual patient; and

- c. lacked any therapeutic effect and was not eligible for lawful sale under federal or North Carolina law.

206. Each Defendant knew or should have known that it was unjustly receiving and retaining benefits derived from these transactions. OpenLoop and Triad Rx knowingly manufactured, distributed, and profited from the sale of unapproved new drugs; MEDVi and other marketing fronts funneled consumer payments for these same products while misrepresenting their source, composition, and legitimacy.

207. Through these false, misleading, and unfair practices, Defendants have unjustly obtained profits, gains, and advantages at the expense of Plaintiff and Class Members, including lost funds, loss of market integrity, and the dilution of consumer trust in legitimate GLP-1 therapies.

208. Defendants have had the use and benefit of the monies paid by Plaintiff and Class Members and have accrued interest, profits, or other financial gains therefrom.

209. Equity and good conscience require that Defendants disgorge these ill-gotten gains and make restitution to Plaintiff and Class Members for the full value of the benefits unjustly obtained.

210. Plaintiff and Class Members have suffered pecuniary harm as a direct and proximate result of Defendants' conduct and have no adequate remedy at law. Plaintiff and Class Members are entitled to restitution, disgorgement, and/or the imposition of a constructive trust over all profits, benefits, and other compensation obtained by Defendants as a result of their fraudulent and inequitable conduct.

C. Causes of Action Brought on Behalf of the Multistate Consumer Protection Subclass

COUNT VI
Violation Of Consumer Protection Statutes
(Against All Defendants on Behalf of Plaintiff and the Multistate Consumer Protection Subclass)

211. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

212. This claim is brought by Plaintiff, individually and on behalf of the Multistate Consumer Protection Subclass, for violations of the following consumer-protection statutes:

- a. the California Unfair Competition Law, Bus. & Prof. Code § 17200, et seq. which Defendants violated by engaging in “unlawful, unfair or fraudulent business act[s] or practice[s] and unfair, deceptive, untrue or misleading advertising.” Cal. Bus. & Prof. Code § 17200. By distributing a new drug in California, Defendants have committed a *per se* unlawful practice. *See* Cal. Health & Safety Code § 111550(a) (“No person shall sell, deliver, or give away any new drug ... unless ... a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the [FDCA].”), Defendants committed a further violation by engaging in unfair and unconscionable acts that offend established public policy, that are unethical, and unscrupulous, and that were and are substantially injurious to Plaintiff and the members of the Multistate Consumer Protection Subclass;
- b. the California False Advertising Law Business and Professions Code § 17500, et seq. which Defendants violated by advertising “untrue or misleading” statements that Defendants knew “or which by the exercise of reasonable care should [have] known, to be untrue or misleading” Cal. Bus. & Prof. Code § 17500;
- c. the Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. § 6-1-101, et seq., which Defendants violated by “[e]ither knowingly or recklessly engag[ing] in [the alleged] unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice,” Colo. Rev. Stat. § 6-1-105(kkk), including by, without limitation (see § 6-1-105(3)), advertising goods with intent not to sell as advertised, § 6-1-105(1)(i); failing to disclose material information concerning goods which information was known at the time of sale if such failure to disclose such information was intended to induce the purchaser to enter into a transaction, Colo. Rev. Stat. § 6-1-105(u); and failing to “obtain all governmental licenses or permits required to . . . sell the goods.” § 6-1-105(z). By distributing a new drug

in Colorado, Defendants have violated § 6-1-105(z) as a matter of law and committed a *per se* unconscionable practice. *See* Colo. Rev. Stat. § 12-280-131(1) (“No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.”). Defendants committed a further violation by engaging in unfair and unconscionable acts that offend established public policy, that are unethical and unscrupulous, and that were and are substantially injurious to Plaintiff and the members of the Multistate Consumer Protection Subclass;

- d. the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110b prohibits “unfair methods of competition or unfair [] acts or practices in the conduct of any trade or commerce.” Conn. Gen. St. § 42-110b. Under Connecticut law, an act is “unfair” when it offends public policy as it has been established by statutes, the common law, or otherwise, or when it is immoral, unethical, oppressive, or unscrupulous. By distributing a new drug in Connecticut, Defendants have committed a *per se* unfair act or practice. *See* Conn. Gen. Stat. § 21a-110(a) (“No person shall sell . . . any new drug” that has not “been approved under Section 355 [§ 505 of the FDCA].”);
- e. the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq., which Defendants violated by engaging in “Unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce” §501.204. FDUTPA further forbids Defendants from violating “[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices.” Fla. Stat. Ann. § 501.203(3)(c). By distributing a new drug in Florida, Defendants have committed a *per se* unconscionable act or practice. *See* Fla. Stat. § 499.023 (“A person may not sell, offer for sale, hold for sale, manufacture, repack, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the [FDCA]. . . .”);
- f. the Illinois Uniform Deceptive Trade Practices Act , 815 ILCS 510/1, et seq., which Defendants violated by engaging in one or more of the following unfair or deceptive business practices prohibited by 815 ILCS 510/2(a): representing that the Products had a characteristic that they did not actually have; representing that the Products were of a particular quality, grade, or standard when, in fact, they were not of that quality, grade, or standard; advertising the Products with the intent not to sell them as advertised; and engaging in other conduct which similarly creates a likelihood of confusion or misunderstanding. 815 ILCS 510/2(a)(5), (7), (9), and (12). By distributing a new drug in Illinois, Defendants

have committed a *per se* unfair act or practice. *See* 410 Ill. Comp. Stat. Ann. 620/17 (“No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the [FDCA].”);

- g. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 et seq., which Defendants violated by engaging in one or more “[u]nfair methods of competition and unfair or deceptive acts or practices, including, but not limited to, the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the ‘Uniform Deceptive Trade Practices Act’ [815 Ill. Comp. Stat. Ann. 510/2], approved August 5, 1965, in the conduct of any trade or commerce.” 815 Ill. Comp. Stat. Ann. 505/2. By distributing a new drug in Illinois, Defendants have committed a *per se* unfair act or practice. *See* 410 Ill. Comp. Stat. Ann. 620/17 (“No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under Section 505 of the [FDCA].”);
- h. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq., which Defendants violated by engaging in one or more “Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce”, including by “(c) Representing that goods or services have .. characteristics, ingredients, uses, benefits... that they do not have ...”, “(e) Representing that goods ... are of a particular standard, quality, ... if they are of another”, and “(s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer.” § 445.903. By distributing a new drug in Michigan, Defendants have committed a *per se* unconscionable act or practice. *See* Mich. Comp. Laws § 333.7402(1) (“a person shall not create, manufacture, deliver, or possess with intent to deliver a counterfeit substance or a controlled substance analogue intended for human consumption. ... For purposes of this section, section 505 of the [FDCA] shall be applicable to the introduction or delivery for introduction of any new drug into intrastate, interstate, or foreign commerce.”);
- i. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq., which Defendants violated by engaging in acts of “deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or

omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.” Mo. Rev. Stat. § 407.020. Defendants committed a further violation by engaging in unfair and unconscionable acts that offend established public policy, that are unethical and unscrupulous, and that were and are substantially injurious to Plaintiff and the members of the Multistate Consumer Protection Subclass. *See* Mo. Code Regs. tit. 15, § 60-8.020(1). By distributing a new drug in Missouri, Defendants have committed a *per se* unconscionable act or practice. *See* Mo. Rev. Stat. § 196.105 (“No person shall sell, deliver, offer for sale, hold for sale or give away any new drug”);

- j. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8, et seq., which Defendants violated by engaging in deception, fraud, false pretense, false promise, misrepresentation, or by the knowing, concealment, suppression, or omission of material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of goods. NJCFA § 56:8-2. By distributing a new drug in New Jersey, Defendants have committed a *per se* fraudulent act or practice. *See* N.J. Stat. Ann. § 24:6A-1 (“No person shall introduce or deliver for introduction into intrastate commerce in the State of New Jersey any new drug unless . . . an application with respect thereto has become effective under the [FDCA].”);
- k. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, et seq., which Defendants violated by engaging in “[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of . . . trade or commerce,” § 57-12-3, including, taking “advantage of the lack of knowledge . . . of a person to a grossly unfair degree,” § 57-12-3(E)(1). By distributing a new drug in New Mexico, Defendants have committed a *per se* unconscionable trade practice. *See* N.M. Stat. Ann. § 26- 1-14 (“No person shall sell, deliver, offer for sale, hold for sale or give away any new drug or device unless . . . an application has been approved for the drug and approval has not been withdrawn under Section 505 of the [FDCA].”);
- l. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law §§ 349, 350, et seq., which Defendants violated by engaging in “Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [NY]” NYGBL § 349; and through “[f]alse advertising in the conduct of any business, trade or commerce.” N.Y. Gen. Bus. Law §350. False advertising includes “advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect,” taking into account “the extent to which the advertising fails to reveal facts material in the

light of . . . representations [made] with respect to the commodity.” By distributing a new drug in New York, Defendants have committed a *per se* deceptive act or practice. *See* N.Y. Educ. Law § 6817(1)(a) (“Except as otherwise provided in the [FDCA], no person shall sell, deliver, offer for sale, hold for sale, or give away any new drug.”);

- m. Plaintiff realleges the allegations in Paragraphs 171-185 as to the North Carolina Subclass and asserts that those same practices likewise constitute unfair and deceptive acts or practices under North Carolina law for the reasons stated therein.
- n. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-20, et. seq., prohibits “unfair methods of competition or unfair [] acts or practices in the conduct of any trade or commerce.” S.C. Code Ann. § 39-5-20(a). Under South Carolina law, an act is “unfair” when it is offensive to public policy or when it is immoral, unethical or oppressive. By distributing a new drug in South Carolina, Defendants have committed a *per se* unfair act or practice. *See* S.C. CODE § 39-23-70(a) (“No person shall introduce or deliver for introduction into intrastate commerce any new drug unless . . . an application with respect thereto has been approved and such approval has not been withdrawn under Section 505 of the [FDCA].”);
- o. the Tennessee Consumer Protection Act, Tenn. Code Ann. 47-18-104 , et. seq., prohibits “unfair or deceptive acts or practices affecting the conduct of any trade or commerce.” Tenn. Code Ann. § 47-18-104(a). The TCPA explicitly defines “advertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state” to be an unfair or deceptive act or practice that is declared to be unlawful. Tenn. Code Ann. § 47-18-104(b)(43)(C). By distributing a new drug in Tennessee, Defendants have committed a *per se* unfair act or practice. Tenn. Code § 53-1-110(a) (“No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless an application with respect to the drug has become effective under § 505 of the [FDCA].”);
- p. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq. which Defendants violated by engaging in “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct [its] trade,” Wash. Rev. Code § 19.86.020. Defendants committed a further violation by engaging in unfair and unconscionable acts that offend established public policy, that are unethical and unscrupulous, and that were and are substantially injurious to Plaintiff and members of the Multistate Consumer Protection Subclass. By distributing a new

drug in Washington, Defendants have committed a *per se* unfair act or practice. *See* Wash. Rev. Code § 69.04.570 (“no person shall introduce or deliver for introduction into intrastate commerce any new drug which is subject to section 505 of the [FDCA]...”).

213. Defendants engaged in unfair and deceptive acts or practices in and affecting commerce by marketing, prescribing, manufacturing, and selling unapproved oral tirzepatide formulations to consumers, including Plaintiff and the Multistate Consumer Protection Subclass, through misleading online representations that such products were safe, effective, and medically supervised treatments for weight loss and diabetes management.

214. Defendants’ conduct included, but was not limited to:

- a. Representing that their compounded oral tirzepatide products were clinically effective and comparable to FDA-approved injectable GLP-1 medications (¶¶ 66-81, 91-92);
- b. Advertising that such products were prescribed by “world-class, U.S.-based, board-certified clinicians,” when in fact no meaningful individualized physician evaluation occurred (¶¶ 63-64, 66-81, 85-86, 98);
- c. Misrepresenting or concealing that no oral formulation of tirzepatide has been approved by the U.S. Food and Drug Administration, and that no scientific evidence supports the safety or efficacy of the compounded oral tirzepatide formulation (¶¶ 64-75; *see also* ¶¶ 40-49);
- d. Failing to disclose that the products were mass-produced by Triad Rx rather than compounded individually for any particular patient (¶¶ 90, 96-97, 101); and
- e. Using deceptive endorsements, fabricated testimonials, and fictitious medical affiliations to induce consumer purchases (¶¶ 61, 66-81, 87, 93-102).

215. These representations and omissions were material because they would affect the purchase decisions of a reasonable consumer. Plaintiff and Class Members reasonably believed they were purchasing a legitimate and medically effective GLP-1 medication, specifically “oral tirzepatide,” under physician supervision.

216. In truth, Defendants’ oral tirzepatide product was pharmacologically ineffective, unapproved, and unsafe for human consumption. The advertising and representations described above were false and misleading and had the capacity to deceive consumers.

217. Defendants’ acts and omissions occurred in and affected commerce within the meaning of the various consumer protection statutes because they involved the marketing, sale, and delivery of pharmaceutical products to consumers in the Multistate Consumer Protection Subclass states and throughout the United States.

218. Defendants owed Plaintiff and Class Members a duty to disclose the true nature of their products and operations because such facts were known exclusively to Defendants, were material to consumers’ purchasing decisions, and were actively concealed through coordinated misrepresentations on their websites and marketing platforms.

219. Plaintiff and Class Members reasonably relied on Defendants’ misrepresentations and omissions when purchasing oral tirzepatide. But for these deceptive statements, they would not have purchased the products or paid the inflated prices demanded.

220. As a direct and proximate result of Defendants’ unfair and deceptive acts and omissions, Plaintiff and Class Members suffered ascertainable losses, including the purchase price of the ineffective medication and additional costs related to cancelling subscriptions or replacing the products with legitimate treatment.

221. Defendants’ conduct also constitutes a *per se* violation of each state’s consumer protection statute. Every state within the Multistate Consumer Protection Subclass prohibits the in-state sale, offer for sale, or delivery of a “new drug” that has not received premarket approval from FDA or the state’s appropriate regulatory authority.

- a. The oral tirzepatide products are drugs within the meaning of these laws because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. 21 U.S.C. § 321(g).
- b. These drugs are also *new drugs* as defined by section 201(p) of the FDCA (21 U.S.C. § 321(p)), because they are not generally recognized as safe and effective for their labeled uses.
- c. With certain exceptions not applicable here, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FDCA (21 U.S.C. § 355(a)).
- d. No approved applications pursuant to section 505 of the FDCA are in effect for these oral tirzepatide products. Accordingly, their introduction or delivery for introduction into interstate commerce violates FDCA sections 505(a) and 301(d) (21 U.S.C. § 331(d)).

222. Defendants’ manufacture, marketing, and sale of compounded oral tirzepatide—an unapproved “new drug”—constitute violations of each state’s drug-approval provisions. Because these statutes are designed to protect consumers from unsafe and ineffective pharmaceutical products, violations of such laws are *per se* unfair or deceptive acts or practices

under the consumer protection statutes of the states in the Multistate Consumer Protection Subclass.

223. Moreover, Defendants cannot invoke the Section 503A compounding exemption of the federal FDCA, 21 U.S.C. § 353a. That safe harbor applies only where compounded medications are prepared pursuant to a valid prescription for an *identified individual patient* and tailored to that patient's specific medical needs. The oral tirzepatide products at issue here were mass-produced by Triad Rx at the direction of OpenLoop for distribution through numerous GLP-1 marketing websites, not compounded in response to any individualized prescription. As such, Defendants' conduct falls outside the 503A exemption and squarely within the prohibition on the sale of unapproved new drugs.

224. Pursuant to the remedial provisions of the applicable consumer protection statutes, Plaintiff and the Multistate Consumer Protection Subclass seek all available relief, including treble damages where authorized, reasonable attorneys' fees, injunctive relief prohibiting Defendants from marketing or selling unapproved oral tirzepatide products, and any further relief the Court deems just and proper.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of other members of each Class proposed in this Action, respectfully request that the Court enter judgment in Plaintiff's favor and against all Defendants as follows:

- A. Declaring that this is a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the proposed Class requested herein, designating Plaintiff as Class Representative and appointing the undersigned counsel as Class Counsel.

- B. Entry of a Declaratory Judgment that declares the misconduct alleged in this Complaint and adduced through discovery a violation of applicable statutory and common law.
- C. Enjoining Defendants, their agents, employees, successors, and assigns from continuing to manufacture, market, advertise, sell, or distribute “oral tirzepatide” products, and requiring Defendants to implement appropriate compliance, quality-control, and disclosure measures to prevent future violations;
- D. Ordering restitution and disgorgement of all monies wrongfully obtained from Plaintiff and Class Members through the sale of unapproved and ineffective compounded “oral tirzepatide” products;
- E. Awarding actual damages, compensatory damages, and punitive damages in an amount to be determined at trial;
- F. Awarding treble damages as permitted by 18 U.S.C. § 1964(c), N.C. Gen. Stat. § 75-16, and other applicable statutes;
- G. Ordering Defendants to pay attorneys’ fees and litigation costs to Plaintiff and Class Members;
- H. Ordering Defendants to pay both pre- and post-judgment interest on any amounts awarded; and
- I. Ordering such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims in this Class Action Complaint so triable.

Dated: November 20, 2025

Respectfully submitted,

**CHIMICLES SCHWARTZ KRINER &
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