UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

NOVO NORDISK INC. Plaintiff, v. BROOKSVILLE PHARMACEUTICALS INC., Defendant.	Case No. 8:23-cv-01503-WFJ-TGW

FIRST AMENDED COMPLAINT

Plaintiff Novo Nordisk Inc. ("Plaintiff" or "Novo Nordisk"), by and through its attorneys, Wicker Smith and Covington & Burling LLP, files this First Amended Complaint against Defendant Brooksville Pharmaceuticals Inc. ("Defendant" or "Brooksville") to enjoin Brookville from its unlawful business practice of selling adulterated and misbranded injectable, non-FDA approved drugs that claim to contain semaglutide and which pose potential significant risks to patient health. Novo Nordisk does not seek through this lawsuit money damages arising from Brooksville's past practice of selling these adulterated and misbranded drugs, but only to prevent Brooksville 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. Novo Nordisk does not sell its semaglutide active pharmaceutical ingredient ("API") to Brooksville Pharmaceuticals Inc., or any other compounding pharmacies, for the purposes of compounding either injectable or oral semaglutide products.

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

9. According to FDA, "compounded drugs are not FDA-approved,"[1] and "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]

10. 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,"

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[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.*

and it has warned that "[p]atients should not use a compounded drug if an approved drug is available to treat a patient."[4]

11. 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* (April 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 Medical Licensure* (Aug. 29, 2023), https://www.msbml.ms.gov/sites/default/files/news/Semaglutide%20Guidance%20

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]

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

12. The danger is not merely theoretical, as manufacturing and distribution of impure and improperly formulated compounded drugs have endangered or

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08-29-23.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.

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]

13. 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 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

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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.*

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

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]

14. 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 seriously injured a dozen Florida residents.[14]

15. In the years since these events, 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."[15] These alerts have warned about compounded drugs

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[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).

[15] FDA, *Compounding Risk Alerts* (last updated Oct. 10, 2023),

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]

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

16. FDA has also reported that it has "received an increased number of

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.

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]

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

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[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.

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

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

18. 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.

19. 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 or where "its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess." §§ 499.006(2), (7) Fla. Stat.

20. Under Florida law, a drug is misbranded if, among other things, its labeling is in any way "false or misleading." § 499.007(1), Fla. Stat.

21. 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 and impurities with amino acid additions and deletions 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; and (b) its strength is at least 19 percent less than what is reported on its label, thus rendering it potentially less effective.

22. 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 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.

II. THE PARTIES

23. 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.

24. 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 Brooksville Pharmaceuticals Inc., or any other compounding

pharmacies, for the purposes of compounding semaglutide products.

25. 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.

26. Defendant is a corporation organized and existing under the laws of Florida, with its principal place of business at 16140 Flight Path Drive, Brooksville, Florida 34604.

27. 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

28. This Court has subject matter jurisdiction under 28 U.S.C. § 1332. The parties are citizens of different States, and the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

29. This Court has personal jurisdiction over Defendant. Defendant's principal place of business is located in this District, 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.

30. 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 that Pose Potential Risk to, and May Be Injurious to the Health of, Patients

31. 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, both unknown impurities and impurities with amino acid additions and deletions.

32. Unknown impurities in drug products potentially present unknown 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.[21]

[21] Arne Staby et al., *Influence of Production Process and Scale on Quality of*

B. Defendant's Adulterated and Misbranded Drugs Have a Strength At Least 19 Percent Less than What Is Reported on Their Label

33. Defendant's drugs have also been found to have a strength substantially below their labeled strength.

34. Defendant's "1 mL Sterile Multiple Dose Vial" is labeled as having "2.09 mg" of active pharmaceutical ingredient which equates to a labeled strength of 2.09 mg/mL. It further states that its "Semaglutide Injection Solution" contains a strength of "2 MG/ML."

35. Novo Nordisk's testing of the Defendant's drugs, however, has revealed that they contain only 1.62 mg/mL of semaglutide, which is at least 19 percent less than its labeled strength.

36. Thus, Defendant's drugs are at least 19 percent lower in strength than labeled.

37. Upon information and belief, Defendant's drugs are less effective than Novo Nordisk's FDA-approved medicines.

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

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

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

39. 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 and unfair competition. Novo Nordisk does not seek through this lawsuit money damages arising from Brooksville's past practice of selling these adulterated and misbranded drugs, but only to prevent Brooksville from continuing this practice, which potentially puts patients at risk.

V. CAUSE OF ACTION

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

40. Plaintiff realleges and incorporates by reference each and every

allegation set forth in paragraphs 1–39, above, as if fully stated herein.

41. 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.

42. 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.

43. 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).

44. Manufacturing compounded drugs claiming to contain semaglutide that contain potentially harmful impurities and lack the labeled strength 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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" or "its strength differs

from, or its purity or quality falls below the standard of, that which it purports or is represented to possess." § 499.006(2), (7), Fla. Stat. Florida's adulterated drug provisions are designed to ensure that Floridians are treated with safe and sanitary medicines.

51. 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.

52. 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 not present in the pharmaceutical-grade semaglutide in Novo Nordisk's FDA-approved products, indicating that the drugs were made under conditions whereby they could have been rendered "injurious to health" and because their "strength differs from . . . that which [they] purport[] or [are] represented to possess."[22] Defendant's drugs are misbranded in violation of the Florida Drug and Cosmetic Act because they have a different strength than that

[22] 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.

which they are labeled to possess.

53. 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.

54. Plaintiff is "aggrieved" under FDUTPA.

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

56. 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.

57. 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.

VI. 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, which injunction has a value in excess of $75,000 for purposes of jurisdiction;

2. A judgment that Defendant violated the FDUTPA;

3. Declaratory relief;

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

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

Dated: November 29, 2023

Respectfully submitted,

By: */s/ Jordan S. Cohen*

Jordan S. Cohen, Esquire
Florida Bar No. 551872
JCohen@wickersmith.com
WICKER SMITH O'HARA MCCOY & FORD, P.A.
515 E. Las Olas Boulevard
SunTrust Center, Suite 1400
Ft. Lauderdale, FL 33301
Phone: (954) 847-4800
Fax: (954) 760-9353

Michael X. Imbroscio (*admitted pro hac vice*)
Amee Frodle (*admitted pro hac vice*)
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 pending*)
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.