UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

NOVO NORDISK, INC.,

Plaintiff,

v. Case No. 8:23-cv-1503-WFJ-TGW

BROOKSVILLE PHARMACEUTICALS INC.,

Defendant.

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ORDER

This matter comes before the Court following a telephonic hearing on Defendant Brooksville Pharmaceuticals, Inc.'s ("Defendant") Motion to Dismiss (Dkt. 17) Plaintiff Novo Nordisk, Inc.'s ("Plaintiff") Complaint (Dkt. 1), with Defendant's Memorandum in Support (Dkt. 19). Plaintiff filed a Response in Opposition (Dkt. 26), to which Defendant filed a Reply (Dkt. 27). Upon careful review, the Court grants Defendant's Motion to Dismiss with leave to amend.

BACKGROUND

Plaintiff is an international pharmaceutical company with approval from the Food and Drug Administration ("FDA") to produce drugs containing semaglutide. Dkt. 1 ¶ 2. Plaintiff sells three FDA-approved, prescription drugs that use

semaglutide as the primary ingredient: Wegovy, Ozempic, and Rybelsus. *Id.* Defendant is a pharmacy that sells compounded drugs containing semaglutide. *Id.* ¶ 9.

On July 6, 2023, Plaintiff filed suit. Dkt. 1. Plaintiff alleges that Defendant violated the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. §§ 501.201–.213, by manufacturing and selling to the public, without FDA approval, drugs containing semaglutide. *Id.* ¶¶ 28–32. Plaintiff avers that Defendant's allegedly unlawful use of semaglutide amounts to unfair competition that is damaging to Plaintiff's goodwill and reputation, *id.* ¶ 37, as well as public safety, *id.* ¶ 33.

Defendant moved to dismiss on August 14, 2023. Dkt. 17. Defendant argues that Plaintiff failed to state a claim upon which relief may be granted under Federal Rule of Civil Procedure 12(b)(6). Dkt. 19 at 1–2.

LEGAL STANDARD

To defeat Defendant's Motion to Dismiss, Plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* While a complaint "does not need

detailed factual allegations" to survive a motion to dismiss, it "requires more than labels and conclusions." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In considering the motion, the Court must accept all factual allegations of the complaint as true and construe them in the light most favorable to Plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Legal conclusions must be supported by factual allegations. *Iqbal*, 556 U.S. at 679. "[T]he well-pleaded factual allegations, documents central to or referenced in the complaint, and matters judicially noticed" govern whether a claim is "plausible on its face." *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004).

DISCUSSION

Defendant moved to dismiss on three grounds: (1) Plaintiff failed to demonstrate Article III standing; (2) Plaintiff's claim is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"); and (3) Plaintiff did not satisfy the pleading elements of a FDUTPA claim. Dkt. 19. The Court will address each issue in turn.

I. Standing

Article III standing requires plaintiffs to demonstrate that: (1) they suffered an "injury-in-fact;" (2) there is a causal connection between the asserted injury-in-fact and the challenged action of the defendant; and (3) "the injury will be redressed by a favorable decision." *Shotz v. Cates*, 256 F.3d 1077, 1081 (11th Cir. 2001).

In the instant case, Defendant challenges standing by arguing that Plaintiff's "bare assertions and speculation are not enough" to exemplify injury-in-fact. Dkt. 19 at 15–16. Defendant further argues that even if the Court recognizes an injury, the Complaint does not establish causal connection. Dkt. 19 at 15.

Injury-in-fact is established when a plaintiff "shows that he or she suffered an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (quotation omitted). A concrete injury is "real, and not abstract." *Id.* at 340. A particularized injury "affect[s] [a] plaintiff in a personal and individual way." *Id.* at 339. Claims for injunctive relief, moreover, require a "real and immediate . . . threat of *future* injury." *Shotz*, 256 F.3d at 1081 (emphasis in original) (citation omitted). Economic injury is sufficient to establish standing. *Debernardis v. IQ Formulations LLC*, 942 F.3d 1076, 1084 (11th Cir. 2019).

The Court finds that Plaintiff has standing. Plaintiff sufficiently stated a present and future economic injury-in-fact that is concrete and particularized. Additionally, Plaintiff stated sufficient facts to establish a causal connection. Plaintiff is the only pharmaceutical company with express FDA approval to create, manufacture, and sell drugs containing semaglutide. Dkt. 1 ¶ 34. Because Defendant also creates, manufactures, and sells drugs that contain semaglutide in the same geographical areas where Plaintiff conducts business, *id.*, the parties are in economic

competition. *Id.* ¶ 35. Thus, the Court can reasonably infer that any sale by Defendant reduces, and will continue to reduce, Plaintiff's individual profits.

II. Preemption

Defendant next argues that Plaintiff's claims are impliedly preempted by the FDCA. Dkt. 19 at 16–17. Courts may grant motions to dismiss based on preemption when the basis for preemption appears on the face of the complaint. *See Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984), *aff'd,* 764 F.2d 1400 (11th Cir. 1985) (internal citations omitted). The United States has sole enforcement authority under the FDCA. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Private enforcement of the FDCA is barred. *See Nexus Pharms. Inc. v. Cent. Admixture Pharm. Servs.*, 48 F.4th 1040, 1044 (9th Cir. 2022).

Nevertheless, a claim that alleges "the breach of a well-recognized duty owed to [a plaintiff] under state law" will survive implied preemption, even if based on conduct that violates the FDCA. *Jacob v. Mentor Worldwide, LLC*, 40 F.4th 1329, 1336 (11th Cir. 2022) (citing *Godelia v. Doe*, 881 F.3d 1309, 1317 (11th Cir. 2018) and *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017)). To "escape implied preemption," the alleged conduct must "give rise to liability under state law even if the Act did not exist." *Id.* For example, in the *Jacob* / *Godelia* / *Mink* trilogy, plaintiffs relied upon failure to comply with the FDCA as prima facie evidence of

negligence. *Id.* at 1337; *Godelia*, 881 F.3d at 1318; *Mink*, 860 F.3d at 1330. In these cases, relied upon by Plaintiff, failure to comply with the FDCA did not create a cause of action. Instead, lack of compliance was cited as evidence to support personal injury claims brought under "traditional state tort law which had predated the federal enactments in question." *Buckman Co.*, 531 U.S. at 353.

In contrast, claims that "rel[y] on a state statute which itself relies on the federal statute, not traditional state tort law theory," *Nexus*, 48 F.4th at 1046, "exist solely by virtue of the FDCA . . . requirements," *Buckman*, 531 U.S. at 353. Where "the existence of [the FDCA] is a critical element" of a case, the claim is impliedly preempted. *Id.*

In *Nexus*, the Ninth Circuit considered a cause of action similar to the instant case. Nexus Pharmaceuticals sued a compounding pharmacy for manufacturing drugs that were allegedly copies of Nexus's FDA-approved drug, Emerphed. *Nexus*, 48 F.4th at 1044. Nexus cited multiple state statutes, including the Florida Drug and Cosmetic Act, that "prohibit the sale of drugs not approved by the FDA." *Id.* The Ninth Circuit held that these types of claims are akin to private enforcement of the FDCA. *Id.* at 1049.

The Court finds the instant case more analogous to *Nexus* than to *Jacob*, *Godelia*, and *Mink*. Plaintiff's claim, as written, is that Plaintiff suffers economic loss due to Defendant's violation of the Florida Drug and Cosmetic Act, which is

itself "a law that says in substance 'comply with the FDCA.'" *Id.* at 1050. The Court can identify no alleged conduct that would "give rise to liability under state law even if the [FDCA] did not exist." *Jacob*, 40 F.4th at 1336 (citations omitted). To survive a motion to dismiss, Plaintiff must plead factual content that allows the Court to infer "the breach of a well-recognized duty owed to [Plaintiff] under state law." *Id.*

III. Pleading

Finally, Defendant argues that Plaintiff inadequately pled the elements of a FDUTPA claim. FDUTPA provides a private cause of action for losses caused by violations of the Act. Fla. Stat. § 501.211(1). Violations of FDUTPA include violations of "[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). Plaintiff points to the Florida Drug and Cosmetic Act, Fla. Stat. § 499.023, as one such law proscribing unconscionable acts or practices. Dkt. 1 ¶ 48. That statute provides:

> "A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce."

Fla. Stat. § 499.023. A drug is "otherwise permitted" when, as with semaglutide,[1] there is a shortage of the FDA-approved medication.[2]

As a result, the fact that Defendant markets and sells drugs containing semaglutide does not, on its own, state a violation of Florida's Drug and Cosmetic Act or subsequent individual cause of action under FDUTPA. Plaintiff fails to state facts showing that Defendant violated, is violating, or is likely to violate the Florida Drug and Cosmetic Act. The Complaint's description of Defendant's products as "Unapproved New Drugs," Dkt. 1 at ¶ 9, is simply a label. Plaintiff must plead factual content that allows the Court to draw a reasonable inference that Defendant's drugs violate the Florida Drug and Cosmetic Act.

CONCLUSION

Plaintiff's claim, as written, is preempted by the FDCA and fails to state a claim under FDUTPA. Accordingly, it is hereby **ORDERED** and **ADJUDGED** that Defendant's Motion to Dismiss (Dkt. 17) is **GRANTED WITHOUT PREJUDICE**. Should Plaintiff chose to amend, it should do so within twenty-one (21) days.

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[1] *FDA Drug Shortages*, U.S. Food and Drug Administration, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm (last accessed Nov. 6, 2023).
[2] *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, Food and Drug Administration Guidance Document (Jan. 2018) at 5.

DONE and **ORDERED** at Tampa, Florida, on November 8, 2023.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

Copies Provided To
Counsel of Record