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o Nordisk Inc. v. Dunklau Pharmacy Holdings, LLC et al, Docket No. 3:24-cv-006
). Tenn. May 30, 2024), Court Docket

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASVHILLE DIVISION

NOVO NORDISK INC. Plaintiff, v. DUNKLAU PHARMACY HOLDINGS, LLC, D/B/A MIDTOWN EXPRESS PHARMACY; DR. HANK, LLC, D/B/A 247 HEALTH Defendants.	Case No.

COMPLAINT

Plaintiff Novo Nordisk Inc. ("Plaintiff" or "Novo Nordisk"), by and through its attorneys, Riley & Jacobson PLC and Covington & Burling LLP, files this Complaint against Defendants Dunklau Pharmacy Holdings, LLC, d/b/a Midtown Express Pharmacy ("Midtown"), and Dr. Hank, LLC, d/b/a 247 Health ("247 Health") (together, "Defendants") to enjoin Defendants from their unlawful, false, and misleading business practice of marketing and selling adulterated and misbranded oral sublingual non-FDA approved drugs that claim to contain semaglutide, which pose potential significant risks to patient health. Novo Nordisk does not seek through this lawsuit money damages arising from Defendants' past practice of selling these adulterated and misbranded drugs, but only to prevent Defendants from continuing this practice, which puts patients at potential risk, and alleges the following:

I. FACTUAL ALLEGATIONS

A. Novo Nordisk Is the Only Company in the U.S. with FDA-Approved Drugs Containing Semaglutide

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of this commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule which serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"):

- Wegovy® (semaglutide) injection 2.4 mg, for chronic weight management;
- Ozempic® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg, for adults with type 2 diabetes; and
- Rybelsus® (semaglutide) tablets 7 mg or 14 mg, for adults with type 2 diabetes.

3. Wegovy® is an injectable medication indicated to reduce excess body weight and maintain weight reduction long-term in adults and children aged ≥ 12 years with obesity, and some adults that are overweight with weight-related medical problems, along with a reduced calorie diet and increased physical activity. Wegovy® is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as cardiovascular death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

4. Ozempic® is an injectable medication and Rybelsus® is an oral medicine that are indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. Ozempic® also lowers the risk of major cardiovascular events such as stroke, heart attack or death in adults with type 2 diabetes and known heart disease.

5. Each of Wegovy®, Ozempic®, and Rybelsus® has a unique safety and efficacy profile which is detailed in its respective product label.

6. Wegovy®, Ozempic®, and Rybelsus® are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

7. Wegovy®, Ozempic®, and Rybelsus® have been extensively studied in clinical trials and are FDA-approved for the treatment of patients with serious chronic diseases.

8. Novo Nordisk is the only company in the U.S. with FDA-approved products containing semaglutide. FDA has not approved any generic versions of semaglutide.

9. Novo Nordisk does not sell its semaglutide active pharmaceutical ingredient ("API") to Defendants, or any other compounding pharmacies, for the purposes of compounding semaglutide products.

B. Unnecessary Use of Compounded Drugs Claiming to Contain "Semaglutide" Exposes Patients to Potentially Serious Health Risks

10. According to FDA, "compounded drugs are not FDA-approved," and "the agency does not review compounded versions of these drugs for safety, effectiveness, or quality."[1] Compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs."[2] The Agency has also warned that "[u]necessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks" and that "poor compounding

[1] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (last updated Jan. 10, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[2] FDA, *Compounding and the FDA: Questions and Answers* (last updated June 29, 2022), https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient . . . [which] can lead to serious patient injury and death."[3]

11. Regulatory agencies in the United States and throughout the world have warned the public that taking unapproved compounded or counterfeit products that claim to contain semaglutide can endanger patients. FDA has publicly warned that "illegally marketed semaglutide" "could contain the wrong ingredients, contain too little, too much or no active ingredient at all, or contain other harmful ingredients," and it has warned that "[p]atients should not use a compounded drug if an approved drug is available to treat a patient."[4] FDA recently warned two online entities that unapproved drugs purportedly containing semaglutide "may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether."[5]

12. At least nine state regulators have also issued statements concerning compounding of products that claim to contain semaglutide.[6] For instance, the Alabama Board of Medical

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[3] *Id.*

[4] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (last updated Jan. 10, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[5] FDA, *Warning Letter to www.gorillahealing.com* (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023; FDA, *Warning Letter to www.semaspace.com* (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwsemaspacecom-665848-10022023.

[6] *See* N.J. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Nov. 6, 2023), https://www.njconsumeraffairs.gov/phar/Documents/Semaglutide-Compounding-Statement-04282023.pdf; N.C. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), http://www.ncbop.org/PDF/SemaglutideCompounding.pdf; Miss. Bd. Pharmacy, *Compounded Products Due to Shortage or Due to Special Patient Needs*, https://www.mbp.ms.gov/sites/default/files/inline-

Examiners has cautioned that semaglutide products other than those manufactured by Novo Nordisk "may be contaminated, improperly stored and transported, or adulterated."[7] The Executive Director of the Mississippi Board of Pharmacy advised the Mississippi State Board of Medical Licensure that "substitute ingredients," manufactured in foreign jurisdictions "have not been proven to be legitimate, effective, or manufactured under sanitary conditions."[8] The Mississippi State Board of Examiners "strongly advise[d] medical licensees to refrain from prescribing, dispensing, or administering compounded semaglutide until further notice," because such drugs are "unproven and potentially unsafe."[9]

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images/Semaglutide.compoundguidance%20%28002%29.pdf; Ky. Bd. Pharmacy, Newsletter (June 2023),https://pharmacy.ky.gov/Newsletters/June%202023.pdf ; W. Va. Bd. Pharmacy, *Statement Concerning Semaglutide Compounding* (Apr. 2023), https://www.wvbop.com/admin/attachment/FINALSemaglutideCompoundingStatement21APR2023WVBoPdatedFV.pdf; Meg Farris, *Low-cost weight loss drug banned in La.*, 4WWL (Apr. 27, 2023), https://www.wwltv.com/article/news/health/weight-loss-wednesday/low-cost-weight-loss-drug-banned/289-d2608b63-f8c2-4eb4-9982-0530331d50ea (reflecting ban by Louisiana Board of Pharmacy); Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists; *Id.* ("The Alabama Board of Pharmacy has notified all licensed pharmacists and pharmacies that even when compounding of a semaglutide drug product is allowable under the Food, Drug, and Cosmetic Act, the use of semaglutide salts, the use of any non-pharmaceutical grade active pharmaceutical ingredient (API), or one not produced by an FDA-registered establishment, is prohibited."); Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure* (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[7] Ala. Bd. Med. Exam'rs & Med. Licensure Comm'n, *Concerns with Semaglutide and Other GLP-1 Receptor Agonists*, https://www.albme.gov/press-release/concerns-with-semaglutide-and-other-glp-1-receptor-agonists.

[8] Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of Medical Licensure*, 2 n.4 (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[9] *Id.* at 1–2.

13. Earlier this year, the Obesity Action Coalition, the Obesity Society, and the Obesity Medicine Association released a "Statement to Patients on Compounded GLP-1 Alternatives" that concludes: "[W]e do not recommend the use of these alternatives. If you use these compounded alternatives, you may not be getting what you hoped for. You may also get something you did not want (other active substances have been found in some compounded versions)."[10] And the Australian government recently moved to ban compounding pharmacies in Australia from making GLP-1s like semaglutide based on the safety concerns.[11]

C. Erroneously Manufactured Compounded Drugs Have Historically Endangered Patient Health and Safety

14. The danger is not merely theoretical, as manufacturing and distribution of improperly formulated compounded drugs have endangered or adversely impacted public health. There is a long history of U.S. illnesses and deaths associated with erroneously compounded drugs distributed to patients in various states, including Tennessee.[12]

15. One of the most significant outbreaks was the New England Compounding Center crisis. In 2012, nearly 800 patients in 20 states were diagnosed with a fungal infection after receiving injections of an unapproved preservative-free methylprednisolone acetate drug

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

[11] Ministers Department of Health and Aged Care, *Protecting Australians from Unsafe Compounding of Replica Weight Loss Products* (May 22, 2024), https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products?language=en.

[12] Pew Charitable Trusts, *U.S. Illnesses and Deaths Associated with Compounded or Repackaged Medications 2001-19* (Mar. 2, 2020), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2020/us-illnesses-and-deaths-associated-with-compounded-or-repackaged-medications-2001-19.

manufactured in Massachusetts.[13] The U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died.[14] Tennessee alone reported 153 cases of persons with fungal infections linked to steroid injections and 16 deaths.[15] As FDA has stated, the 2012 fungal meningitis outbreak "was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs," and "many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then."[16]

16. There have been other notable public health incidents involving adulterated compounded drugs affecting Tennessee patients. One notable example occurred in 2013, where a compounding pharmacy in Newbern, Tennessee, prepared preservative-free compounded drugs that were contaminated with bacterial and fungal growth, resulting in patients developing skin and soft tissue abscesses.[17]

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[13] DOJ, *New England Compounding Center Pharmacist Sentenced for Role in Nationwide Fungal Meningitis Outbreak* (Jan. 31, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-31-2018-new-england-compounding-center-pharmacist-sentenced-role-nationwide-fungal.

[14] *Id.*

[15] CDC, *Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count* (updated Oct. 30, 2015), https://archive.cdc.gov/#/details?q=https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html&start=0&rows=10&url=https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html.

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

[17] FDA, *Update on Main Street Family Pharmacy Products: Samples of injectable methylprednisolone acetate test positive for microbial contamination* (last updated June 13, 2013), http://wayback.archive-it.org/7993/20170112024957/http:/www.fda.gov/Drugs/DrugSafety/

17. In the years since the New England Compounding Center crisis, FDA has issued "compounding risk alerts to inform health care professionals, compounders and consumers about risks associated with compounded drugs, including information on adverse events, outbreaks or product quality."[18] These alerts have warned about compounded drugs that did not contain the active ingredient listed on the label of the product[19] and the variability in dosages of the active ingredients in compounded drug products intended for oral and sublingual administration.[20] FDA believes that these issues make it "challenging to predict which potential risks may be associated with these products," and place patients "at risk for serious adverse events, misuse, and abuse."[21]

D. Patients Have Already Reported Adverse Events After Taking Compounded Drugs Claiming to Contain "Semaglutide"

18. FDA has reported that it has "received an increased number of adverse event reports and complaints concerning" compounded drugs claiming to contain semaglutide and has reminded patients and health care professionals that the "agency does not review compounded versions of

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ucm355575.htm.

[18] FDA, *Compounding Risk Alerts* (last updated Oct. 10, 2023), https://www.fda.gov/drugs/human-drug-compounding/compounding-risk-alerts.

[19] FDA, *FDA investigates two adverse events associated with United Pharmacy's compounded glutamine, arginine, and carnitine product for injection* (last updated June 21, 2018), https://www.fda.gov/drugs/human-drug-compounding/fda-investigates-two-adverse-events-associated-united-pharmacys-compounded-glutamine-arginine-and.

[20] FDA, *FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders* (last updated Oct. 10, 2023), https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine.

[21] *Id.*

these drugs for safety, effectiveness, or quality."[22]

19. Despite the historic underreporting of adverse events caused by compounded drugs, according to FDA's Adverse Event Reporting System, there have been 442 cases of adverse events associated with compounded products that claim to contain semaglutide, as of March 31, 2024. Approximately 72 percent (319) of those cases have been classified as "serious" adverse events, approximately 22 percent of those cases (99) have resulted in hospitalization, and seven of those cases involved patient deaths. Several cases listed in the database claim that the compounded product was ineffective or had product quality issues.

20. Tennessee patients have already been put at risk of receiving improperly compounded products purporting to contain semaglutide. One compounding pharmacy located in Nashville allegedly filled thousands of prescriptions per day for compounded weight loss drugs, including those claiming to contain semaglutide.[23] The pharmacy reportedly received complaints about medications being sent to the wrong address, suffered a lapse in national accreditation, and experienced a poor state inspection. One former customer complained that the compounded weight loss drug she received from the pharmacy was ineffective or possibly diluted.[24] After inspecting the facility, the Tennessee Board of Pharmacy met to discuss immediately suspending

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[22] Letter from F. Gail Bormel, Director, CDER Off. Compounding Quality & Compliance, to Lemrey Carter, Exec. Dir./Sec'y, Nat'l Ass'n Bds. Pharmacy (Oct. 10, 2023), *available at* https://www.fda.gov/media/173456/download?attachment; FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (last updated Jan. 10, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[23] Daniel Gilbert, *The boom in imitation Ozempic went bust for one pharmacy and its clients*, The Washington Post (Jan. 15, 2024), https://www.washingtonpost.com/business/2024/01/15/aca-pharmacy-weight-loss-drugs/.

[24] *Id.*

the pharmacy's operations due to sterility issues and the pharmacy ultimately surrendered its sterile compounding license.[25] A few days later, the pharmacy permanently closed.

E. Defendants' Activities Violate Tennessee Laws Against Selling Adulterated and Misbranded Drugs

21. The Tennessee Food, Drug and Cosmetic Act, among other things, prohibits compounding pharmacies in Tennessee from manufacturing or selling any compounded drug that is adulterated or misbranded. Tenn. Code § 53-1-103(a)(1), (2).

22. Tennessee's adulterated drug provisions are designed to ensure that Tennesseans are treated with safe and effective medicines. Under Tennessee law, a drug is adulterated under state law if, among other things, "its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." Tenn. Code § 53-1-108(3).

23. Under Tennessee law, a drug is misbranded under state law if, among other things, "its labeling is false or misleading in any particular." Tenn. Code § 53-1-109(a)(1).

24. Defendants market and sell to patients certain non-FDA approved compounded drugs that claim to contain "1MG/ML" of "semaglutide," which Defendants call "Weight Drops (Semaglutide)." However, testing of Defendants' compounded drugs performed on Novo Nordisk's behalf has revealed that Defendants' drug product is both adulterated and misbranded because *no* semaglutide was detected. Accordingly, their strength, purity, and quality fall well below what they purport to contain. Additionally, by claiming that Weight Drops (Semaglutide)

[25] Tenn. Bd. Pharmacy, *Board Meeting*, (Aug. 3, 2023), https://www.tn.gov/content/dam/tn/health/healthprofboards/pharmacy/Mins08-23.pdf; Order of Voluntary Surrender In Lieu of Summary Action, In the Matter of ACA Pharmacy, LLC (Tenn. Dep't of Health Bd. Pharmacy, Aug. 4, 2023), *available at* https://www.washingtonpost.com/documents/89376bb9-113b-46e8-8a4c-a6145cfb6178.pdf.

contain semaglutide when they do not, Defendants' unapproved drug's labeling is false and misleading.

25. Weight Drops (Semaglutide) solution highlights one of the many risks associated with compounded drugs: that the ingredients listed on the labeling of the compounded drug may not accurately reflect the ingredients contained within the product. When the ingredients in the product do not match the labeling, patients are exposed to potential safety and effectiveness risks, including lack of efficacy of a product used in treating their condition. Furthermore, patients taking an ineffective drug purporting to contain semaglutide are losing the opportunity to receive treatment that would be effective at treating their condition, such as Ozempic® or Wegovy®.

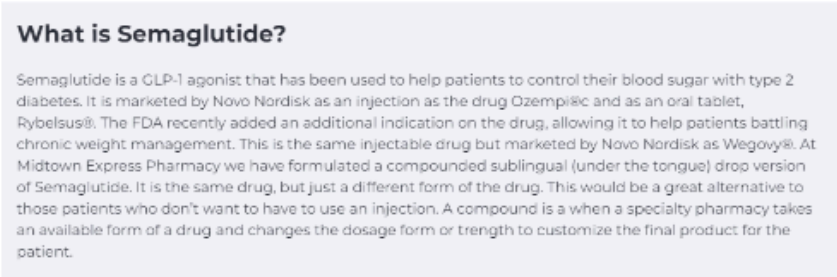
F. Defendants Falsely Market Their Drug as Containing Semaglutide and as Being a More Effective Version of Novo Nordisk's FDA-Approved Semaglutide Products

26. Defendants' marketing and sales of Weight Drops (Semaglutide), their sublingual, unapproved compounded drug claiming to contain "semaglutide," are false and misleading in several respects.

27. Centrally, Defendants' claim that their compounded drug is, or contains, semaglutide is blatantly false. As described above, testing of Defendants' unapproved drug detected *no* semaglutide.

28. In addition, Defendants have made numerous statements falsely equating its drug to Novo Nordisk's FDA-approved semaglutide medicines. Again, Defendants' drug contains no semaglutide. And even if Defendants' drug did contain some level of semaglutide, the statements would remain false and misleading because they misrepresent the nature of compounded drugs like Defendants', as well as their relationship to Novo Nordisk's FDA-approved medicines. Illustrative examples of Defendants' false statements are collected in the paragraphs that follow, as well as Exhibits A through H.

29. Midtown falsely or misleadingly markets its unapproved drug as being "a compounded sublingual (under the tongue) drop version of Semaglutide" which is "marketed by Novo Nordisk as an injection as the drug Ozempic® and as an oral tablet, Rybelsus®." Midtown notes that its unapproved drug is "the same drug, but just a different form of the drug," and that its unapproved drug is a "great alternative to those patients who don't want to have to use an injection." The below image, attached hereto as Exhibit A, is a true and correct representation of information provided by Midtown to prospective customers via its website (https://midtownexpresspharmacy.com/blog/semaglutide-powered-weight-loss/).

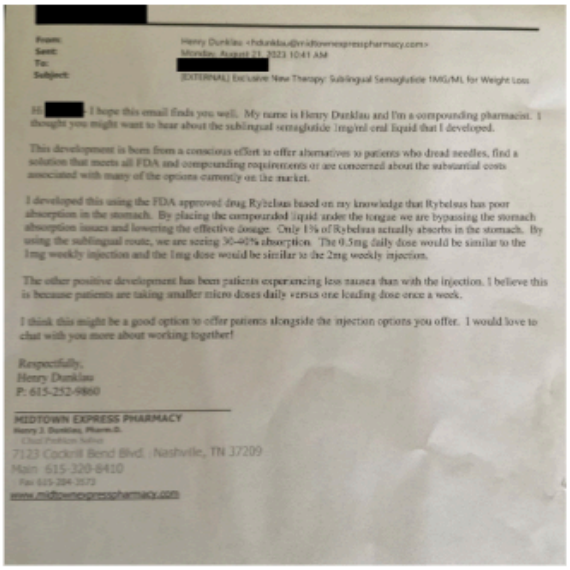


What is Semaglutide?

Semaglutide is a GLP-1 agonist that has been used to help patients to control their blood sugar with type 2 diabetes. It is marketed by Novo Nordisk as an injection as the drug Ozempi®c and as an oral tablet, Rybelsus®. The FDA recently added an additional indication on the drug, allowing it to help patients battling chronic weight management. This is the same injectable drug but marketed by Novo Nordisk as Wegovy®. At Midtown Express Pharmacy we have formulated a compounded sublingual (under the tongue) drop version of Semaglutide. It is the same drug, but just a different form of the drug. This would be a great alternative to those patients who don't want to have to use an injection. A compound is a when a specialty pharmacy takes an available form of a drug and changes the dosage form or trength to customize the final product for the patient.

30. Such statements are false, including because testing of Defendants' drug did not detect any semaglutide.

31. Dr. Henry Dunklau, the president and owner of Midtown, has sent at least one email to prescribers falsely and misleadingly claiming that he developed the unapproved drug "using the FDA approved drug Rybelsus based on [his] knowledge that Rybelsus has poor absorption in the stomach." He also claimed that "[t]he 0.5mg daily dose would be similar to the 1mg weekly injection and the 1mg dose would be similar to the 2mg weekly injection." The below image, attached hereto as Exhibit B, is a true and correct representation of information provided by Midtown to prospective customers via email.



From: Henry Dunklau <hdunklau@midtownexpresspharmacy.com>
Sent: Monday, August 21, 2023 10:41 AM
To: [redacted]
Subject: [EXTERNAL] Exclusive New Therapy: Sublingual Semaglutide 1MG/ML for Weight Loss

Hi [redacted], I hope this email finds you well. My name is Henry Dunklau and I'm a compounding pharmacist. I thought you might want to hear about the sublingual semaglutide 1mg/ml oral liquid that I developed.

This development is born from a conscious effort to offer alternatives to patients who dread needles, find a solution that meets all FDA and compounding requirements or are concerned about the substantial costs associated with many of the options currently on the market.

I developed this using the FDA approved drug Rybelsus based on my knowledge that Rybelsus has poor absorption in the stomach. By placing the compounded liquid under the tongue we are bypassing the stomach absorption issues and lowering the effective dosage. Only 1% of Rybelsus actually absorbs in the stomach. By using the sublingual route, we are seeing 30-40% absorption. The 0.5mg daily dose would be similar to the 1mg weekly injection and the 1mg dose would be similar to the 2mg weekly injection.

The other positive development has been patients experiencing less nausea than with the injection. I believe this is because patients are taking smaller micro doses daily versus one loading dose once a week.

I think this might be a good option to offer patients alongside the injection options you offer. I would love to chat with you more about working together!

Respectfully,
Henry Dunklau
P: 615-252-9860

MIDTOWN EXPRESS PHARMACY
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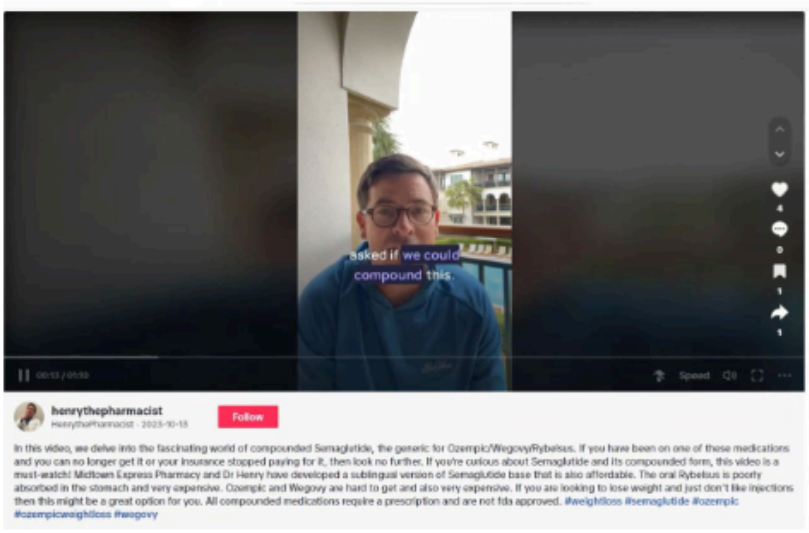
32. Midtown has similarly promoted its drug via TikTok by describing it as "power[ed] by semaglutide, an FDA-approved drug." The below images, attached hereto as Exhibit C, are true and correct representations of information provided by Midtown to prospective customers via TikTok video.

@henrythepharmacist, TikTok (Jan. 30, 2024) (available at https://www.tiktok.com/t/ZT8TgbXo5/).

33. Such claims about the relationship between Defendants' drug and Novo Nordisk's FDA-approved medicines are false. Testing of Defendants' drug detected no semaglutide, rendering false any comparison to Rybelsus® or an injectable product, Ozempic® or Wegovy®, that contains semaglutide. In addition, to the extent that Defendants' drug contains any semaglutide, that semaglutide is certainly not the same semaglutide that was reviewed and evaluated by FDA in connection with its approval of Novo Nordisk's FDA-approved semaglutide medicines, Rybelsus®, Wegovy®, and Ozempic®.

34. Midtown's claims about the efficacy of its drugs as compared to Novo Nordisk's FDA-approved semaglutide medicine are also false because FDA has not evaluated the efficacy of Defendants' drug and, on information and belief, no other data exists to support such assertions.

35. Midtown has promoted its drug via TikTok by describing it as "the generic for Ozempic/Wegovy/Rybelsus." The below image, attached hereto as Exhibit D, is a true and correct representation of information provided by Midtown to prospective customers via TikTok video.



@henrythepharmacist, TikTok (Oct. 13, 2023) (available at https://www.tiktok.com/t/ZT8TG75tn/).

36. This claim is false, including because FDA has not approved any generic versions of semaglutide and therefore has not determined that Defendants' product meets the safety and efficacy standards required for generic drugs.

37. Dr. Henry Dunklau, 247 Health's Chief Pharmacy Officer, advertises Weight Drops (Semaglutide) on 247 Health's website, stating that "Weight Drops are compounded with the power of semaglutide, an FDA-approved medication that aids in weight loss. But what truly sets this product apart from our competitors is how easy and pain-free it is to use." The below image, attached hereto as Exhibit E, is a true and correct representation of information provided by 247 Health on its website, and the full video is available at https://youtu.be/I2yDt3er7-A.

Transform Your Health With Weight Drops | Chief Pharmacist Demo, 247 Health, available at https://youtu.be/I2yDt3er7-A and at 247Health.com.

38. 247 Health's website contains multiple claims that its products are FDA-approved or are compounded from FDA-approved medications. The below image, attached hereto as

Exhibit F, is a true and correct representation of information provided by 247 Health on its website.

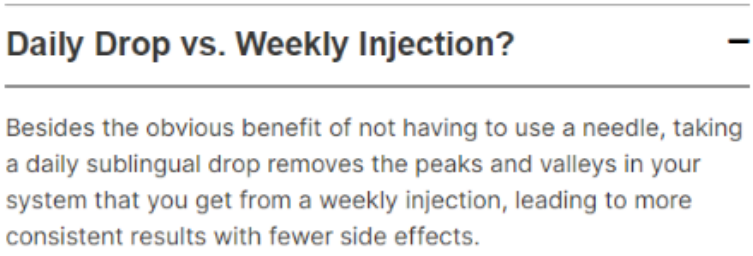
39. Such statements are false, including because testing of Defendants' drug did not detect any semaglutide.

40. Such claims about the relationship between Defendants' drug and Novo Nordisk's FDA-approved medicines are false. Testing of Defendants' drug detected no semaglutide.

41. 247 Health advertises that its Weight Drops (Semaglutide) have "fewer side effects" than injectable weight loss drugs, like Novo Nordisk's semaglutide medicines, Ozempic® and Wegovy®. The below image, attached hereto as Exhibit F, is a true and correct representation of claims made by 247 Health on its website.

https://247health.com/

42. 247 Health also advertises that its drops "remove[] the peaks and valleys in your systems that you get from a weekly injection, leading to more consistent results with fewer side effects." The below image, attached hereto as Exhibit G, is a true and correct representation of information provided by 247 Health on its website.



https://247health.com/

43. 247 Health's claims about the efficacy of its drugs as compared to Novo Nordisk's FDA-approved semaglutide medicine are false. FDA has not evaluated the efficacy of Defendants' drug and, on information and belief, no other data exists to support such assertions. Defendants' claims are also necessarily false and misleading given that testing of Defendants' drug detected no semaglutide.

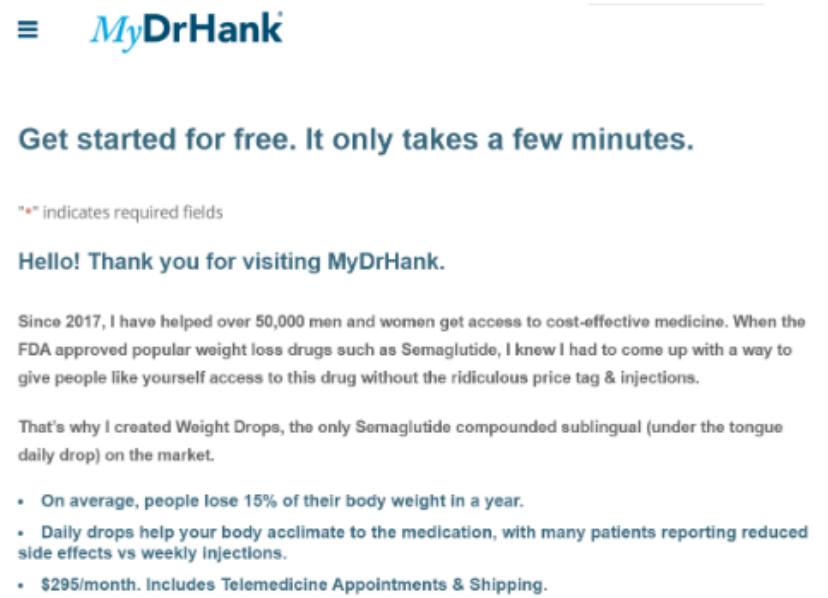
44. 247 Health also advertises its compounded drug by including links to articles from The New York Times, Wall Street Journal, Forbes, The Guardian, and CBS News, falsely and misleadingly representing that those articles support the efficacy and safety of its compounded drug. However, each of these articles instead discusses Novo Nordisk's semaglutide medicines or other FDA-approved weight loss medicines, not Defendants' compounded drug. The below image, attached hereto as Exhibit G, is a true and correct representation of information provided by 247 Health on its website.

https://247health.com/.[26]

45. Such claims about the relationship between Defendants' drug and Novo Nordisk's FDA-approved medicines are false. Testing of Defendants' drug detected no semaglutide.

[26] This website links to the following articles: Gina Kolata, *'A Game Changer': Drug Brings Weight Loss in Patients With Obesity*, N.Y. Times (Feb. 10, 2021), https://www.nytimes.com/2021/02/10/health/obesity-weight-loss-drug-semaglutide.html; Peter Loftus, *A Promising Weight-Loss Aid Emerges: Diabetes Drugs*, Wall St. J. (June 21, 2022), https://www.wsj.com/articles/a-promising-weight-loss-aid-emerges-diabetes-drugs-11655823679; Bruce Y. Lee, *Is Wegovy, New Obesity Drug Approved By FDA, Really A 'Game Changer'?*, Forbes (June 7, 2021), https://www.forbes.com/sites/brucelee/2021/06/07/is-wegovy-new-obesity-drug-approved-by-fda-really-a-game-changer/?sh=9c59a8a65f2c; Nicola Davis, *Diabetes Dru gLeads to Notable Weight Loss In People With Obesity – Study*, Guardian (June 5, 2022), https://www.theguardian.com/science/2022/jun/05/diabetes-drug-tirzepatide-leads-to-notable-weight-loss-in-people-with-obesity-study; Julie Appleby, *New Generation of Weight Loss Medications Offer Promise – But at a Price* , CBS News (Oct. 19, 2022), https://www.cbsnews.com/news/weight-loss-medications-wegovy-price/.

46. MyDrHank.com ("MyDrHank"), a website owned and operated by Dr. Hank, LLC d/b/a 247 Health, advertises its "Semaglutide compounded sublingual" Weight Drops (Semaglutide) as containing semaglutide, and as being FDA-approved like "popular weight loss drugs," which refers to Novo Nordisk's FDA-approved semaglutide medicines. MyDrHank also advertises that its Weight Drops (Semaglutide) have "reduced side effects vs weekly injections," such as Novo Nordisk's injectable semaglutide medicines. The below image, attached hereto as Exhibit H, is a true and correct representation of information provided by MyDrHank on its website.



https://mydrhank.com/weight-loss-pt1/

47. Such statements are false, including because testing of Defendants' drug did not detect any semaglutide.

48. Such claims about the relationship between Defendants' drug and Novo Nordisk's FDA-approved medicines are false. Testing of Defendants' drug detected no semaglutide. To the extent that Defendants' drug contains any semaglutide, that semaglutide is certainly not the same semaglutide that was reviewed and evaluated by FDA in connection with its approval of Novo Nordisk's FDA-approved semaglutide medicines, Rybelsus®, Wegovy®, and Ozempic®. In addition, semaglutide has not been approved by FDA, which approves medicines, not active pharmaceutical *ingredients* like semaglutide.

49. MyDrHank's claims about the efficacy of its drugs as compared to Novo Nordisk's FDA-approved semaglutide medicine are also false because, on information and belief, no data exists to support such assertions. Defendants' claims are also necessarily false and misleading given that testing of Defendants' drug detected no semaglutide.

50. Defendants' statements are likely to deceive consumers into believing, erroneously, that its unapproved drug purporting to contain semaglutide does contain semaglutide, and that it is the same as Novo Nordisk's FDA-approved semaglutide medicines but in a different form. Defendants' statements are also likely to deceive customers into believing that the compounded drug is safe and effective by comparing it to Novo Nordisk's FDA-approved semaglutide medicine.

51. Defendants knew or should have known that these statements were false and that they would be likely to induce customers to rely on these statements in order to purchase Defendants' unapproved compounded drugs, believing them to contain semaglutide and to be a

safer, more effective alternative to Novo Nordisk's FDA-approved medicines containing semaglutide.

G. Plaintiff Has Been Injured by Defendants' Unlawful, Deceptive, and Unfair Competition

52. Novo Nordisk is the only company in the United States with FDA-approved products containing semaglutide.

53. Defendants sell their adulterated and misbranded drugs claiming to contain semaglutide to customers in Tennessee and other states (originating from Defendants located and/or conducting business in Tennessee). As noted above, Novo Nordisk is the only company that offers FDA-approved medicines containing semaglutide. As a result of Defendants' unlawful, deceptive, and unfair competition, which jeopardizes public health, Novo Nordisk has and will continue to suffer ascertainable loss, in the form of harm to its goodwill and reputation. Additionally, absent Defendants' unlawful and unfair actions, sales made by Defendants in Tennessee and in these other states would and will have been made by Novo Nordisk; thus, Novo Nordisk has and will suffer ascertainable loss in the form of lost sales and customers as a direct result of Defendants' unlawful acts and false advertising. Novo Nordisk does not seek through this lawsuit money damages arising from Defendants' past practice of selling these adulterated and misbranded drugs, but only to prevent Defendants from continuing this practice, which potentially puts patients at risk.

H. Plaintiff Seeks to Enjoin Defendants From Their Unlawful Practices

54. Novo Nordisk brings this action under Tennessee's Consumer Protection Act ("TCPA") to stop Defendants from unlawfully manufacturing, marketing, selling, and distributing their adulterated and misbranded drugs. Novo Nordisk seeks a declaration that Defendants' business practices violate TCPA and the Lanham Act by manufacturing, distributing, and selling their adulterated and misbranded drugs and entry of a preliminary and permanent injunction

prohibiting Defendants from committing such violations. Novo Nordisk also seeks attorney's fees and court costs, but does not seek monetary damages for Defendants' past violations of TCPA or the Lanham Act.

II. THE PARTIES

55. Novo Nordisk is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in New Jersey.

56. Novo Nordisk promotes, offers, and/or sells FDA-approved semaglutide-based products—Wegovy®, Ozempic®, and Rybelsus®—throughout the United States. Novo Nordisk is the only company in the U.S. with FDA-approved products containing semaglutide. FDA has not approved any generic versions of semaglutide. Novo Nordisk does not sell its semaglutide active pharmaceutical ingredient ("API") to Defendants, or any other compounding pharmacies, for the purposes of compounding semaglutide products.

57. Novo Nordisk and/or its parents and affiliates have invested significant time and resources to research, develop, manufacture, and test Wegovy®, Ozempic®, and Rybelsus® in order to obtain regulatory approval from FDA to market these drugs.

58. Midtown is a limited liability company organized and existing under the laws of Tennessee, with its principal place of business at 7123 Cockrill Bend Blvd., Nashville, TN 37209. The managing member of Midtown is Dr. Henry Dunklau. Upon information and belief, Midtown manufactures its drugs in this judicial district and sells them in this judicial district, throughout Tennessee, and in several other states.

59. Dr. Hank, LLC does business as 247 Health and owns and operates the website located at 247Health.com. *See* 247 Health Terms of Use, available at https://247health.com/terms-of-use/. On a video on 247Health.com Dr. Henry Dunklau states that he is the "Chief Pharmacy

Officer of 247 Health and the pharmacy owner of Midtown Express Pharmacy in Nashville, Tennessee" and advertises that the compounded drugs marketed and sold by 247 Health are compounded "right here at our pharmacy in Nashville, Tennessee." Upon information and belief, 247 Health obtains its Weight Drops (Semaglutide) from Midtown and sells them in this judicial district, throughout Tennessee, and in several other states.

60. Dr. Hank, LLC also owns and operates the website located at MyDrHank.com. *See* MyDrHank Terms of Use, available at https://mydrhank.com/terms-of-use/. Upon information and belief, MyDrHank obtains its Weight Drops (Semaglutide) from Midtown and sells them in this judicial district, throughout Tennessee, and in several other states.

III. JURISDICTION AND VENUE

61. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1338(a). The Court has supplemental jurisdiction over the state law cause of action pleaded herein pursuant to 28 U.S.C. § 1338(b) and 28 U.S.C. § 1367(a).

62. This Court has personal jurisdiction over Defendants. Defendants sell its drugs in this District and, upon information and belief, Defendants ship those adulterated and misbranded drugs throughout Tennessee and into several other states from this District. Plaintiff's claims arise out of or relate to Defendants' activities in this District.

63. Venue in this District is proper under 28 U.S.C. § 1391(b).

IV. FIRST CAUSE OF ACTION

(Defendants' False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B))

64. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1–63, above, as if fully stated herein.

65. Defendants' practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

66. Defendants have violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in their commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendants' business practices and products, as set forth above. Defendants have misrepresented that their drug contains semaglutide, and that it is the same, similar, or superior to Novo Nordisk's FDA-approved drugs.

67. The above-described acts of Defendants, if not enjoined by this Court, are likely to deceive members of the general public.

68. The above-described acts of Defendants have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiff.

69. The above-described acts of Defendants have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

70. By reason of Defendants' acts as alleged above, Plaintiff has suffered and will continue to suffer injuries, including injury to Plaintiff's business reputation. However, Plaintiff's remedies at law are not adequate to compensate for all the injuries inflicted by Defendants. Accordingly, Plaintiff is entitled to entry of preliminary and permanent injunctive relief requiring Defendants to cease their false and misleading advertising and promotion and unfair competitive practices.

71. This is an exceptional case, making Plaintiff eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

V. SECOND CAUSE OF ACTION

(Violation of Tennessee Consumer Protection Act ("TCPA")
Tenn. Code § 47-18-101, *et seq.*)

72. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1–71, above, as if fully stated herein.

73. The TCPA "protect[s] consumers and legitimate business enterprises from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within this state." Tenn. Code § 47-18-102(2).

74. The TCPA makes "unlawful" "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code § 47-18-104(a).

75. Defendants have violated the TCPA by "[r]epresenting that" their drugs have "characteristics, ingredients, uses, benefits or quantities that they do not have." Tenn. Code § 47-18-104(b)(5). Defendants falsely represent that their drugs contain semaglutide, while the drugs contain *no* semaglutide.

76. In addition, Defendants have violated the TCPA by "[a]dvertising goods or services with intent not to sell them as advertised." Tenn. Code § 47-18-104(b)(9). Defendants advertise their drug as containing semaglutide, while the drug does not actually contain semaglutide.

77. Defendants further engage in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of TCPA when they unlawfully manufacture and sell their adulterated and misbranded drugs in Tennessee (and into other states).

78. Manufacturing and selling compounded drugs that do not contain semaglutide and that falsely purport to contain semaglutide and have better efficacy than Novo Nordisk's FDA-approved drugs is an unfair practice, insofar as it is an abusive business practice that causes or is

likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. It is also deceptive, insofar as it causes or tends to cause consumers to believe what is false or that misleads or tends to mislead a consumer as to a matter of fact.

79. The practices described herein also offend established public policy regarding the protection of consumers and competitors against companies, like Defendants, that engage in unfair methods of competition. Defendants' conduct has caused and will continue to cause ascertainable loss and substantial injury to Novo Nordisk in the form of harm to Novo Nordisk's goodwill and reputation and lost customers that is not outweighed by countervailing benefits to any consumers or competition.

80. The practices described herein have caused harm and injury to consumers and Plaintiff and, if not enjoined, will continue to cause harm and injury to consumers and to Plaintiff.

81. The TCPA further forbids any person from "[a]dvertising, promoting, selling or offering for sale any good or service that is illegal or unlawful to sell in the state." Tenn. Code § 47-18-104(b)(43)(C).

82. The Tennessee Food, Drug and Cosmetic Act specifies that it is unlawful for any person to perform any of the following acts in Tennessee: "[t]he manufacture, sale, or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded," and "[t]he adulteration or misbranding of any food, drug, device or cosmetic." Tenn. Code § 53-1-103(a)(1), (2).

83. A drug is adulterated under state law if, among other things, "its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." Tenn.

Code § 53-1-108(3).[27] Tennessee's adulterated drug provisions are designed to ensure that Tennesseans are treated with safe and effective medicines.

84. A drug is misbranded under state law if, among other things, "its labeling is false or misleading in any particular." Tenn. Code § 53-1-109(a)(1).

85. Defendants have violated TCPA by selling a drug that "is illegal or unlawful to sell in the state." Tenn. Code § 47-18-104(b)(43)(C). Defendants' drugs are adulterated in violation of the Tennessee Food, Drug and Cosmetic Act because they do not contain the strength that they purport or are represented to possess. Defendants' drugs are misbranded in violation of the Tennessee Food, Drug and Cosmetic Act because their labeling and marketing and promotional materials falsely and misleadingly represent them to (i) contain semaglutide, and to (ii) be more effective than Novo Nordisk's FDA-approved semaglutide-based medicines.

86. The TCPA creates a cause of action for anyone "who suffers an ascertainable loss" by a violation of TCPA to bring an action against "the person who has violated, is violating, or who is otherwise likely to violate" the Act. Tenn. Code § 47-18-109(a)(1), (b).

87. As described above, Plaintiff has suffered an ascertainable loss under TCPA.

88. Defendants are a "person" who has violated and is violating TCPA.

89. As a result of Defendants' unlawful and unfair competition, Novo Nordisk has suffered actual damages, including harm to its goodwill and reputation, and lost sales and customers, as well as other injuries.

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[27] Semaglutide is not listed in an official compendium, which means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto. It is therefore not subject to subdivision (2). *See* Tenn. Code § 53-1-108(3).

90. Plaintiff is entitled to declaratory and preliminary and permanent injunctive relief, the value of which exceeds $75,000, as well as reasonable attorney's fees and costs pursuant to Tennessee Code § 47-18-109(e)(1).

VI. CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests judgment against Defendants as follows:

1. That the Court enter a judgment against Defendants that Defendants have:
   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a); and
   b. Violated the TCPA.
2. That the Court enter judgment that each of the above acts was willful.
3. That the Court preliminarily and permanently enjoin and restrain Defendants and their agents, servants, employees, successors, and assigns, and all other persons acting in concert or conspiracy with or affiliated with Defendants from:
   a. continuing the unlawful and unfair business practices alleged in this complaint;
   b. advertising, stating, or suggesting that any compounded drugs, including but not limited to any compounded drugs that either are available, directly or indirectly, from or through Defendants or the use of which or access to which is facilitated by, or with the involvement of, Defendants:
      i. are sponsored by or associated with Novo Nordisk;
      ii. are approved by FDA; have been reviewed by FDA for safety, effectiveness, or quality; or have been demonstrated to FDA to be safe or effective for their intended use;
      iii. achieve or have been shown to achieve certain therapeutic results, effects,

or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines; relying on or making reference to the therapeutic results, effects, or outcomes of Novo Nordisk's medicines; or suggesting that any compounded drugs are interchangeable or equivalent to genuine Novo Nordisk medicines;

iv. are Novo Nordisk medicines, or are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

v. contain any ingredient (including but not limited to semaglutide) that is supplied by Novo Nordisk, is approved by FDA, or is the same as any ingredient in any Novo Nordisk medicine;

c. engaging in any unfair competition with Plaintiff; and/or

d. engaging in any deceptive acts or practices.

4. That the Court require Defendants to disclose conspicuously and prominently in any public-facing materials for any compounded drugs, including but not limited to all advertising, marketing, and promotional materials, that: (a) the compounded drugs are compounded drugs that have not been approved by FDA; have not been reviewed by FDA for safety, effectiveness, or quality; and have not been demonstrated to FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by FDA; and (c) FDA-approved products containing semaglutide are available.

5. That the Court award Plaintiff its reasonable attorneys' fees pursuant to 15 U.S.C. § 1117, Tennessee law, and any other applicable provisions of law.

6. That the Court award Plaintiff the costs of suit incurred herein.

7. That the Court award such other or further relief as it may deem just and proper.

Dated: May 30, 2024

Respectfully submitted,

By: */s/ Steven A. Riley*

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