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]nnecessary 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

[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®.

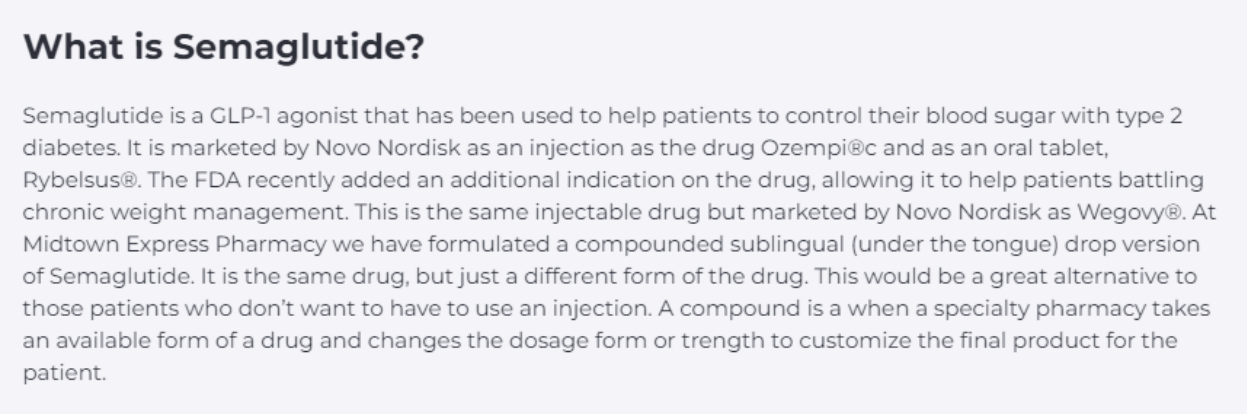
F. Defendants Falsely Market Their Drug as Containing Semaglutide and as Being a More Effective Version of Novo Nordisk's FDA-Approved Semaglutide Products

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/).

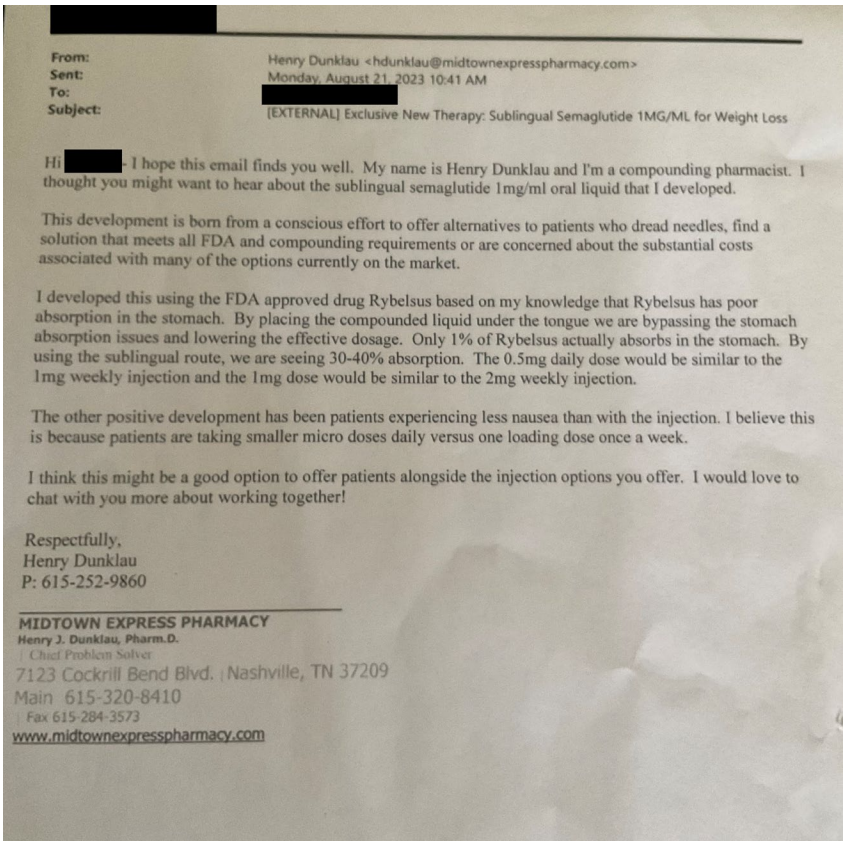


What is Semaglutide?

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.



[redacted]

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
Henry J. Dunklau, Pharm.D.
Chief Problem Solver
7123 Cockrill Bend Blvd. | Nashville, TN 37209
Main 615-320-8410
Fax 615-284-3573
www.midtownexpresspharmacy.com

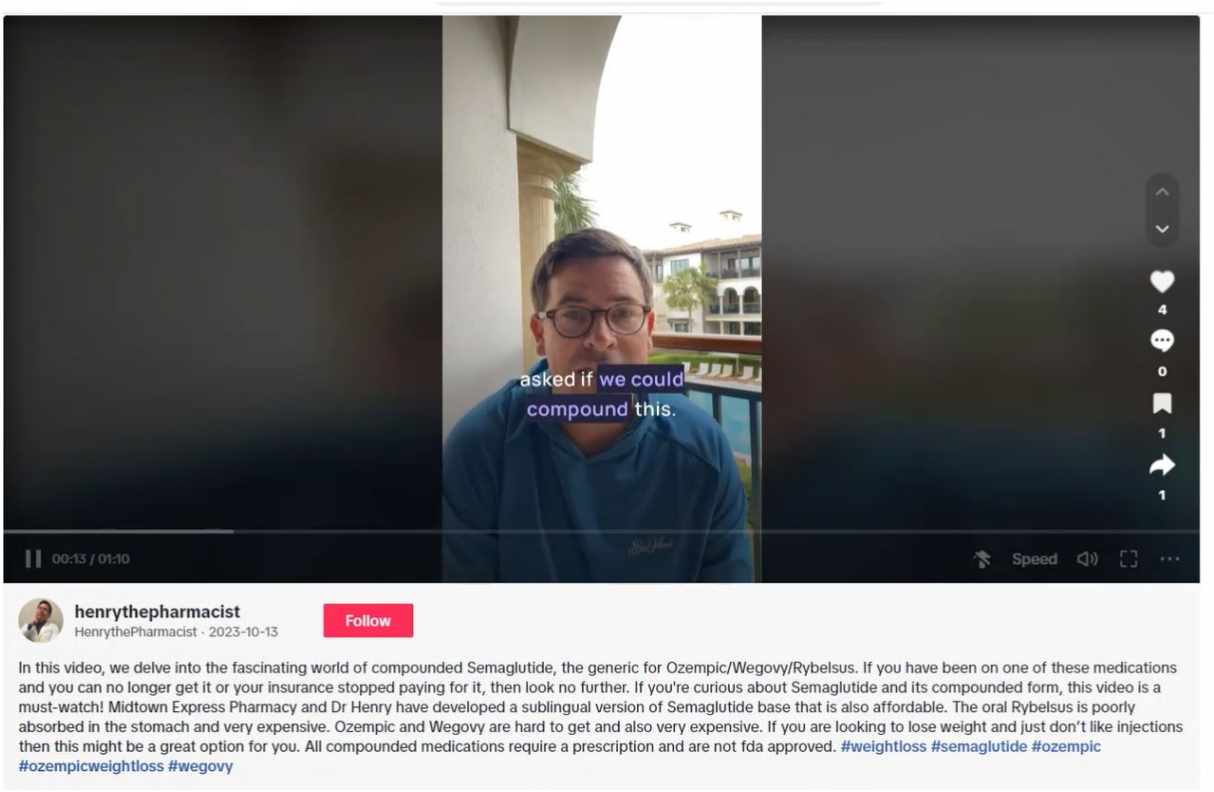
32. Midtown has similarly promoted its drug via TikTok by describing it as "power[ed] by semaglutide, an FDA-approved drug." The below images, attached hereto as Exhibit C, are true and correct representations of information provided by Midtown to prospective customers via TikTok video.

@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/).

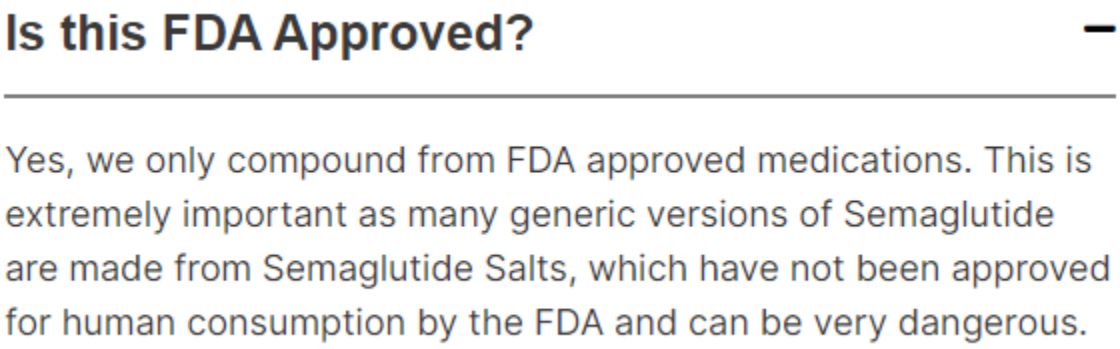
36. This claim is false, including because FDA has not approved any generic versions of semaglutide and therefore has not determined that Defendants' product meets the safety and efficacy standards required for generic drugs.

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.



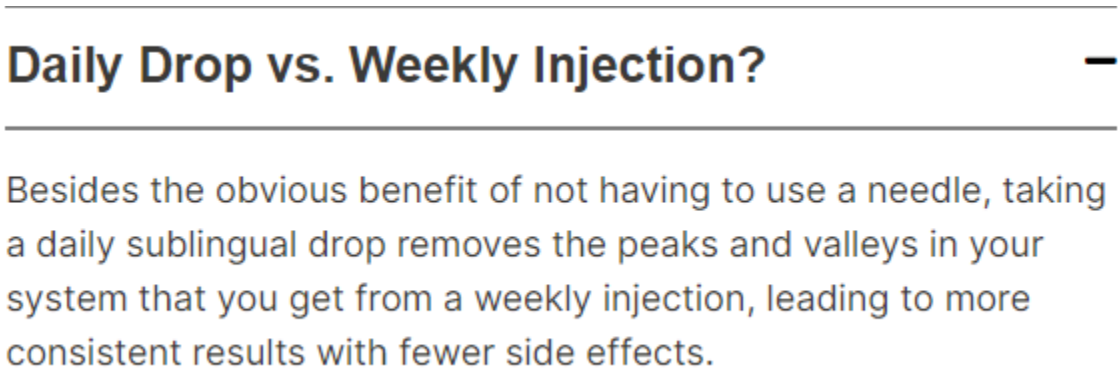
39. Such statements are false, including because testing of Defendants' drug did not detect any semaglutide.

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/

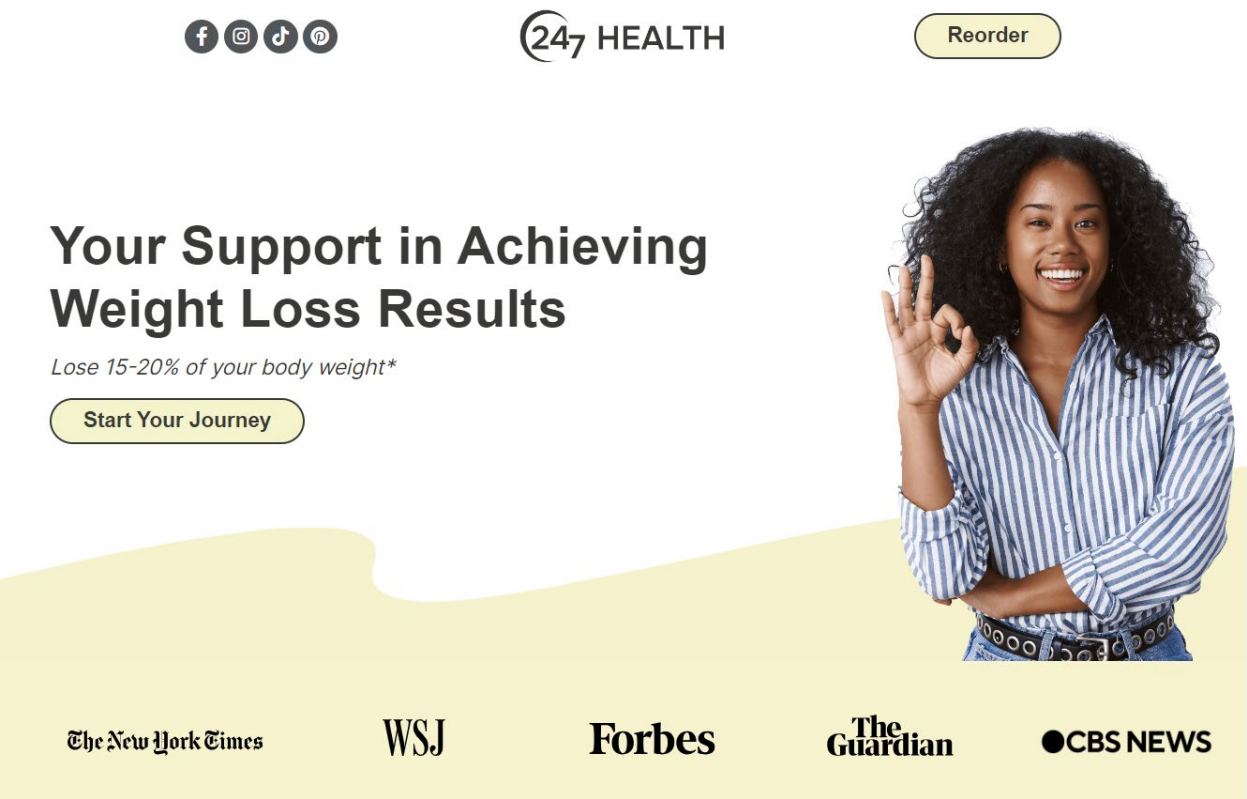
42. 247 Health also advertises that its drops "remove[] the peaks and valleys in your systems that you get from a weekly injection, leading to more consistent results with fewer side effects." The below image, attached hereto as Exhibit G, is a true and correct representation of information provided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

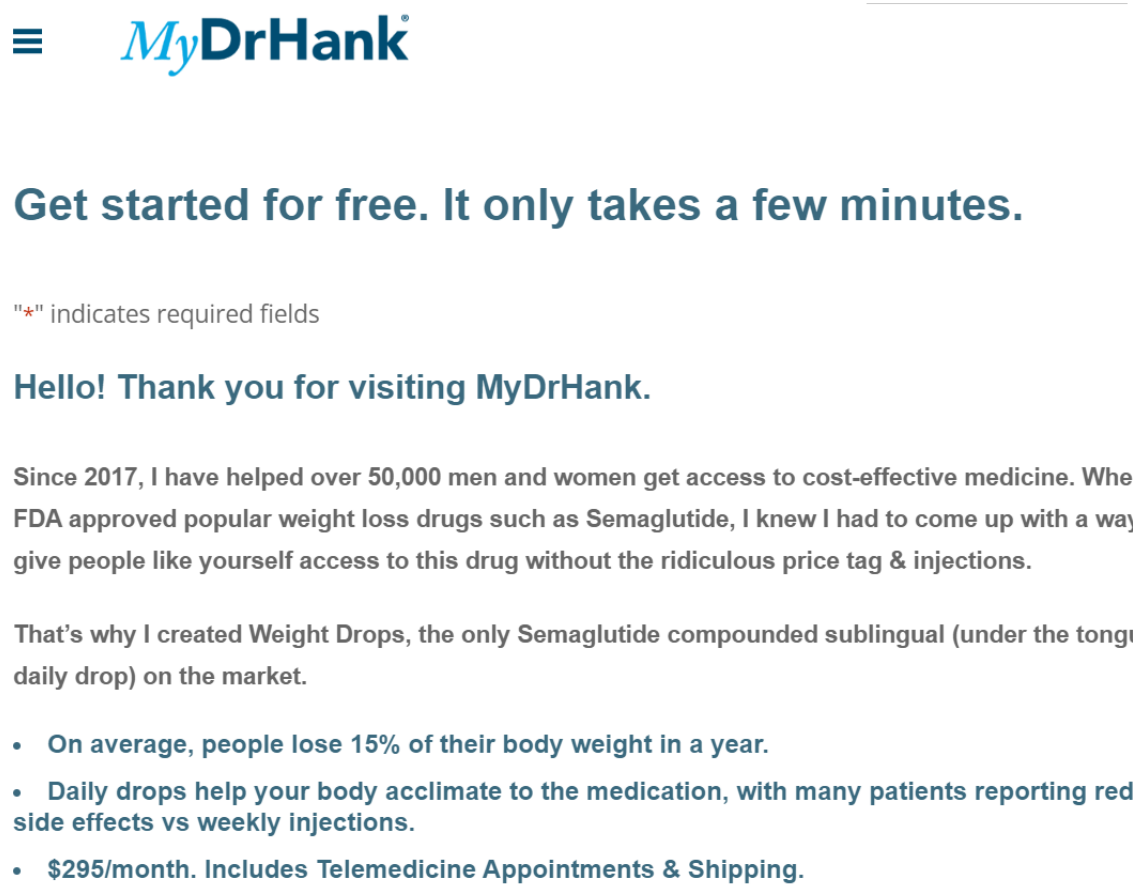


https://247health.com/.[26]

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.

[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*

Steven A. Riley (TN Bar No. 6258)
Milton S. McGee, III (TN Bar No. 24150)
Joseph K. Robinson (TN Bar No. 40440)
RILEY & JACOBSON, PLC
1906 West End Ave.
Nashville, TN 37203
(615) 320-3700
sriley@rjfirm.com
tmcgee@rjfirm.com
jrobinson@rjfirm.com

Michael X. Imbroscio (*pro hac vice forthcoming*)
Amee Frodle (*pro hac vice forthcoming*)
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001-4956
Telephone: (202) 662-6000
Facsimile: (202) 662-6291
mimbroscio@cov.com
afrodle@cov.com

Gregory L. Halperin (*pro hac vice forthcoming*)
COVINGTON & BURLING LLP
The New York Times Building,
620 Eighth Avenue
New York, NY 10018-1405
(212) 841-1166
ghalperin@cov.com

Attorneys for Plaintiff
NOVO NORDISK INC.

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Novo Nordisk Inc.

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Steven A. Riley, Milton S. McGee, III, Riley & Jacobson, PLC, 1906 West End Ave., Nashville, TN 37203 (615) 320-3700; see attachment

DEFENDANTS

Dunklau Pharmacy Holdings, LLC d/b/a Midtown Express Pharmacy; Dr. Hank, LLC d/b/a 247 Health

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

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

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☒ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Violation of Lanham Act; violation of Tennessee Consumer Protection Act

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ Injunction

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
May 30, 2024

SIGNATURE OF ATTORNEY OF RECORD
s/ Steven A. Riley

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

Exhibit A

615-320-8410

MIDTOWN
Express Pharmacy

Semaglutide Powered Weight Loss

July 18, 2023

Losing weight is always difficult if you don't have all the information you need. Its generally as simple as a math equation. You to consume less calories that your body burns daily to ultimately lose weight. Proper diet and exercise is the best way to lose weight and maintain a healthy weight. With that said, its not a fast process and despite your best efforts sometimes, you aren't seeing the results you want and need to see to stay motivated. In some situations, medications may be used in addition to diet and exercise to help give you a jump start. The majority of the medications on the market help reduce your hunger thus reducing how much

you are eating, which gets us back to the equation above. The newest options on the market are GLP-1 agonists like Semaglutide.

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.

What is the Dosage and How is it Supplied?

The medication comes in a 30ml glass bottle with a calibrated dropper. If you are taking semaglutide for the first time, you maybe instructed to start at a lower dose and titrate up based on side effects. Generally, you will take a lower dose for 7 days, then go up incrementally thereafter. You should always take your medication as directed by your doctor and/or pharmacist.

What are the Side Effects of Semaglutide?

The most common side effects are gastrointestinal in nature. You may experience abdominal pain, constipation, diarrhea, nausea and vomiting. These side effects maybe most common at the initiation of the medication and when you increase the dosage amount. If you experience a rash, swelling, or trouble breathing, you should stop using immediately and seek medical attention.

How Do I Get a Compounded Medication?

All compounded medications do require a prescription from your prescriber. We have created a template on this page for you to print out and take to your prescriber. They will then determine if this is appropriate for you to use. The completed prescription can then be brought to the pharmacy, faxed in, electronically prescribed or phoned in by your prescriber's office. You may call the pharmacy at 615-320-8414 for any additional questions.

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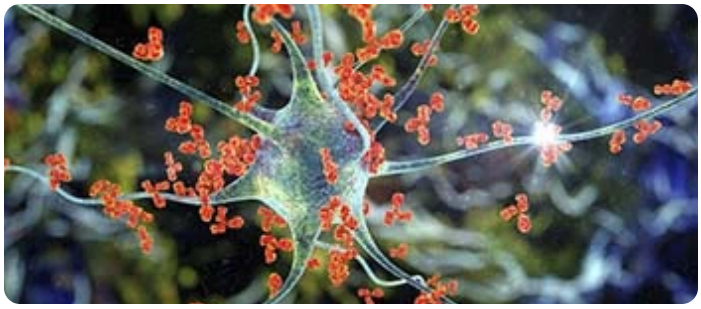

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MIDTOWN
Express Pharmacy

Midtown Express Pharmacy

7123 Cockrill Bend Blvd.
Nashville, TN 37209

View Directions

Give us a call!

615-320-8410

Monday - Friday: 9:00am - 5:00pm

Saturday & Sunday: Closed

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Compounding

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Refill Your Rx

Blog

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Exhibit B

[redacted]

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
Henry J. Dunklau, Pharm.D.
Chief Problem Solver
7123 Cockrill Bend Blvd. | Nashville, TN 37209
Main 615-320-8410
Fax 615-284-3573
www.midtownexpresspharmacy.com

Exhibit C


Semaglutide
Weight Drops
TikTok
are compounded with the
power of SEMA glutide


TikTok
and FDA proved drug that
aids in weight loss

Exhibit D

Case 3:24-cv-00667 Document 1-5 Filed 05/30/24 Page 2 of 2 PageID #: 47

TikTok

Search

For You

Following

Friends

Explore New

LIVE

Profile

Log in to follow creators, like videos, and view comments.

Log in

Create TikTok effects, get a reward

About Newsroom Contact Careers

TikTok for Good Advertise

TikTok LIVE Creator Networks

Developers Transparency

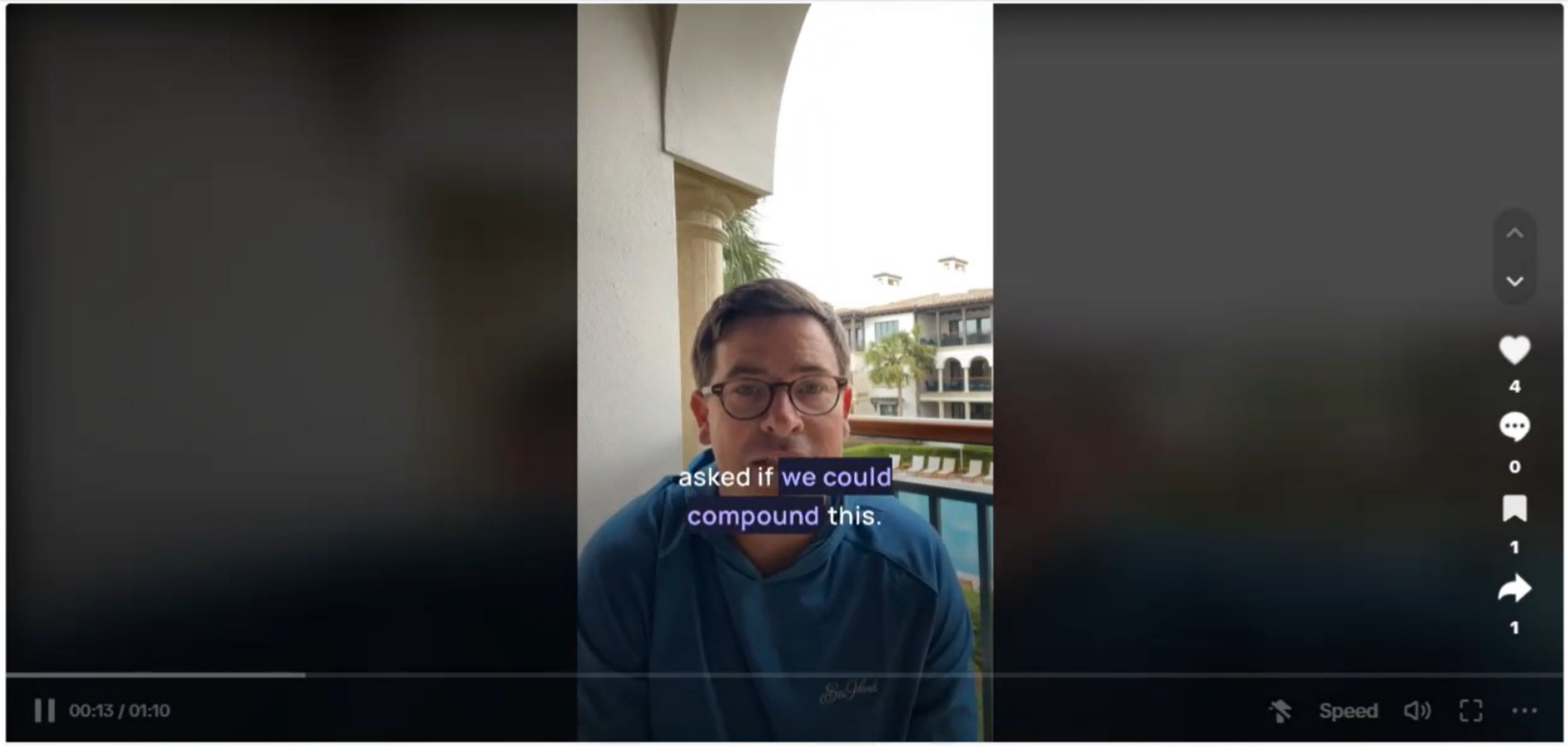
TikTok Rewards TikTok Embeds

Help Safety Terms Privacy Policy

Privacy Center Creator Portal

Community Guidelines

See more



henrythepharmacist

HenrythePharmacist · 2023-10-13

Follow

In this video, we delve into the fascinating world of compounded Semaglutide, the generic for Ozempic/Wegovy/Rybelsus. If you have been on one of these medications and you can no longer get it or your insurance stopped paying for it, then look no further. If you're curious about Semaglutide and its compounded form, this video is a must-watch! Midtown Express Pharmacy and Dr Henry have developed a sublingual version of Semaglutide base that is also affordable. The oral Rybelsus is poorly absorbed in the stomach and very expensive. Ozempic and Wegovy are hard to get and also very expensive. If you are looking to lose weight and just don't like injections then this might be a great option for you. All compounded medications require a prescription and are not fda approved. #weightloss #semaglutide #ozempic #ozempicweightloss #wegovy

Exhibit E


Transform Your Health With Weight Drops | Chief Pharmacist Demo
Watch later
Share
power of Semaglutide,
YouTube

Exhibit F

247 HEALTH

Reorder

Your Support in Achieving Weight Loss Results

*Lose 15-20% of your body weight**

Get Started

The New York Times · WSJ · Forbes · USA TODAY · CBS NEWS

Start Your Weight Loss Transformation Today

Taking Semaglutide is 5x more effective for weight loss than just diet & exercise.

Get Started

1 **Enter Your Information**

Enter your information into a HIPAA compliant form that takes less than 10 minutes to complete.

2 **We Secure Your Prescription**

We connect you with a doctor to secure your prescription within 24 hours.

3 **You Become Your New Self**

Every month, you'll get Weight Drops (Semaglutide) discreetly shipped to your door for free.

Get Started

Unbeatable Price

$199/month. No Membership, Shipping, or Hidden Fees.

Click Below To Start The Weight Loss Experience You Deserve.

Get Started

Ditch The Injections For Daily Drops

Our patients often notice fewer side effects, a benefit of the lower daily dosages we prescribe. This approach allows for effective weight loss with increased comfort and safety.

There's a reason why everyone is talking about semaglutide. **It works.**

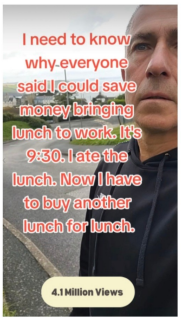
Your current weight: 200

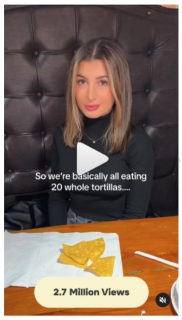
You can lose: **30+ LBS**

Weight Drops Success Story

Dr. Henry Dunklau, ***247 Health's Chief Pharmacy Officer***, is living proof of how effective this innovative medication is for patients battling chronic weight management. Dr. Dunklau has ***lost over 35 pounds on Weight Drops!***

In the below video he demonstrates just how easy, safe, & pain-free it is to lose weight with Weight Drops.





Join Millions Who Trust 247 Health

Get Started

1,300,000 Followers

421,000 Followers

Questions? We Have Answers!

- What is Semaglutide? +
- What is Compounded Semaglutide? +
- Is this FDA Approved? −

Yes, we only compound from FDA approved medications. This is extremely important as many generic versions of Semaglutide are made from Semaglutide Salts, which have not been approved for human consumption by the FDA and can be very dangerous.

- Daily Drop vs. Weekly Injection? +
- Where do you apply Semaglutide? +
- Are There Side Effects of Semaglutide? +
- Do I need a prescription? +
- Why Do I Need a Telemedicine Appt? +
- Do You Accept Insurance? +
- Where is 247 Health Located? +

247 HEALTH

Get the Weight Loss Experience You Deserve

Get Started

Exhibit G

247 HEALTH

Reorder

Your Support in Achieving Weight Loss Results

*Lose 15-20% of your body weight**

Get Started

The New York Times · WSJ · Forbes · USA TODAY · CBS NEWS

Start Your Weight Loss Transformation Today

Taking Semaglutide is 5x more effective for weight loss than just diet & exercise.

Get Started

1. **Enter Your Information** — Enter your information into a HIPAA compliant form that takes less than 10 minutes to complete.
2. **We Secure Your Prescription** — We connect you with a doctor to secure your prescription within 24 hours.
3. **You Become Your New Self** — Every month, you'll get Weight Drops (Semaglutide) discreetly shipped to your door for free.

Get Started

Unbeatable Price

$199/month. No Membership, Shipping, or Hidden Fees.

Click Below To Start The Weight Loss Experience You Deserve.

Get Started

Ditch The Injections For Daily Drops

Our patients often notice fewer side effects, a benefit of the lower daily dosages we prescribe. This approach allows for effective weight loss with increased comfort and safety.

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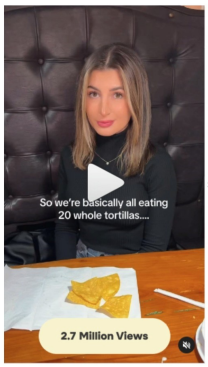

Join Millions Who Trust 247 Health

Get Started

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Questions? We Have Answers!

- What is Semaglutide? +
- What is Compounded Semaglutide? +
- Is this FDA Approved? +
- Daily Drop vs. Weekly Injection? −

Besides the obvious benefit of not having to use a needle, taking a daily sublingual drop removes the peaks and valleys in your system that you get from a weekly injection, leading to more consistent results with fewer side effects.

- Where do you apply Semaglutide? +
- Are There Side Effects of Semaglutide? +
- Do I need a prescription? +
- Why Do I Need a Telemedicine Appt? +
- Do You Accept Insurance? +
- Where is 247 Health Located? +

247 HEALTH

Get the Weight Loss Experience You Deserve

Get Started

Exhibit H

MyDrHank®

SHOP PRODUCTS REORDER

Get started for free. It only takes a few minutes.

"*" indicates required fields

Hello! Thank you for visiting MyDrHank.

Since 2017, I have helped over 50,000 men and women get access to cost-effective medicine. When the FDA approved popular weight loss drugs such as Semaglutide, I knew I had to come up with a way to give people like yourself access to this drug without the ridiculous price tag & injections.

That's why I created Weight Drops, the only Semaglutide compounded sublingual (under the tongue daily drop) on the market.

- On average, people lose 15% of their body weight in a year.
- Daily drops help your body acclimate to the medication, with many patients reporting reduced side effects vs weekly injections.
- $295/month. Includes Telemedicine Appointments & Shipping.

Please enter your First & Last name below to get started on your weight loss journey:

First Name *

Last Name *

May I have the best phone number to reach you at please?

By entering your phone number, you agree to receive help from our support team, shipping updates, & marketing texts from MyDrHank to the number you provided. Message and data rates may apply. Reply STOP at any time to opt out.

Phone Number *

Numbers Only Please Ex. 8885888094

May I also have your email address? It helps us keep you up to date on your shipments & we also send out free resources to help you on your weight loss journey.

Email *

Email Address: (example@gmail.com)

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This is not medical advice. You and your physician will determine if (and potentially how) you should take your medication.

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