UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

NOVO NORDISK INC. Plaintiff, v. WELLS PHARMACY NETWORK, LLC, Defendant.	Case No.

COMPLAINT

Plaintiff Novo Nordisk Inc. ("Plaintiff" or "Novo Nordisk"), by and through its attorneys, Wicker Smith and Covington & Burling LLP, files this Complaint against Defendant Wells Pharmacy Network, LLC ("Defendant" or "Wells Pharmacy") to enjoin Wells Pharmacy from its unlawful business practice of selling adulterated and misbranded injectable non-FDA approved drugs that claim to contain semaglutide and to be approved by FDA, which pose potential significant risks to patient health. Novo Nordisk does not seek through this lawsuit money damages arising from Wells Pharmacy's past practice of selling these adulterated and misbranded drugs, but only to prevent Wells Pharmacy from continuing this practice, which puts patients at potential risk, and alleges the following:

I. NATURE OF THE ACTION

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

1. Novo Nordisk is a leading healthcare company, focused on driving change to defeat serious chronic diseases, built upon its heritage in diabetes.

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 for chronic weight management in adults and children aged ≥ 12 years with obesity (BMI ≥ 30 for adults, BMI ≥ 95th percentile for age and sex for children), or some adults with excess weight (BMI ≥ 27) (overweight) with weight-related medical problems, along with a reduced calorie meal plan and increased physical activity.

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 Wells Pharmacy, or any other compounding pharmacies, for the purposes of compounding either injectable or oral 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 verify the safety or effectiveness of compounded drugs."[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 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

[1] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (last updated Oct. 31, 2023), 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.

[3] *Id.*

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]

12. At least nine state regulators have also issued statements concerning compounding of products that claim to contain semaglutide.[5] For instance, the

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[4] FDA, *Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss* (last updated Oct. 31, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

[5] *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-images/Semaglutide.compoundguidance%20%28002%29.pdf; Ala. Bd. Pharmacy, *Compounding Semaglutide* (May 18, 2023), https://www.aparx.org/news/641379/Compounding-Semaglutide.htm; Ky. Bd. Pharmacy, Newsletter (June 2023), https://pharmacy.ky.gov/2023%20Newsletters/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; Miss. State Bd. Med. Licensure, *Guidance Regarding Semaglutide-Based Medications From the Mississippi State Board of*

Alabama Board of Medical Examiners has cautioned that semaglutide products other than those manufactured by Novo Nordisk "may be contaminated, improperly stored and transported, or adulterated."[6] 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."[7] 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."[8]

Medical Licensure (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%2008-29-23.pdf.

[6] 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.

[7] 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.

[8] *Id.* at 1–2.

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

13. The danger is not merely theoretical, as manufacturing and distribution of impure and 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, including injectable drugs with impurities and with strengths that differed from the labeled concentration or dose.[9]

14. 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 manufactured in Massachusetts.[10] The U.S. Centers for Disease Control and Prevention reported that 64 patients in nine states died, though other sources report the death toll as exceeding 100 victims.[11] Florida

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[9] 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.

[10] 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.

[11] *Id.*

alone reported 25 cases of persons with fungal infections linked to steroid injections and 7 deaths.[12] 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."[13]

15. There have been other notable public health incidents involving adulterated repackaged drugs, including in Florida. One notable example occurred in 2011, where a compounding pharmacy in South Florida prepared injectable repackaged drugs in unsanitary conditions that became contaminated and ultimately seriously injured a dozen Florida residents.[14]

16. In the years since these events, FDA has issued "compounding risk alerts to inform health care professionals, compounders and consumers about risks

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[12] CDC, *Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count* (updated Oct. 30, 2015), https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html.

[13] 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.

[14] Andrew Pollack, *Avastin Injections Are Reported to Cause Blindness*, N.Y. Times, Aug 30, 2011; R.A. Goldberg et al., *An Outbreak of Streptococcus Endophthalmitis After Intravitreal Injection of Bevacizumab*, 153 Am. J. Ophthalmology 204 (2012).

associated with compounded drugs, including information on adverse events, outbreaks or product quality."[15] These alerts have warned about compounded drugs with strengths below what is labeled, the presence of impurities, and hypersensitivity reactions, which are immunologic responses.[16] They also have described the risks associated with compounding drug products when there are "[c]omplexities related to the quality and sourcing of the" API and formulation.[17] FDA recently warned that unapproved injectable drugs purportedly containing semaglutide "can pose a serious risk of harm to users because they bypass many of the body's natural defenses against toxic ingredients, toxins, or dangerous organisms that can lead to serious and life-threatening conditions such as septicemia or sepsis."[18]

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

[16] FDA, *FDA Investigates Two Serious Adverse Events Associated with ImprimisRx's Compounded Curcumin Emulsion Product for Injection* (last updated June 21, 2018), https://www.fda.gov/drugs/human-drug-compounding/fda-investigates-two-serious-adverse-events-associated-imprimisrxs-compounded-curcumin-emulsion.

[17] FDA, *FDA Alerts Health Care Professionals and Compounders of Potential Risks Associated with the Compounding of Remdesivir Drug Products* (last updated Feb. 4, 2021), https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-and-compounders-potential-risks-associated-compounding.

[18] 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.

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

17. FDA has also 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 these drugs for safety, effectiveness, or quality."[19]

18. Despite the historic underreporting of adverse events caused by compounded drugs, according to FDA's Adverse Event Reporting System, there have been 281 cases of adverse events associated with compounded products that claim to contain semaglutide, as of September 20, 2023. Approximately 75 percent (215) of those cases have been classified as "serious" adverse events, approximately 25 percent of those cases (68) have resulted in hospitalization, and two of those cases involved patient deaths. Several adverse events listed in the database, like hematuria

[19] 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 Oct. 31, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

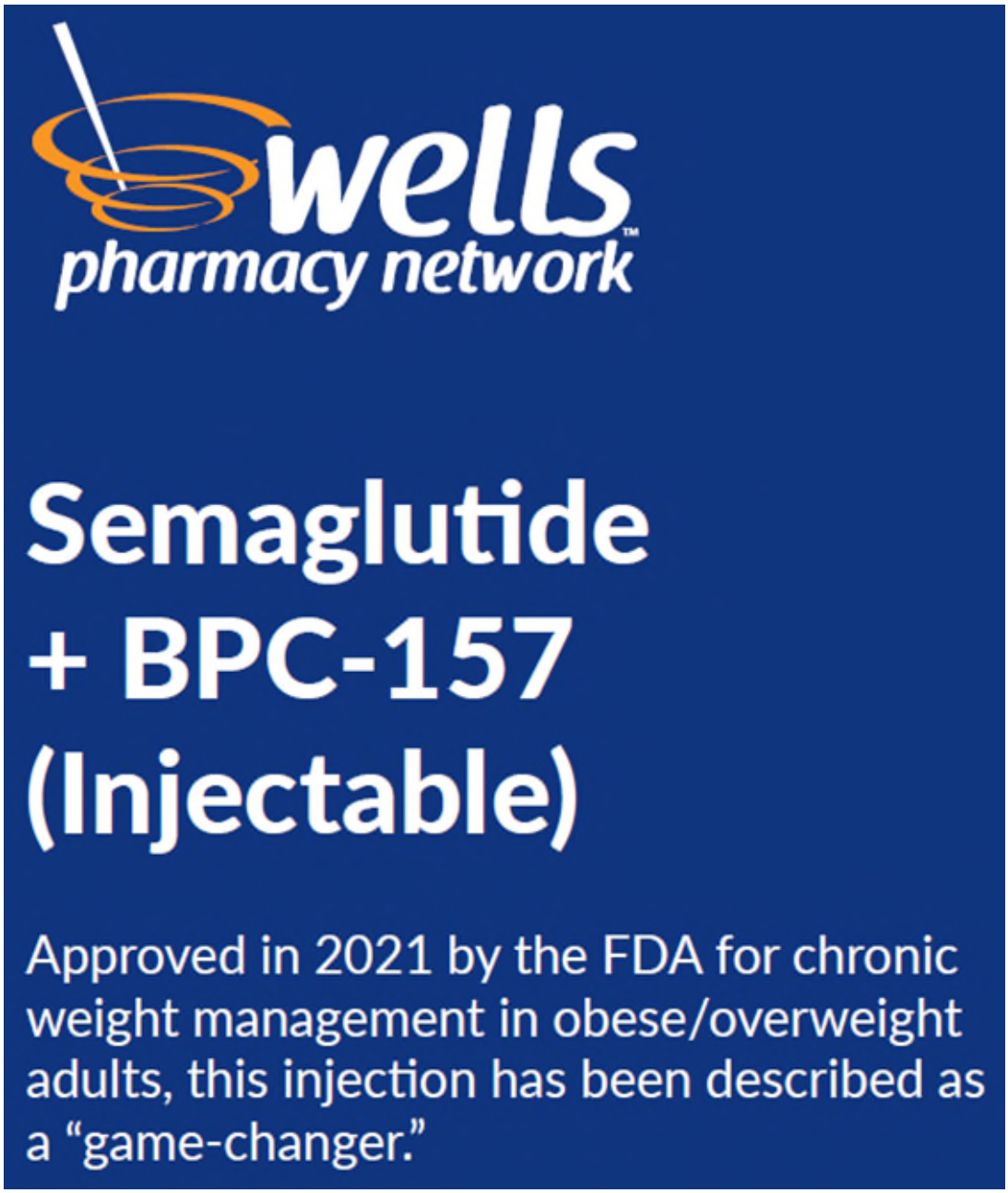
and myalgia, are clinical signs of delayed hypersensitivity associated with immunogenicity.[20]

E. Defendant Falsely Markets Its Drugs as Being FDA Approved and Subjected to Clinical Testing and Trials

19. Defendant markets and sells to patients an injectable, unapproved compounded drug that claims to contain "Semaglutide + BPC-157."

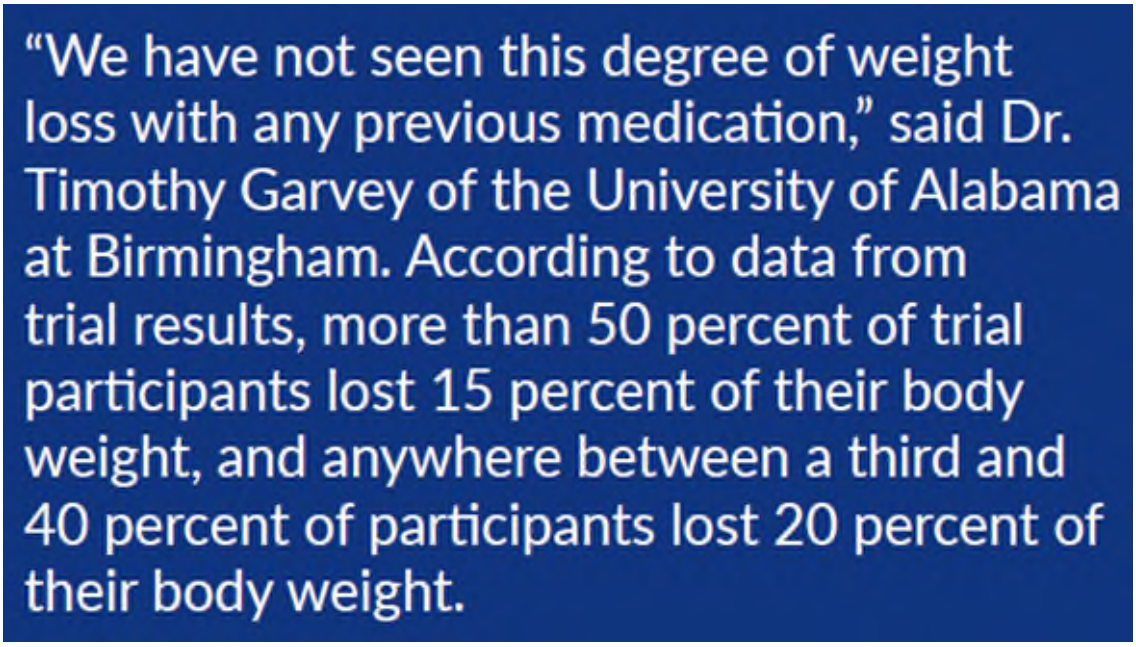
20. Defendant falsely or misleadingly markets its unapproved drug as having been "[a]pproved in 2021 by the FDA." The below image, attached hereto as Exhibit A, is a true and correct representation of information provided by Defendant to prospective customers.

[20] *See* FDA, *Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products* 5 (Aug. 2014), https://www.fda.gov/media/85017/download.



21. Such claims are false. FDA has not approved Defendant's drug and, on information and belief, the quoted language refers to Novo Nordisk's FDA-approved semaglutide medicine rather than Defendant's unapproved compounded drug.

22. Defendant has also used false or misleading statements in advertising and promotion that claim or imply that Defendant's compounded drugs have been subjected to clinical studies and trials, such as the following statement:

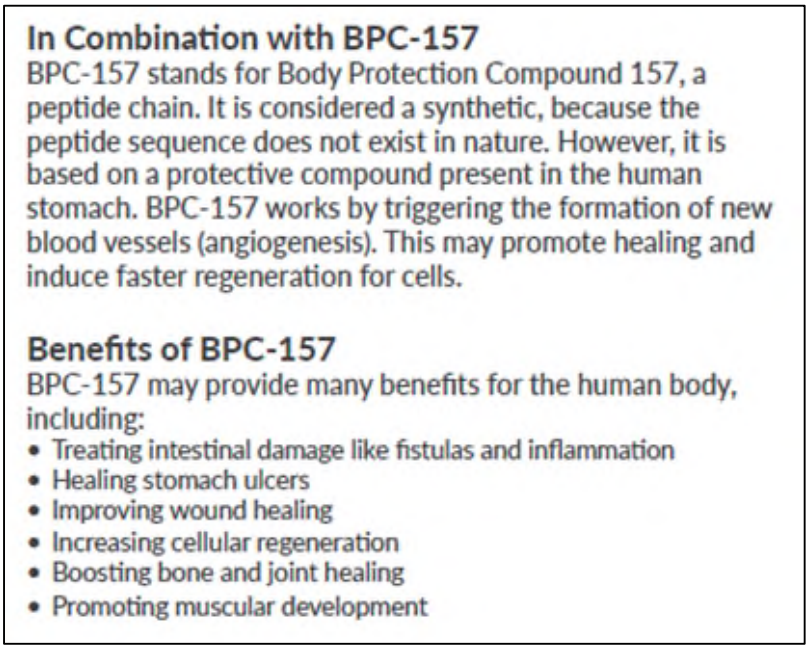


23. In reality, Dr. Garvey was referring to clinical trials performed by Novo Nordisk and/or its parents or affiliates related to FDA-approved semaglutide-based medicines. The quoted data does not apply to Defendant's drug.

24. Defendant has also used false or misleading statements in advertising and promotion that claim or imply that BPC-157, a substance which FDA has warned should not be used in compounding,[21] is safe and effective, stating that it is

[21] FDA, *Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding* (last updated on Sept. 29, 2023), https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substances-nominated-use-compounding.

"protective" and "provide[s] many benefits for the human body" without disclosing its significant safety risks:



In Combination with BPC-157

BPC-157 stands for Body Protection Compound 157, a peptide chain. It is considered a synthetic, because the peptide sequence does not exist in nature. However, it is based on a protective compound present in the human stomach. BPC-157 works by triggering the formation of new blood vessels (angiogenesis). This may promote healing and induce faster regeneration for cells.

Benefits of BPC-157

BPC-157 may provide many benefits for the human body, including:

- Treating intestinal damage like fistulas and inflammation
- Healing stomach ulcers
- Improving wound healing
- Increasing cellular regeneration
- Boosting bone and joint healing
- Promoting muscular development

25. Defendant's statements are likely to deceive consumers into believing, erroneously, that FDA has approved Defendant's drug and that the quoted language and clinical trial data refers to Defendant's drug. Defendant's statements as to the additional compound, BPC-157, are also likely to deceive customers into believing that the compounded drug is safe and effective, without disclosing any safety risks.

26. Defendant 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 Defendant's unapproved compounded drugs, believing them to be FDA-approved, safe, and effective.

F. Defendant's Activities Violate Florida Laws Against Selling Adulterated and Misbranded Drugs

27. The Florida Drug and Cosmetic Act, among other things, prohibits compounding pharmacies in Florida from manufacturing or selling any compounded drug that is adulterated or misbranded or has been otherwise rendered unfit for human or animal use. § 499.005, Fla. Stat.

28. Florida's adulterated drug provisions are designed to ensure that Floridians are treated with safe and sanitary medicines. Under Florida law, a drug is adulterated if, among other things, it has been produced, prepared or held under conditions whereby it could be "injurious to [the] health" of patients. § 499.006(2) Fla. Stat.

29. Under Florida law, a drug is misbranded if, among other things, its labeling, including any "written, printed, or graphic matters . . . [a]ccompanying or related to such drug," is in any way "false or misleading." §§ 499.003(27)(b) 499.007(1), Fla. Stat.

30. Defendant markets and sells to patients certain non-FDA approved compounded drugs that claim to contain "semaglutide." However, testing of Defendant's compounded drugs performed on Novo Nordisk's behalf has revealed that Defendant's drug product is both adulterated and misbranded because: (a) it contains unknown impurities, including one sample consisting of 33% unknown impurities, and impurities with amino acid additions and deletions and dimers not

found in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products—all of which potentially pose safety risks to patients, including possibly serious and life-threatening reactions like anaphylaxis; (b) it contains BPC-157, a substance that FDA has determined should not be used in compounding because it raises significant safety risks; and (c) its labeling and marketing and promotional materials contain false and misleading statements that claim or imply that it has been approved by FDA, that it has been subjected to the same clinical studies and trial as Novo Nordisk's FDA-approved drugs, and that BPC-157 is beneficial for the human body without disclosing its significant safety risks.

G. Plaintiff Seeks to Enjoin Defendant From Its Unlawful Practices

31. Novo Nordisk brings this action under Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA") to stop Defendant from unlawfully manufacturing, marketing, selling, and distributing its adulterated and misbranded drugs. Novo Nordisk seeks a declaration that Defendant's business practices violate FDUTPA and the Lanham Act by manufacturing, distributing, and selling its adulterated and misbranded drugs and an injunction prohibiting Defendant from committing such violations. Novo Nordisk also seeks attorney's fees and court costs, but does not seek monetary damages for Defendant's past violations of FDUTPA or the Lanham Act.

II. THE PARTIES

32. 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.

33. 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 Wells Pharmacy Network, LLC, or any other compounding pharmacies, for the purposes of compounding semaglutide products.

34. 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.

35. Defendant is a limited liability company organized and existing under the laws of Florida, with its principal place of business at 3420 Fairlane Farms Road, Suite 300, Wellington, FL 33414. Upon information and belief, Defendant manufactures its adulterated and misbranded drugs in this judicial district at 1210 SW 33rd Ave., Ocala, FL. Defendant manufactures its drugs in this judicial district and sells them in this judicial district, throughout Florida, and in several other states.

III. JURISDICTION AND VENUE

36. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b) and 28 U.S.C. § 1367(a).

37. This Court has personal jurisdiction over Defendant. Defendant manufactures its drugs in this District and, upon information and belief, Defendant ships those adulterated and misbranded drugs throughout Florida and into several other states from this District. Plaintiff's claims arise out of or relate to Defendant's activities in this District.

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

IV. FACTUAL ALLEGATIONS

A. Defendant's Adulterated and Misbranded Drugs Contain Impurities and Ingredients that Pose Potential Risk to, and May Be Injurious to the Health of, Patients

39. FDA inspected Defendant's facility in Ocala, Florida, in July 2013, March 2014, June 2014, August-September 2016, and June 2018, and after each inspection, FDA issued a list of inspectional observations called Form FDA 483s.[22]

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22 FDA, *Compounding: Inspections, Recalls, and other Actions*, https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions (search "Wells Pharmacy Network, LLC, Ocala, FL – 503A Facility").

The 2013 and 2014 inspections of the facility found: (a) "serious deficiencies . . . for producing sterile drug products, which could lead to contamination of the products, which put patients at risk," and (b) "fail[ure] to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess."[23] Based on these findings, FDA issued in November 2014 a warning letter to Defendant. During the August-September 2016 inspection, FDA investigators observed "high levels of fungal growth" in the areas where drugs intended to be sterile are produced.[24] Following that inspection, on September 20, 2016, Defendant issued a voluntary nationwide recall of sterile products due to concern for lack of sterility assurance.[25] During the June 2018 inspection, FDA observed the use of a non-pharmaceutical grade component in the formulation of a drug product.[26]

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[23] FDA, *Wells Pharmacy Network LLC Warning Letter FLA-15-07* (Nov. 10, 2014),https://web.archive.org/web/20170406034011/https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423242.htm.

[24] FDA, *Form FDA 483 Issued to Wells Pharmacy Network, LLC* (Sept. 13, 2016), https://www.fda.gov/media/100171/download.

[25] Debra Goldschmidt, *Wells Pharmacy Network Recalls Hundreds of Products*, CNN (Sept. 22, 2016), https://www.cnn.com/2016/09/22/health/wells-pharmacy-network-recall/index.html.

[26] FDA, *Form FDA 483 Issued to Wells Pharmacy Network, LLC* (June 22, 2018), https://www.fda.gov/media/114926/download.

40. Consistent with FDA's 2018 observation that Defendant used a non-pharmaceutical grade ingredient to formulate a drug product, testing performed of Defendant's drugs on Novo Nordisk's behalf has revealed that they have peptide-related impurities that are not present in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products, including, but not limited to, unknown impurities and impurities with amino acid additions and deletions. Indeed, 33 percent of one of the Defendant's samples that were tested consisted of unknown impurities that are not present in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products.

41. Unknown impurities in drug products present unknown potential safety risks to patients because they have not been characterized or justified by toxicological studies, clinical trials, or a scientific rationale. The impurities with amino acid additions and deletions that are not found in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products also pose potential safety risks to patients because they have the potential to stimulate an immunological reaction upon repeated injections, which can lead to serious and life-threatening reactions like anaphylaxis.[27]

[27] Arne Staby et al., *Influence of Production Process and Scale on Quality of Polypeptide Drugs: a Case Study on GLP-1 Analogs*, 37 Pharm. Res. 120, 135 (Apr. 2020); FDA, *Guidance for Industry: Immunogenicity Assessment for Therapeutic Protein Products* 4 (Aug. 2014),

42. Defendant's drugs were compounded with BPC-157, a substance that FDA determined should not be used in compounding because it "may pose risk for immunogenicity," and "may have complexities with regard to peptide-related impurities."[28] "FDA has identified no, or only limited, safety-related information" for delivery of BPC-157 by subcutaneous injection.[29]

43. Testing also showed that Defendant's drugs contain unknown semaglutide dimers and dimers that result from interactions of semaglutide with other ingredients, including semaglutide-BPC-157 dimers, which are not present in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products. Upon information and belief, there are no toxicological studies, clinical studies, or scientific rationale to justify the presence of such dimers. High-molecular-weight proteins like dimers can affect immunogenicity and the resultant safety of the drug.[30]

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https://www.fda.gov/media/85017/download ("The following sections describe a few of the major safety concerns associated with immunogenicity: 1. Anaphylaxis . . . .").

[28] FDA, *Safety Risks Associated with Certain Bulk Drug Substances Nominated for Use in Compounding* (last updated on Sept. 29, 2023), https://www.fda.gov/drugs/human-drug-compounding/safety-risks-associated-certain-bulk-drug-substances-nominated-use-compounding.

[29] *Id.*

[30] Arne Staby et al., *Influence of Production Process and Scale on Quality of Polypeptide Drugs: a Case Study on GLP-1 Analogs*, 37 Pharm. Res. 120, 122 (Apr. 2020).

B. Defendant Misrepresents That Its Adulterated and Misbranded Drugs Have Been Clinically Studied, Approved by FDA, and Deemed Safe

44. As set forth above, Defendant's promotional materials for Defendant's compounded, injectable drug that claims to contain "Semaglutide + BPC-157" falsely or misleadingly represent that Defendant's drug has been approved by FDA or subjected to the same clinical studies and trials as Novo Nordisk's FDA-approved semaglutide-based products.

45. Defendant's promotional materials further misleadingly imply that BPC-157 is safe and effective, stating that it is "protective" and "provide[s] many benefits for the human body" without disclosing its significant safety risks.

C. Plaintiff Has Been Injured by Defendant's Unlawful, Deceptive, and Unfair Competition

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

47. Defendant sells its adulterated and misbranded drugs claiming to contain semaglutide to customers in Florida and other states (which Defendant makes from Florida). As noted above, Novo Nordisk is the only manufacturer of FDA-approved medicines containing semaglutide. As a result of Defendant's unlawful, deceptive, and unfair competition, which jeopardizes public health, Novo Nordisk has and will continue to suffer harm to its goodwill and reputation. In addition, absent Defendant's unlawful and unfair actions, sales made by Defendant in Florida and in

these other states would and will have been made by Novo Nordisk; thus, Novo Nordisk has and will suffer lost sales and customers as a direct result of Defendant's unlawful acts and false advertising. Novo Nordisk does not seek through this lawsuit money damages arising from Wells Pharmacy's past practice of selling these adulterated and misbranded drugs, but only to prevent Wells Pharmacy from continuing this practice, which potentially puts patients at risk.

V. FIRST CAUSE OF ACTION

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

48. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1–47, above, as if fully stated herein.

49. Defendant's practices, as described in this Complaint, constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

50. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendant's business practices and products, as set forth above. Defendant has misrepresented that its drug has been approved by FDA, has been subjected to the same clinical studies and trial as Novo Nordisk's FDA-approved

drugs, has been described positively in public press or media, is safe and effective, and has "protective" benefits without disclosure of its significant safety risks.

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

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

53. The above-described acts of Defendant 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.

54. By reason of Defendant's 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 Defendant. Accordingly, Plaintiff is entitled to entry of injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

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

VI. SECOND CAUSE OF ACTION

(Common Law Unfair Competition)

56. Plaintiff realleges and incorporates by reference each and every allegation set forth in paragraphs 1–55, above, as if fully stated herein.

57. The above-described acts of Defendant constitute common law unfair competition.

58. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiff's goodwill and reputation.

59. The above-described acts of Defendant were deceptive or fraudulent and are likely to cause consumer confusion, and consumers would be induced to rely and act on such statements by Defendant.

60. By reason of the above-described acts of Defendant, Plaintiff has suffered damage to the goodwill and reputation associated with its FDA-approved medicines containing semaglutide.

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

62. The above-described acts of Defendant 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.

63. By reason of Defendant's acts, Plaintiff's remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiff is entitled to entry of permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

VII. THIRD CAUSE OF ACTION

(Violation of Florida Deceptive and Unfair Trade Practices Act ("FDUTPA")
(Fla. Stat. § 501.201, Fla. Stat., *et seq*)

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

65. FDUTPA "protect[s] the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." § 501.202(2), Fla. Stat.

66. FDUTPA makes "unlawful" "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." § 501.204(1), Fla. Stat.

67. Defendant engages in unfair, unconscionable, and deceptive conduct in "trade" and "commerce" in violation of FDUTPA when it unlawfully manufactures and sells its adulterated and misbranded drugs in Florida (and into other states).

68. Manufacturing compounded drugs claiming to contain semaglutide that contain potentially harmful impurities and dangerous ingredients and that falsely purport to be FDA approved and subjected to the same clinical testing and trials as Novo Nordisk's FDA-approved drugs is an unfair practice, insofar as it is immoral, unethical, oppressive, unscrupulous, and/or substantially injurious to consumers and to Plaintiff. It is also deceptive, insofar as it is likely to mislead.

69. The practices described herein also offend established public policy regarding the protection of consumers and competitors against companies, like Defendant, that engage in unfair methods of competition. Defendant's conduct has caused and will continue to cause 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.

70. 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.

71. Defendant's business acts and practices are also unfair because they have caused harm and injury-in-fact to Novo Nordisk for which Defendant has no justification other than to increase, beyond what Defendant would have otherwise realized, its revenue from the sale of its adulterated and misbranded drugs.

72. FDUTPA further forbids any person from violating "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." § 501.203(3)(c), Fla. Stat.

73. The Florida Drug and Cosmetic Act specifies that it is unlawful for any person to perform any of the following acts in Florida: "[t]he manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use." § 499.005(1), Fla. Stat.

74. A drug is adulterated under state law if, among other things, "[i]t has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health." § 499.006(2), Fla. Stat. Florida's adulterated drug provisions are designed to ensure that Floridians are treated with safe and sanitary medicines.

75. A drug is misbranded under state law if, among other things, "its labeling is in any way false or misleading." § 499.007(1), Fla. Stat.

76. Defendant has violated FDUTPA by violating a "statute . . . which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices." § 501.203(3)(c), Fla. Stat. Here, Defendant violated Florida's Drug and Cosmetic Act which proscribes certain unconscionable acts and practices. Defendant's drugs are adulterated in violation of the Florida Drug and Cosmetic Act

because they contain impurities and ingredients indicating that the drugs were made under conditions whereby they could have been rendered "injurious to health."[31] Defendant's drugs are misbranded in violation of the Florida Drug and Cosmetic Act because their labeling and marketing and promotional materials falsely and misleadingly represent them: (i) to be approved by FDA, (ii) to be subjected to the same clinical trials and testing as Novo Nordisk's FDA-approved semaglutide-based medicines, and (iii) to contain an allegedly "protective" ingredient without disclosing that ingredient's significant safety risks.

77. FDUTPA creates a cause of action for "anyone aggrieved" by a violation of FDUTPA to bring an action against "a person who has violated, is violating, or is otherwise likely to violate" the Act. § 501.211(1), Fla. Stat.

78. Plaintiff is "aggrieved" under FDUTPA.

79. Defendant is a "person" who has violated and is violating FDUTPA.

80. As a result of Defendant's unlawful and unfair competition, Novo Nordisk has suffered actual damages, including harm to its goodwill and reputation, as well as other injuries.

[31] 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. § 499.003(34), Fla. Stat.

81. Plaintiff is entitled to declaratory and injunctive relief, the value of which exceeds $75,000 for purposes of jurisdiction, as well as reasonable attorney's fees and costs pursuant to §§ 501.2105, 501.211, Fla. Stat.

VIII. CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor:

1. A permanent injunction enjoining Defendant from continuing the unlawful and unfair business practices alleged in this complaint;

2. A judgment that Defendant violated the FDUTPA;

3. A judgment that Defendant engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

4. Declaratory relief;

5. Attorney's fees and costs incurred in this action; and

6. Any further relief the Court may deem just and proper.

Dated: November 29, 2023

Respectfully submitted,

By: */s/ Jordan S. Cohen*

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