UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 23-cv-23586-ALTMAN/Reid

ELI LILLY AND COMPANY,

Plaintiff,

v.

RXCOMPOUNDSTORE.COM, LLC,

Defendant.
_____/

ORDER GRANTING MOTION TO DISMISS

The Defendant has moved to dismiss the Plaintiff's Amended Complaint. *See* Motion to Dismiss [ECF No. 26]. Having carefully reviewed the Motion, the Response, the Reply, and the governing law, we now **GRANT** the Defendant's Motion to Dismiss ***with prejudice***.[1]

THE FACTS[2]

On September 19, 2023, our Plaintiff (Eli Lilly & Co.) sued our Defendant (RXCompoundStore.com, LLC), asserting violations of Florida's Drug and Cosmetic Act (the "Florida DCA") and Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"). *See generally* Complaint [ECF No. 1]. Eli Lilly has since filed an Amended Complaint [ECF No. 18], which is the operative complaint here. On the same day that it filed its initial complaint against RXCompoundStore (a compounding pharmacy based in Miami), Eli Lilly sued two other pharmacies in the Middle District of Florida, lodging virtually identical complaints. *See Eli Lilly & Co. v. Archangel Raphael LLC d/b/a Better Life Pharmacy*, 23-cv-02111 (M.D. Fla. Sept. 19, 2023) (Scriven, J.); *Eli Lilly & Co. v. Wells Pharmacy*

[1] The Motion to Dismiss is ripe for resolution. *See* Plaintiff's Response to Motion to Dismiss (the "Response") [ECF No. 29]; Defendant's Reply Memorandum in Support of Motion to Dismiss (the "Reply") [ECF No. 33].

[2] We take the following facts from the Plaintiff's Amended Complaint and accept them as true for purposes of this Order.

Network, LLC, 23-cv-00576 (M.D. Fla. Sept. 19, 2023) (Moody, J.). It also filed other similar complaints in courts around the country. *See, e.g.*, *Eli Lilly & Co. v. Revive RX, LLC*, 23-cv-03521 (S.D. Tex. Sept. 19, 2023) (Rosenthal, J.).

In each of these cases, Eli Lilly seeks to prevent the defendant-pharmacy from selling compounded versions of the "pharmaceutical ingredient tirzepatide." Amended Complaint ¶ 15. Eli Lilly has a vested interest in preventing the Defendant from selling these drugs because it's "the only company that has an FDA-approved drug containing tirzepatide[3] as its active pharmaceutical ingredient," *ibid.*, and because it's the "only supplier of FDA-approved tirzepatide drugs in the United States," *id.* ¶ 25. Eli Lilly contends that our Defendant's tirzepatide products have not been "approved under section 505 of the [Federal Food, Drug, and Cosmetic Act (the 'FDCA')]" *or* by the United States Food and Drug Administration (the "FDA"). *Id.* ¶¶ 31, 48. "Because Defendant's tirzepatide drugs have not been tested in clinical trials and their composition is unknown given their lack of approval," the Plaintiff adds, "it is unknown whether they are safe and effective." *Id.* ¶ 30. Plus, Eli Lilly says, the Defendant's sale of drugs containing tirzepatide has "injured Lilly [both] financially" and reputationally. *Id.* ¶¶ 50–52.

The Florida DCA provides that no person may "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." *Id.* ¶ 27 (quoting FLA. STAT. § 499.023). FDUTPA, on the other hand, creates a private right of action for violations of "[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or

[3] Eli Lilly has "regulatory approval" from the FDA to market and sell Mounjaro® as a "treatment for type 2 diabetes mellitus." Amended Complaint ¶ 17. "In addition to Mounjaro®, [the] FDA recently approved Lilly's Zepbound™ (tirzepatide) for chronic weight management for adults with obesity . . . or those who are overweight . . . and also have weight-related medical problems." *Id.* ¶ 15 n.1.

unfair, deceptive, or unconscionable acts or practices." *Id.* ¶¶ 2–3 (quoting FLA. STAT. §§ 501.203(3)(c), 501.211).[4] Eli Lilly, therefore, brings this case under FDUTPA "to stop [RXCompoundStore] from engaging in unfair trade practices by unlawfully manufacturing and selling unapproved drugs in Florida," in violation of the Florida DCA and without FDA approval. *Id.* ¶ 1. Eli Lilly requests a "permanent injunction enjoining Defendant from continuing [its] unlawful and unfair business practices," "[a] judgment that Defendant violated FDUTPA," "[d]eclaratory relief," and attorneys' fees and costs. *Id.* ¶¶ 64–67.

On February 5, 2024, Judge Moody granted the defendant-pharmacy's motion to dismiss in one of the parallel Eli Lilly cases, dismissing the entire action "with prejudice" on the ground that any "further amendment [would be] futile." Order on Mot. to Dismiss, *Wells Pharmacy Network*, ECF No. 30 at 1; *see also* Defendant's Notice of Filing Supplemental Authority in Support of its Pending Motion to Dismiss [ECF Nos. 34 & 34-1]. The defendant-pharmacy's motion to dismiss is still pending in Judge Scriven's case. *See* Mot. to Dismiss, *Archangel Raphael LLC*, ECF No. 24.

THE LAW

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To meet this "plausibility standard," a plaintiff must "plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at

[4] According to the Plaintiff, the Florida legislature "included a safe harbor in FDUTPA making clear that that statute does not prohibit '[a]n act or practice required or specifically permitted by federal or state law.' . . . . As a result, if a practice complies with federal law, it is not 'unfair' under FDUTPA and not actionable." Amended Complaint ¶ 4 (quoting FLA. STAT. § 501.212(1)).

555). "[T]he standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence' of the required element." *Rivell v. Private Health Care Sys., Inc.*, 520 F.3d 1308, 1309–10 (11th Cir. 2008) (quoting *Twombly*, 550 U.S. at 545). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. On a motion to dismiss, "the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff." *Dusek v. JPMorgan Chase & Co.*, 832 F.3d 1243, 1246 (11th Cir. 2016).

ANALYSIS

The Defendant moves to dismiss the Complaint for three reasons: *First*, it argues that the Plaintiff lacks standing to pursue its requests for declaratory and injunctive relief. *See* Motion to Dismiss at 8. *Second*, it says that the "Plaintiff's claim is preempted by the FDCA," which "makes clear there shall be no private claims to enforce the statute." *Id.* ¶ 11. *Third*, the Defendant contends that the Plaintiff "fails to plausibly allege a claim under FDUTPA" because it "does not allege any facts to support deception[,] [n]o consumers were misled, and Plaintiff makes only conclusory allegations of unfairness[.]" *Id.* ¶ 18. We'll address each of these arguments in turn.

I. Standing to Seek Declaratory and Injunctive Relief

The Defendant argues that the Plaintiff lacks standing to seek declaratory and injunctive relief because Eli Lilly "alleges only that it has suffered 'financial harm' and injury to its goodwill and reputation . . . but does not allege how this is possible, let alone plausible." Motion to Dismiss at 10. "There are no allegations," the Defendant says, "that Defendant uses Plaintiff's product names or the name Mounjaro® . . . . Without plausible allegations concerning past harm, future harm is even more speculative and remote." *Ibid.* "In sum," the Defendant concludes, "Plaintiff cannot demonstrate the elements of standing for injunctive and declaratory relief." *Ibid.* We disagree.

To establish its standing under Article III of the U.S. Constitution, a plaintiff must have suffered an "injury in fact" that is "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010). "In order to demonstrate that there is a case or controversy that satisfies Article III's standing requirement when a plaintiff is seeking declaratory relief—as opposed to seeking damages for past harm—the plaintiff must allege facts from which it appears that there is a 'substantial likelihood that he will suffer injury in the future.'" *A&M Gerber Chiropractic LLC v. GEICO Gen. Ins. Co.*, 925 F.3d 1205, 1210–11 (11th Cir. 2019) (quoting *Malowney v. Fed. Collection Deposit Grp.*, 193 F.3d 1342, 1346 (11th Cir. 1999)). The Eleventh Circuit applies this same standard to claims for injunctive relief: "Because injunctions regulate future conduct, a party has standing to seek injunctive relief only if the party shows a real and immediate—as opposed to a merely conjectural or hypothetical—threat of future injury." *Houston v. Marod Supermarkets, Inc.*, 733 F.3d 1323, 1329 (11th Cir. 2013).

Here, Eli Lilly has sufficiently alleged a substantial likelihood of future injury. It, for example, claims that it's losing money and good will because of the Defendant's *ongoing* sales of drugs containing tirzepatide:

> Defendant's actions have injured Lilly financially in an amount that exceeds $75,000. Lilly is the only supplier in the United States of FDA-approved tirzepatide drugs. Defendant sells its unapproved drugs purporting to contain tirzepatide to customers in Florida and many other states. Some sales made by Defendant would have been made by Lilly but for Defendant's unlawful and unfair competition, and Lilly has suffered financial harm as a direct result of Defendant's unlawful and unfair competition. Defendant's unlawful sales of its purported tirzepatide drug are also *injuring* Lilly's reputation because of Defendant's business and trade practices that jeopardize public health.

Amended Complaint ¶¶ 50–52 (emphasis added). These allegations are sufficient to establish that Eli Lilly is *continuing* to suffer an injury in fact. *See Maisonet v. Comm'r, Ala. Dep't of Corr.*, 2022 WL 4283560, at *2 (11th Cir. Sept. 16, 2022) (per curiam) ("Because declaratory and injunctive relief necessarily do not redress past harm, standing for such claims requires a showing of an ongoing or future injury . . . .

[To establish standing for declaratory and injunctive relief, a plaintiff] must allege either a current, ongoing injury or that a future injury is 'certainly impending.'"); *Young v. Cmty. Health Sys., Inc.*, 2023 WL 6121795, at *2 (11th Cir. Sept. 19, 2023) (per curiam) (holding that the plaintiff "must establish that she is suffering an ongoing harm or in danger of suffering a harm in the near future" to "pursue claims for declaratory or injunctive relief"); *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 125 (2014) ("Lexmark does not deny that Static Control's allegations of lost sales and damage to its business reputation give it standing under Article III[,] . . . and we are satisfied that they do."); *cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) ("[P]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief if unaccompanied by any continuing, present adverse effects." (cleaned up)).

We therefore agree with Judge Moody who held, in a nearly identical case, that Eli Lilly's allegations were "sufficient to establish" an ongoing injury in fact. *See* Order on Mot. to Dismiss, *Wells Pharmacy Network,* ECF No. 30 at 4 ("Lilly alleged that it has lost and is losing sales because of [the defendant-pharmacy's] conduct . . . . Lilly also alleged reputational injury . . . . Accordingly, the Court denies Wells's standing argument.").[5] Like Judge Moody, then, we reject the Defendant's standing objection.

II. Preemption

But preemption is another matter. In its primary argument for dismissal, RXCompoundStore contends that Eli Lilly's claim—which Eli Lilly purports to bring under the Florida DCA and

[5] To the extent our Defendant calls into question the other two prongs of Article III standing, Eli Lilly has met its burden there too. As to traceability, the Plaintiff alleges that the Defendant is "*injuring* the reputation of Plaintiff *because of* Defendant's business and trade practices that jeopardize public health." Amended Complaint ¶ 31 (emphases added). That's enough to show traceability. As for redressability, Eli Lilly says that its requested relief would prevent the Defendant "from causing Lilly to lose future sales or goodwill." Reply at 17; *see also* Amended Complaint ¶ 64 (requesting an injunction to prevent the Defendant from "*continuing* the unlawful and unfair business practices" (emphasis added)). That's enough for now.

FDUTPA—is preempted by federal law.[6] Specifically, the Defendant argues that the FDCA includes no private right of action, and that a party may not use "state laws—i.e., [ ] FDUTPA and the [Florida] DCA—to enforce the terms of the FDCA." Motion to Dismiss at 12. In considering this very same argument, Judge Moody found that Eli Lilly's claims were preempted by the FDCA. And we agree.

To begin with, we think Eli Lilly is using state law to enforce the terms of the FDCA, which (as the Defendant correctly points out) is a task generally "reserved to the FDA[.]" Response at 13. Eli Lilly tells us that, under Section 505 of the FDCA, most "[n]ew [d]rugs" must be "approved" by the FDA. Amended Complaint ¶ 28 (citing 21 U.S.C. § 355). It acknowledges, however, that Section 503A of the FDCA "exempts compounded drugs from the FDA approval requirement" in certain "circumstances specified by Congress." *Id.* ¶ 34 (citing 21 U.S.C. § 353a(a)). In the Plaintiff's words:

> The first of section 503A's requirements is the "prescription requirement." This provision limits the exemption from FDA approval to drugs that are "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order *that a compounded product is necessary for the identified patient*." [21 U.S.C. § 353a(a)] (emphasis added).
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> Section 503A's prescription requirement is the key bulwark that separates legitimate compounding of individually-tailored, patient-specific alternatives to FDA-approved drugs from manufacturing in the guise of "compounding." . . . . Maintaining this distinction is critical to the public health. Because compounded drugs are not reviewed by FDA for safety, effectiveness, or quality, they are more dangerous than FDA-approved drugs.

Id. ¶¶ 36–38. Eli Lilly insists that the Defendant's tirzepatide drugs don't fall into this exempted category because the "Defendant does not comply with the prescription requirement," instead "produc[ing] and sell[ing] its tirzepatide drugs based on prescription orders that do nothing more than

[6] Federal preemption is an affirmative defense. *See Quiller v. Barclays Am./Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984). While "the existence of an affirmative defense" will not generally "support a motion to dismiss[,] . . . a complaint may be dismissed under Rule 12(b)(6) when its own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Ibid.*

request 'tirzepatide,' without any statement that a compounded alternative to Lilly's FDA-approved tirzepatide drugs is necessary for the identified patient." *Id.* ¶ 41. Eli Lilly therefore asks us to accept its conclusion that the Defendant (1) "does not comply with section 503A" of the FDCA and (2) "sells unapproved new drugs in violation of the Florida Drug and Cosmetic Act," which itself prohibits the sale of new drugs "unless an approved application has become effective under s. 505 of the [FDCA]." *Id.* ¶¶ 5, 12, 35.

But the Plaintiff cannot "call[ ] upon the court to adjudicate whether [the Defendant] ha[s] complied with the FDCA." Order on Mot. to Dismiss, *Wells Pharmacy Network*, ECF No. 30 at 6. As the Supreme Court has made clear, "the FDCA and its regulations provide the United States with nearly exclusive enforcement authority, including the authority to seek criminal sanctions in some circumstances. 21 U.S.C. §§ 333(a), 337. *Private parties may not bring enforcement suits.* § 337." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (emphasis added); *see also Novo Nordisk, Inc. v. Brooksville Pharms. Inc.*, 2023 WL 7385819, at *2 (M.D. Fla. Nov. 8, 2023) (Jung, J.) ("The United States has sole enforcement authority under the FDCA . . . . Private enforcement of the FDCA is barred."). Given the federal government's "nearly exclusive" authority to enforce the FDCA, courts around the country have generally refused to encroach on that authority by adjudicating claims that a party has (or has not) complied with the FDCA—even where (as here) the plaintiff tries to bring its claims under *other* federal or state statutes. *See, e.g.*, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) ("Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."); *Zyla Life Scis., LLC v. Wells Pharma of Houston, LLC*, 2023 WL 6301651, at *4 (S.D. Tex. Sept. 27, 2023) (dismissing claims without leave to amend on preemption grounds where the plaintiff's "state law claims impinge on the FDA's sole authority over enforcement of the FDCA's

drug approval requirements [and] depend on speculation that the FDA would have taken regulatory action in response to [d]efendant's sale of compounded indomethacin suppositories, as [p]laintiff does not allege that [d]efendant violated the FDCA but asserts state law claims that hinge on FDCA compliance").

In *Novo Nordisk*—a case with similar facts to ours—the plaintiff sued a compounding pharmacy, alleging that the pharmacy's sale of unapproved drugs containing semaglutide violated the Florida DCA and FDUTPA. In holding that the plaintiff's FDUTPA claim was "preempted by the FDCA," Judge Jung reasoned that—in spite of artful pleading—the FDCA regulations were a "critical element" of the case, transforming the plaintiff's cause of action into an attempt to "private[ly] enforce[ ]" the FDCA. *Novo Nordisk*, 2023 WL 7385819, at *3–4. As Judge Jung explained:

> [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.
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> In contrast, claims that "rel[y] on a state statute which itself relies on the federal statute, not traditional state tort law theory," [*Nexus Pharms. Inc. v. Cent. Admixture Pharm. Servs.*, 48 F.4th 1040, 1046 (9th Cir. 2022)], "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* . . . .
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> 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) . . . . Plaintiff's claim, as written, is preempted by the FDCA[.]

Id. at *3.

Relying on *Nexus* and *Novo Nordisk*, Judge Moody similarly concluded that Eli Lilly's FDUTPA claim was "preempted on the face" of the complaint. *Wells Pharmacy Network*, ECF No. 30 at 5. In his words:

> 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 and therefore preempted. *Id.* at 1049.
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> Another recent case that is highly persuasive is from a district court in the Southern District of Texas that adopted the reasoning of the Ninth Circuit and held that the state law unfair competition claims brought by the plaintiff drug manufacturer, Zyla Life Sciences, against the defendant compounding pharmacy were preempted by the FDCA. Wells discusses this case in its motion and points out that, like Lilly, Zyla was the only FDA-approved seller of a particular drug. The defendant sold a compounded version of Zyla's drug pursuant to Section 503 of the FDCA. Seeking to enjoin the defendant's sales, Zyla filed claims under six states' unfair competition laws, including the FDUTPA. Zyla further argued, like Lilly here, that preemption was inappropriate because the defendant did not comply with section 503A's requirements. The court disagreed and found that Zyla's FDUTPA claim "hinged" on FDCA compliance despite not explicitly alleging that the defendant violated the FDCA, and therefore Zyla's claims impermissibly sought to enforce requirements that added to the FDCA. For this reason, the FDUTPA claims were preempted and dismissed with prejudice. *See Zyla Life Sciences, Inc. v. Wells Pharma of Houston, LLC*, No. 4:22-cv-4400, 2023 WL 6301651, at *1 (S.D. Tex. Sept. 27, 2023) . . . .
>
> Lilly does not allege any claim based on Florida tort law. Instead, Lilly's FDUTPA claim is based on a violation of the FDCA, and is therefore preempted.

Id. at 5–7.

As we've said, our case is almost identical to *Wells Pharmacy*. As in that case, Eli Lilly's FDUTPA claim here is based on the Defendant's alleged violations of the FDCA, and (again, as there) our Plaintiff doesn't bring any claims under Florida tort law. *See* Amended Complaint ¶¶ 28, 31 ("No 'approved application' for Defendant's tirzepatide drugs 'has become effective under s. 505 of the [FDCA].' [FLA. STAT.] § 499.023 . . . . Because Defendant's tirzepatide drugs are not approved under

section 505 of the FDCA and are not 'otherwise permitted by the Secretary' to be distributed in interstate commerce, their sale violates Florida's [DCA].''). The "existence of the FDCA is [thus] a critical element" of Eli Lilly's case, *Novo Nordisk*, 2023 WL 7385819, at *3, and (like many of our colleagues) we won't allow the Plaintiff to use state law as a back door to privately enforce the FDCA. We therefore agree with our colleagues around the country who have repeatedly "concluded that claims based on allegations that a defendant violated the FDCA are impliedly preempted." *Markland v. Insys Therapeutics, Inc.*, 270 F. Supp. 3d 1318, 1328 (M.D. Fla. 2017) (Howard, J.). For all these reasons, we find that the Plaintiff's FDUTPA claim is, on its face, preempted by federal law.[7]

And we won't give the Plaintiff leave to amend *both* because any amendment would be futile *and* because it never asked—either in its Response or in a separate motion for leave to amend—for permission to amend its claim. *See Wells Pharmacy Network*, ECF No. 30 at 7–8 ("Finally, while amendment should be freely given at this stage under Fed. R. Civ. P. 15(a), the [c]ourt concludes that any further amendment of the complaint would be futile. Also, it is notable that Lilly did not seek amendment as an alternative to a dismissal with prejudice in its response."); *Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) ("A district court is not required to grant a plaintiff leave to amend his complaint sua sponte when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court."); *Avena v. Imperial Salon & Spa, Inc.*, 740 F. App'x 679, 683 (11th Cir. 2018) ("[W]e've rejected the idea that a party can await a ruling on a motion to dismiss before filing a motion for leave to amend.").

* * *

After careful review, therefore, we hereby **ORDER and ADJUDGE** as follows:

1. The Defendant's Motion to Dismiss [ECF No. 26] is **GRANTED**.

[7] Because we've found that the Plaintiff's claim is preempted by federal law, we needn't address the Defendant's third and final argument—that the Plaintiff has failed to state a claim under FDUTPA.

2. The Clerk of Court shall **CLOSE** this case.

3. All pending deadlines and hearings are **TERMINATED**, and any pending motions are **DENIED as moot**.

DONE AND ORDERED in the Southern District of Florida on April 9, 2024.

ROY K. ALTMAN
UNITED STATES DISTRICT JUDGE

cc: counsel of record