UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

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| PAMELA ROONEY, ET AL. | CIVIL ACTION |
| VERSUS | NO. 22-1164 |
| THE PROCTER AND GAMBLE COMPANY | SECTION "R" (1) |

**ORDER AND REASONS**

Before the Court is defendant Procter & Gamble Company's motion to dismiss the second amended complaint filed by plaintiffs Pamela and Pat Rooney.[1] Plaintiffs oppose defendant's motion.[2] For the following reasons, the Court GRANTS defendant's motion.

## I. BACKGROUND

This case arises from plaintiff Pamela Rooney's alleged exposure to benzene from her use of Secret aerosol antiperspirant, a product that defendant manufactures, advertises, and sells. Plaintiffs contend that

[1] R. Doc. 26.
[2] R. Doc. 27.

Rooney bought Secret antiperspirant at least once a month for several years,[3] which allegedly caused her to develop triple negative breast cancer.

Plaintiffs contend that in 2021, Valisure LLC, an analytical pharmacy, ran tests on a number of defendant's antiperspirant products, including Secret.[4] Valisure's testing allegedly revealed that samples of Secret antiperspirants contained benzene, a carcinogenic chemical capable of causing, among other things, triple negative breast cancer.[5] The batches of Secret that Valisure tested included values of benzene ranging from 1.10 to 16.2 parts per million ("ppm").[6] For reference, plaintiffs allege that the National Institute of Occupational Safety and Health recommends that protective equipment be worn by workers expecting to be exposed to benzene at concentrations of 0.1 ppm, and identifies skin absorption as a method of benzene exposure.[7] Plaintiffs contend that both the Centers for Disease Control and the U.S. Department of Health and Human Services recognize the carcinogenic properties of benzene.[8] They further allege that the FDA characterizes benzene as a "Class 1" compound, which, according to FDA

3 R. Doc. 25 at 2 ¶ 7.
4 *Id.* at 4 ¶ 16.
5 *Id.*; *id.* at 3 ¶ 12.
6 *Id.* at 4 ¶ 16.
7 *Id.*
8 *Id.* at 13 ¶¶ 37-38.

guidance, "should not be employed in the manufacture of drug substances, excipients, and drug products, because of their unacceptable toxicity or their deleterious environmental effect."[9]

Valisure filed a citizen petition with the FDA asking the agency to recall all batches of defendant's antiperspirant products that contained over 0.1 ppm of benzene.[10] Although the FDA has not responded to Valisure's petition, defendant voluntarily recalled batches of its antiperspirant products from the market after Valisure filed the petition.[11]

Plaintiffs allege that the FDA regulates the manufacture and sale of antiperspirant products, which it treats as an over-the-counter drug product.[12] The FDA maintains a list of acceptable active ingredients for use in antiperspirant products. Benzene is not on the FDA's list of acceptable active or inactive ingredients, nor does defendant include benzene on the list of ingredients on its antiperspirants.[13] In fact, defendant allegedly represents to consumers that benzene is among the materials it does *not* use in any of its products.[14] Plaintiffs thus contend that the antiperspirant is both

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9 *Id.* ¶ 41.
10 *Id.* at 5 ¶ 17.
11 *Id.*
12 *Id.* at 7 ¶ 20.
13 *Id.* at 7-8 ¶ 20.
14 *Id.* at 8 ¶ 20.

"misbranded" and "adulterated" in violation of the Federal Food, Drug, and Cosmetics Act (the "FDCA").

Plaintiffs allege that the benzene in the Secret antiperspirants that Rooney used caused her cancer. They contend that they currently have in their possession five cans of adulterated Secret antiperspirant that Rooney used in the period leading up to her cancer diagnosis, which they represent they will produce to defendant in discovery. Plaintiffs allege that defendant violated the Louisiana Products Liability Act (the "LPLA") by selling Secret antiperspirants without issuing adequate warnings.[15] Plaintiffs also contend that defendant is liable under theories of negligence, gross negligence, strict liability, and "fault,"[16] and that defendant violated the FDCA.[17]

Plaintiffs filed their first complaint in April of 2022.[18] Defendant moved to dismiss for failure to state a claim,[19] in response to which plaintiffs filed an amended complaint.[20] Defendant moved to dismiss the amended complaint on the same grounds,[21] and plaintiffs filed a second amended

15 *Id.* at 15.
16 *Id.* at 3 ¶ 14.
17 *Id.* at 14 ¶¶ 42-47.
18 R. Doc. 1.
19 R. Doc. 7.
20 R. Doc. 15.
21 R. Doc. 16.

complaint.[22] Defendant then moved to dismiss the second amended complaint.[23] That motion is the subject of this Order and Reasons.

In its motion, defendant contends that plaintiffs failed to state a claim under the LPLA because they failed to plausibly allege (1) causation and (2) breach of a duty to warn. Regarding causation, defendant contends that plaintiffs have alleged no facts indicating that Rooney actually used cans of Secret antiperspirant that contained enough benzene to cause her injury.[24] It also contends that benzene is commonly found in a number of sources, including gasoline fumes and car exhaust, and that plaintiffs have not plausibly alleged that Rooney's cancer was caused by benzene exposure from Secret antiperspirants rather than some other source.[25] Defendant also contends it did not breach its duty to warn because it complied with federal regulations. Defendant contends that to the extent plaintiffs bring any other claims, those must be dismissed because the LPLA is the exclusive remedy for lawsuits against manufacturers premised on product defects.[26]

Plaintiffs oppose defendant's motion. The Court considers the parties' arguments below.

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22 R. Doc. 25.
23 R. Doc. 26.
24 R. Doc. 26-1 at 7.
25 *Id.* at 3.
26 *Id.* at 14-16.

## II. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead enough facts to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). A claim is facially plausible "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.* at 678. The Court must accept all well-pleaded facts as true and must draw all reasonable inferences in favor of the plaintiff. *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 239, 244 (5th Cir. 2009). But the Court is not bound to accept as true legal conclusions couched as factual allegations. *Iqbal*, 556 U.S. at 678.

On a Rule 12(b)(6) motion, the Court must limit its review to the contents of the pleadings, including attachments. *Brand Coupon Network, L.L.C. v. Catalina Mktg. Corp.*, 748 F.3d 631, 635 (5th Cir. 2014). The Court may also consider documents attached to a motion to dismiss or an opposition to that motion when the documents are referred to in the pleadings and are central to a plaintiff's claims. *Id.* "In addition to facts alleged in the pleadings, however, the district court 'may also consider matters of which [it] may take judicial notice.'" *Hall v. Hodgkins*, 305 F.

App'x 224, 227 (5th Cir. 2008) (citing *Lovelace v. Software Spectrum, Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996)).

## III. DISCUSSION

### A. The Louisiana Products Liability Act

To maintain a products liability action under the LPLA, a plaintiff must establish that "the defendant is the manufacturer of the product; the claimant's damage was proximately caused by a characteristic of the product; this characteristic made the product unreasonably dangerous; and the claimant's damage arose from a reasonably anticipated use of the product." *Flagg v. Stryker Corp.*, 647 F. App'x 314, 316 (5th. Cir. 2016) (citing La. Rev. Stat. § 9:2800.52). A plaintiff can show that a product was unreasonably dangerous "under one of four theories: (1) the product's construction or composition is defective, (2) the product's design is defective, (3) the product's warnings are inadequate, or (4) by showing a breach of express warranty." *Id.*

Plaintiffs bring an inadequate warning claim. To prevail on such a claim, a plaintiff must establish that, at the time the product left the manufacturer's control, "the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide

an adequate warning of such characteristic and its dangers to users and handlers of the product." *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 261 (5th Cir. 2002).

An "adequate warning" for purposes of the LPLA is "a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made." La. Rev. Stat. § 9:2800.53(9). "Whether a particular warning or instruction is adequate is a question for the trier of fact." *Jack v. Alberto-Culver USA, Inc.*, 949 So. 2d 1256, 1259 (La. 2007). To determine the adequacy of the warning, the following factors are relevant: "(1) the severity of the danger, (2) the likelihood of successful communication of the warning to foreseeable consumers, (3) the intensity and form of the warning, and (4) the cost of improving the strength or mode of the warning." *Walker v. Manitowoc Co.*, 259 So. 3d 465, 477 (La. App. 3d Cir. 2018) (internal quotation marks omitted).

Under the LPLA, plaintiffs bear the burden of establishing that defendant's failure to issue an adequate warning was the proximate cause of Rooney's damages. *Marable v. Empire Truck Sales of Louisiana, LLC*, 221

So. 3d 880, 901 (4th Cir. 2017). Proximate cause is defined as "any cause which, in natural and continuous sequence, unbroken by an efficient, intervening cause, produces the result complained of without which the result would not have occurred." *Id.* To establish proximate causation under the LPLA, plaintiffs must show that "but for the inadequate warning," they "would not have used" the product. *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991). Plaintiffs' allegations regarding causation are deficient in two respects.

First, plaintiffs have failed to plausibly allege that Rooney actually used Secret antiperspirants that contained benzene. Plaintiffs state, in conclusory fashion, that the cans of Secret Rooney used contained benzene.[27] But plaintiffs have alleged no facts supporting this conclusion. Plaintiffs contend that all of the Secret samples tested by Valisure contained benzene,[28] which, if true, would make plausible plaintiffs' contention that the cans Rooney used likewise contained benzene. But the Valisure citizen's petition does not state that every single sample of Secret that Valisure tested contained benzene.[29]

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27 R. Doc. 25 at 7 ¶ 18(a); *id.* at 3 ¶ 8(a).

28 *Id.* at 4 ¶ 16.

29 Because the Valisure citizen's petition is "referred to in the pleadings" and "central to" plaintiffs' claims, the Court may consider the document, which was attached to defendant's motion, at the motion to dismiss stage. *Brand Coupon Network, LLC*, 748 F.3d at 635.

It indicates that at least some of the Secret batches it tested contained benzene, but the petition does not state how many Secret batches Valisure tested total.[30] Indeed, the petition states that of the 108 unique batches of products Valisure tested, only 59 had detectable levels of benzene, and that "many of the body spray products Valisure tested did not contain detectable levels of benzene."[31] The Court thus cannot conclude that "all" of the samples contained benzene. Plaintiffs contend in their opposition to defendant's motion that they matched the numbers on their Secret cans with the lot numbers of products that Valisure confirmed contained benzene, but because this allegation is not in plaintiffs' complaint, the Court cannot consider it at the motion to dismiss stage. *See Anyanwu v. Louisiana*, No. 18-0778, 2019 WL 3325809, at *2 ("[T]he Court cannot consider new factual allegations raised in Plaintiff's opposition that were not specified in the complaint.").

Plaintiffs have also failed to plausibly allege that benzene exposure can cause the type of cancer with which Rooney was diagnosed. Despite plaintiffs' assertion in their complaint that "[t]he development of triple negative breast cancer as a result of benzene exposure has been well

30 R. Doc. 26-2 at 13-18.
31 *Id.* at 2.

documented," they do not refer the Court to any of the purported documentation of the link between benzene and breast cancer. *Compare Baudin v. AstraZeneca Pharms. LP*, 413 F. Supp. 3d 498, 507 (denying defendant's motion to dismiss when plaintiff included "allegations regarding the scientific support for the link between Nexium and gastric cancer"). This omission is striking when compared to plaintiffs' more detailed allegations about the studies linking benzene to cancer generally. Their allegation that benzene can cause triple negative breast cancer is an unsupported, conclusory assertion of fact that is insufficient at the pleading stage. *Iqbal*, 556 U.S. at 678 ("Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." (internal quotation marks omitted)).

### B. Other Theories of Liability

It is unclear, from the face of plaintiffs' complaint, whether they assert any claims other than their claim premised on defendant's inadequate warning under the LPLA. The complaint mentions, among other things, negligence, gross negligence, strict liability, and violations of the FDCA. To the extent plaintiffs intended to allege these theories as freestanding claims for relief, they are dismissed. "There is no private right of action to sue for

violations of the FDCA or associated regulations." *Vesoulis v. ReShape LifeSciences, Inc.*, 2022 WL 989465, at *4 (5th Cir. Apr. 1, 2022). Plaintiffs' other theories must be dismissed because "[t]he LPLA provides the 'exclusive remedy for products liability suits' under Louisiana law." *Flagg*, 647 F. App'x at 316 (quoting *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182 (5th Cir. 2012)); *see also Brennon v. Pfizer, Inc.*, 2009 WL 2525180, at *3 (W.D. La. Aug. 17, 2009) (dismissing plaintiff's claims for strict liability, negligence, gross negligence, and breach of express warranty on the grounds that the LPLA provided the exclusive remedy plaintiff's claims against a manufacturer).

### C. Leave to Amend

Plaintiffs request that, in the event the Court grants defendant's motion to dismiss, they be given leave to amend their complaint to allege facts sufficient to support their claim.[32] Defendant opposes this request on the grounds that any amendment would be futile.[33]

The Court should "freely give" leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2); *Leal v. McHugh*, 731 F.3d 405, 417 (5th

[32] R. Doc. 27 at 2.
[33] R. Doc. 30 at 1.

Cir. 2013). When deciding whether leave to amend should be given, the Court considers several factors, including "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of the amendment." *Forman v. Davis*, 371 U.S. 178, 182 (1962). The Court finds that none of these factors is present here. Specifically, the Court finds that, with sufficiently pleaded facts, the "circumstances relied upon by . . . plaintiff[s] may be a proper subject of relief." *Id.* The Court therefore dismisses plaintiffs' complaint without prejudice and with leave to amend within fourteen days of entry of this Order.

## IV. CONCLUSION

For the foregoing reasons, the Court GRANTS defendants' motion to dismiss, and dismisses plaintiffs' complaint WITHOUT PREJUDICE. The Court further GRANTS plaintiffs leave to file an amended complaint within fourteen days of this Order. The Court also DENIES as MOOT defendants' first two motions to dismiss plaintiffs' original complaint and their first amended complaint. [34]

New Orleans, Louisiana, this 21st day of November, 2022.

SARAH S. VANCE
UNITED STATES DISTRICT JUDGE

[34] R. Docs. 7 & 16.