UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

STEPHANIE FULLER, ET AL.	**CIVIL ACTION**
VERSUS	**No. 20-1675**
EISAI INC., ET AL.	**SECTION I**

ORDER & REASONS

Before the Court are the defendants, Eisai, Inc.'s ("Eisai") and Arena Pharmaceuticals, Inc.'s ("Arena"), motions[1] to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), counts two, three, and four of the plaintiffs' amended complaint[2] for failure to state a claim. The plaintiffs oppose[3] the motions, to which the defendants filed replies.[4] For the following reasons, the motions are granted in part and denied in part.

I. BACKGROUND

Stephanie Fuller ("Fuller") and Robert Fuller[5] (collectively, "the plaintiffs") filed this lawsuit against Eisai and Arena for distributing and manufacturing the

[1] R. Doc. No. 26 (Eisai motion to dismiss); R. Doc. No. 27 (Arena motion to dismiss); *see* R. Doc. No. 27-1, at 1 (stating that Arena "fully joins and adopts the law and arguments set forth in the Memorandum in Support of Defendant Eisai Inc.'s Rule 12(b)(6) Motion to Dismiss Plaintiffs' Amended Complaint In Part").
[2] R. Doc. No. 20.
[3] R. Doc. No. 28.
[4] R. Doc. Nos. 32, 34.
[5] Robert Fuller, Stephanie's spouse, alleges a claim for loss of consortium due to Stephanie's alleged injuries. R. Doc. No. 20, at 1 ¶ 3. The Court refers only to Stephanie when it uses the shorthand "Fuller" herein.

supplemental weight-loss drug Belviq, which Fuller used for approximately two months in 2018.[6] Fuller claims that Belviq caused her to develop breast cancer.[7]

As relevant here, the plaintiffs brought three claims under the Louisiana Products Liability Act ("LPLA"), alleging that the defendants: (1) defectively designed Belviq, (2) defectively manufactured the Belviq doses consumed by Fuller, and (3) breached an express warranty regarding the safety and effectiveness of Belviq.[8] Much of the plaintiffs' allegations relate to what the defendants learned about Belviq throughout its testing and approval process with the Food and Drug Administration ("FDA"). The following is an overview of those allegations as set forth in the amended complaint, which the Court accepts as true for purposes of deciding the present motions.

A. Initial Testing of Belviq & the FDA's Initial Denial

In the first stage of testing, before seeking FDA approval, the defendants conducted two cancer-risk studies on Belviq: one on rats,[9] and the other on mice.[10] The rat study identified Belviq as a potential carcinogen—at least among rats.[11] In

[6] R. Doc. No. 20, at 3 ¶ 15.
[7] *Id.* at 2–3 ¶¶ 10–11. Plaintiffs also allege that Fuller suffers from pain and anguish, "diminished enjoyment of life," and "fear of developing any of the above[-]named consequences." *Id.* at 3 ¶ 10. Plaintiffs state that Fuller began to "suffer from breast cancer on or about June 19, 2019." *Id.* at 3 ¶ 16.
[8] *Id.* at 17, 20, 22. The plaintiffs also bring an inadequate warning claim, *id.* at 15, and a claim for Robert Fuller's loss of consortium, *id.* at 24, neither of which are challenged by the defendants' instant motions.
[9] *Id.* at 7 ¶ 52.
[10] *Id.* at 8 ¶ 56.
[11] *Id.* at 7 ¶ 52.

particular, the rat study found an increase in "mammary tumors" in both sexes.[12] The mouse study produced similar results.[13] The plaintiffs argue that, because of these studies, the defendants had "notice" that Belviq could cause cancer in humans.[14] But, as discussed below,[15] a pathology working group later reexamined these studies and found that the results were less conclusive than initially thought.

The defendants also conducted two human studies between 2006 and 2009, which examined Belviq's efficacy in reducing body weight.[16] These studies "revealed only a 3.3% mean weight loss after one year with [Belviq] over that of the placebo group."[17] And from 2007 to 2010, the defendants conducted a third trial focused on Belviq's efficacy among patients with diabetes.[18] This third trial, published in 2012, indicated a 3.1% mean weight loss with Belviq over that of the placebo group.[19] The plaintiffs argue that these studies prove Belviq's ineffectiveness as a weight-loss drug.

Examining these studies, an FDA advisory committee voted 9-5 against Belviq's approval, explaining that "the potential benefits did not outweigh the potential risks based on concerns about the preclinical carcinogenicity findings . . .

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[12] *Id.*
[13] *Id.* at 8 ¶ 56 (noting that the mouse study "demonstrated an increase in [cancer] in males and . . . females").
[14] *Id.* at 8–9 ¶ 57.
[15] *See infra* notes 23–27 and accompanying text.
[16] *Id.* at 9 ¶ 58.
[17] *Id.* at 9 ¶ 60.
[18] *Id.* at 10 ¶ 66.
[19] *Id.*

and marginal weight loss demonstrated by the clinical trials."[20] In October 2010, the FDA issued a final rejection of Belviq.[21] The FDA's Complete Response Letter stated the reasons for the rejection: "uncertainty in diagnosis of mammary masses in rats," the causal link between Belviq and "mammary adenocarcinoma," and "marginal weight loss results."[22] As explained next, however, the FDA reversed its position and approved Belviq based on a reexamination of the rat study described above.

B. The FDA's Approval of Belviq

The defendants sought to address the FDA's concerns. They convened a working group to reassess the data collected in the rat study.[23] That research clarified Belviq's cancer risk: "a *decreased* number of adenocarcinoma" (*i.e.*, cancer), "and an increased number of fibroadenoma" (*i.e.,* noncancerous tumors), "in both the control and [Belviq] groups."[24] The defendants concluded that Belviq's cancer risk, to the extent one was previously shown, was a "rodent-specific phenomenon."[25] The plaintiffs allege—without explanation—that the working group's process was "skewed in favor of . . . a finding that [Belviq] was not a carcinogen."[26] Simultaneously, the plaintiffs also state that the FDA, when later reviewing the working group's data, itself "disregarded as irrelevant to [the] risk of carcinoma" (*i.e.*,

[20] *Id.* at 9–10 ¶ 62.
[21] *Id.* at 10 ¶ 63.
[22] *Id.* The letter also cited a "failure to identify a mode of action and a clear safety margin for brain astrocytoma." *Id.*
[23] *Id.* at 10 ¶ 64.
[24] *Id.* at 11 ¶ 68 (emphasis added).
[25] *Id.* at 10–11 ¶ 67.
[26] *Id.* at 11 ¶ 70.

cancer) the results relating to "fibroadenoma" (*i.e.*, non-cancerous tumors) in rats.[27] In other words, the FDA agreed with the working group—concluding that Belviq's association with certain tumors in rats was not relevant to Belviq's cancer risk in humans.

In May 2012, an FDA panel voted eighteen-to-four (with one abstention) that "the benefits of Belviq outweighed the risks for an overweight and obese population."[28] The FDA's Deputy Division Director, when reviewing the defendants' renewed application, agreed—finding that "he did not believe Belviq posed a risk for mammary adenocarcinoma in humans."[29] Following FDA approval, Arena, as manufacturer, and Eisai, as the exclusive distributor, jointly launched Belviq in the United States.[30] However, the FDA required the defendants to "conduct six . . . post-marketing studies" on Belviq.[31] As discussed next, those studies led to Belviq's withdrawal from the market.

C. Subsequent Testing of Belviq

As required by the FDA,[32] the defendants conducted a post-marketing trial of Belviq. The trial, published in September 2018, involved 12,000 patients across several countries.[33] Although the trial was conducted to assess Belviq's

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[27] *Id.*
[28] *Id.* at 11–12 ¶ 71.
[29] *Id.* at 12 ¶ 72.
[30] *Id.* at 7 ¶ 47. In 2017, Eisai bought "the global rights to develop and market Belviq" from Arena. *Id.* at 7 ¶ 50.
[31] *Id.*
[32] *See id.* at 11–12 ¶ 71.
[33] *Id.* at 13 ¶ 78.

cardiovascular risks, it "indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration, including pancreatic, colorectal, and lung cancer."[34] Specifically, 7.7% of Belviq patients were diagnosed with cancer, compared to 7.1% of patients in the placebo group.[35]

The FDA issued a safety communication in January 2020, indicating that clinical trial results showed "a possible increased risk of cancer with Belviq" but that "a causal association was . . . uncertain."[36] In February 2020, the FDA concluded that, based on this research, Belviq's risks "outweigh[ed] its benefits" and announced that Eisai had requested to voluntarily withdraw Belviq from the market.[37]

II. LEGAL STANDARD

A. Fed. R. Civ. Proc. 12(b)(6)

Pursuant to Rule 12(b)(6), a district court may dismiss a complaint or part of a complaint when a plaintiff fails to set forth well-pleaded factual allegations that "raise a right to relief above the speculative level." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007). The 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 *Twombly*, 550 U.S. at 570).

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[34] *Id.*
[35] *Id.*
[36] *Id.* at 13 ¶ 77.
[37] *Id.* at 13 ¶ 78. Accordingly, the FDA "recommended that patients stop taking Belviq and dispose of any unused pills" and "also instructed all health care professionals to stop prescribing Belviq and to contact their patients taking Belviq to inform them of the increased risk of cancer and ask that they stop taking Belviq." *Id.*

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.* If the well-pleaded factual allegations "do not permit the court to infer more than the mere possibility of misconduct," then "the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. Proc. 8(a)(2)) (alteration in original).

In assessing the complaint, a court must accept all well-pleaded facts as true and liberally construe all factual allegations in the light most favorable to the plaintiff. *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999); *Gentilello v. Rege*, 627 F.3d 540, 543–44 (5th Cir. 2010). However, courts "do not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005). Furthermore, "the Court must typically limit itself to the contents of the pleadings, including attachments thereto." *Admins. of the Tulane Educ. Fund v. Biomeasure, Inc.*, No. 08-5096, 2011 WL 4352299, at *3 (E.D. La. Sept. 16, 2011) (Vance, J.) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000)). "Dismissal is appropriate when the complaint 'on its face show[s] a bar to relief.'" *Cutrer v. McMillan*, 308 F. App'x 819, 820 (5th Cir. 2009) (quoting *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir. 1986) (alteration in original)).

B. Louisiana Products Liability Act

The LPLA "establishes the exclusive theories of liability" under Louisiana law against manufacturers for damage caused by their products. *Pramann v. Janssen*

Pharms., Inc., No. 16-12413, 2017 WL 58469, at *2 (E.D. La. Jan. 5, 2017) (Africk, J.) (quoting La. Stat. § 9:2800.52 and citing *Jefferson v. Lead Indus. Ass'n*, 106 F.3d 1245, 1248 (5th Cir. 1997)). To succeed on a claim under the LPLA, a plaintiff must prove four elements:

> (1) that the defendant is a manufacturer of the product; (2) that the [plaintiff's] damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the [plaintiff's] damage arose from a reasonably anticipated use of the product by the [plaintiff] or someone else.

Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 260–61 (5th Cir. 2002) (citing La. Stat. § 9:2800.54(A)); *see also Stewart v. Capital Safety USA*, 867 F.3d 517, 520 (5th Cir. 2017) (reciting the same four elements).

A product is unreasonably dangerous under the LPLA "if and only if" the product is unreasonably dangerous (1) in construction or composition, (2) in design, (3) because of inadequate warning, or (4) because of nonconformity to an express warranty. *Rhodes v. Covidien LP*, No. 18-10667, 2019 WL 2162845, at *2 (E.D. La. May 17, 2019) (Vance, J.) (internal citation omitted). "Thus, the LPLA limits the plaintiff to four theories of recovery: construction or composition defect, design defect, inadequate warning, and breach of express warranty." *Id.*; *see also Flagg v. Elliot*, No. 14-852, 2014 WL 3715127, at *4–5 (E.D. La. June 16, 2014) (Feldman, J.) (same), *aff'd in part, rev'd in part sub nom. Flagg v. Stryker Corp.*, 647 F. App'x 314 (5th Cir. 2016) [hereinafter *Flagg*].

III. ARGUMENTS & ANALYSIS

The plaintiffs assert that Belviq was unreasonably dangerous under all four of the LPLA's available theories.[38] Eisai and Arena move to dismiss the plaintiffs' claims for design defect, manufacturing defect, and breach of express warranty under Federal Rule of Civil Procedure 12(b)(6).[39] Arena submitted its own motion to dismiss, but it adopts by reference Eisai's arguments as to all three claims.[40] Arena does, however, offer an additional argument pertaining solely to the plaintiffs' breach of warranty claim against it—that "Arena never distributed nor sold Belviq in the United States and thus it cannot have made any express warranty to Plaintiffs."[41] The Court does not reach that argument, as it finds the plaintiffs have not sufficiently alleged their breach-of-warranty and manufacturing-defect claims.[42] The Court concludes that the plaintiffs have sufficiently alleged only their design-defect claim.

A. Design Defect

To prove a design-defect claim under the LPLA, a plaintiff must show that:

> (1) There existed an alternative design for the product that was capable of preventing the [plaintiff's] damage; and
> (2) The likelihood that the product's design would cause the [plaintiff's] damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

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[38] *See supra* note 8 and accompanying text.
[39] R. Doc. No. 26, at 1; R. Doc. No. 27, at 1.
[40] R. Doc. No. 27-1, at 1 (stating Arena fully joins and adopts the law and arguments set forth in the Eisai's memorandum supporting its motion).
[41] *Id.*
[42] *See infra* note 61.

Johnson v. Teva Pharms. USA, Inc., 758 F.3d 605, 612 (5th Cir. 2014) (quoting La. Stat. § 9:2800.56). "The occurrence of an injury does not give rise to the presumption that the design was unreasonably dangerous." *Rivers v. Remington Arms Co.*, No. 17-17124, 2018 WL 746392, at *4 (E.D. La. Feb. 7, 2018) (Africk, J.) (quoting *Robertson v. AstraZeneca Pharms., LP*, No. 15-438, 2015 WL 5823326, at *4 (E.D. La. Oct. 6, 2015) (Barbier, J.)).

Instead, to prove that a product's design was unreasonably dangerous—and therefore defectively designed under the LPLA—the plaintiff must ultimately show that "'[t]here existed an alternative design for the product capable of preventing the [plaintiff's] damage' and that the danger and gravity of that damage outweighed any adverse effects on the utility of the product and the burden on the manufacturer of adopting the alternative design." *Flagg*, 647 F. App'x at 316 (quoting La. Stat. § 9:2800.56) (second alteration added); *see also Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1198 (E.D. La. 2016) (Feldman, J.) (setting forth the same risk-utility test); *McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999) (Lemelle, J.) (same).

However, at least in the context of pharmaceutical design-defect claims, courts do not require that plaintiffs "plead extremely 'detailed factual allegations'" to survive a motion to dismiss. *Flagg,* 647 F. App'x at 317 (quoting *Iqbal*, 556 U.S. at 678); *id.* at 318 ("Although [the plaintiff] does not plead . . . that the danger of the damage outweighs the burden of adopting the design, those very detailed and specific allegations are not required to plead a plausible claim at this stage."). There is a

simple and practical explanation for this: it avoids insulating from liability those defendants who may be in "sole possession of the necessary document to ultimately prove the claim." *Guidry*, 206 F. Supp. 3d at 1198 (quoting *Flagg*, 647 F. App'x at 317).[43] Therefore, "when the cause of action requires specific elements to be proven, the plausibility standard 'simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' the necessary claims or elements." *Flagg*, 647 F. App'x at 316 (quoting *Twombly*, 550 U.S. at 556) (citation omitted).

Courts have therefore occasionally accepted vague allegations regarding the existence of alternative designs. In *Flagg*, for example, the plaintiff alleged that a toe implant was defectively designed, claiming that a safer design would have been one using merely "a different alloy" than the one used, which "would have a better fatigue life and/or product life." *Id.* at 317.[44] The Fifth Circuit held that these

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[43] As explained in *Guidry*,

> [W]hether the plaintiff can demonstrate an alternative design that satisfies the test under the LPLA is a question of fact to be assessed upon discovery. Requiring plaintiffs to plead "extremely detailed factual allegations to satisfy each element of a products liability action under the LPLA creates a situation where a manufacturer will not be held liable for defective products because it has sole possession of the necessary document to ultimately prove the claim."

Guidry, 206 F. Supp. 3d at 1198 (quoting *Flagg*, 647 F. App'x at 317); *see also Lahaye v. AstraZeneca Pharms., LP*, No. 14-111, 2015 WL 1935947, at *5 (M.D. La. Apr. 28, 2015) (noting that "much of the evidence in pharmaceutical products liability cases may be in the defendant's possession, and thus, without the benefit of discovery, stating more specific allegations may be nearly impossible at this stage").

[44] He further alleged that "the body temperature activated shape memory of the alloy used interfered and negatively influenced the fatigue life and/or product life expectancy of the implant" and that "the shape and incorrect sizing contributed to the fracture of the implant and difficulty in removal once implants [sic] broke." *Id.*

allegations were sufficient. Similarly, in *Guidry*, the plaintiff did not point to "a specific alternative design" for the challenged diabetes drug, arguing instead that other diabetes medications have less severe side effects, and therefore the drug "could have been designed to put less strain on the kidneys." *Guidry*, 206 F. Supp. 3d at 1198. The court found those allegations sufficient. And, in *Simmons*, the plaintiff alleged that lower-viscosity bone cements were safer than the challenged bone cement (with high viscosity), which allegedly suffered from "significantly increased variations in application and setting times." *Simmons v. Cardinal Health, Inc.*, No. 20-2174, 2020 WL 6822537, at *2 (E.D. La. Nov. 20, 2020) (Barbier, J.). The court found that was enough to allege an alternative design.

The plaintiffs allege that Belviq could have been designed "not [as] a serotonin receptor agonist, but rather [as] a pharmaceutical drug that d[oes] not affect the serotonin pathway."[45] The defendants argue this is insufficient because it amounts to little more than a vague allegation that an alternative design of Belviq "is something other than [Belviq]."[46] But the defendants do not deny that such a design exists; they argue merely that the plaintiffs have not described the design with enough detail.[47] The plaintiffs explain why they cannot—the alternative design for

[45] R. Doc. No. 20, at 21 ¶ 132.
[46] R. Doc. No. 26-1, at 6. For support, the defendants cite *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (affirming *summary judgment* where the plaintiff failed to show on appeal "that he presented such a[n alternative] design to the attention of the district court"). The Court questions the relevance of *Theriot* to the defendants' argument—both because of its procedural posture (reviewing summary judgment, not a motion to dismiss) and because it recognized that Theriot *could have* alleged that an alternative design existed. 168 F.3d at 255.
[47] R. Doc. No. 26-1, at 6.

Belviq is "in the exclusive possession, custody and control" of the defendants[48]—and the defendants do not dispute this point either.[49]

Given that Belviq is a "first-in-class" drug,[50] the Court finds it plausible that any alternative design would be in the sole possession of the company that designed it. Therefore, assuming that (1) a non-serotonin-agonist design exists, and (2) such design is in the defendants' exclusive possession, then the plaintiffs need not allege the design any more specifically—especially not under *Flagg's* reasoning. *See Flagg*, 647 F. App'x at 316; *Guidry*, 206 F. Supp. 3d at 1198. Accordingly, the Court finds that the plaintiffs adequately alleged the first element of their design-defect claim.

Perhaps anticipating this, the defendants claim that the somewhat-relaxed pleading standard described above and applied by the Fifth Circuit in *Flagg* is "not the law in this district."[51] For support, the defendants cite only cases that predate *Flagg*.[52] Notably absent from the defendants' memoranda is any citation to *Guidry*—a published case from this district adopting *Flagg*'s standard, as noted above. *See*

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[48] R. Doc. No. 20, at 21 ¶ 131.
[49] *See* R. Doc. No. 26-1, at 6–7 (arguing only that design was insufficiently alleged).
[50] R. Doc. No. 20, at 7 ¶ 51.
[51] R. Doc. No. 32, at 3.
[52] *Id.* at 3–4 (citing *Robertson*, 2015 WL 5823326, at *4 (granting dismissal where plaintiff's complaint alleged merely that "numerous over the counter [sic] medicines and prescription medications whose patents have expired . . . could have been manufactured and/or utilized to treat plaintiff's symptoms")); *id.* at 4 n.2 (citing *Jacobsen v. Wyeth, LLC*, No. 10-823, 2012 WL 3575293, at *10 (E.D. La. Aug. 20, 2012) (Brown, J.) (granting dismissal where plaintiff did not allege any alternative design whatsoever in complaint); *Aucoin v. Amneal Pharms., LLC*, No. 11-1275, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012) (Brown, J.) (same)). Curiously, the defendants also cite a case from the Western District of Louisiana: *Ivory v. Pfizer, Inc.*, No. 09-72, 2009 WL 3230611 (W.D. La. Sep. 30, 2009).

Guidry, 206 F. Supp. 3d at 1198. The Court has found no other cases from this district that eschew the approach either of *Flagg* or *Guidry*. Accordingly, the Court rejects the defendants' argument.

As for the second element of their design-defect claim, the plaintiffs allege that "the likelihood that Belviq's design would cause the Plaintiffs' injuries and damages and the gravity of those injuries and damages outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product."[53] The Court notes that the defendants apparently do not challenge the sufficiency of the plaintiffs' pleadings as to the second element—their arguments focus on solely the first element.[54]

Even if the plaintiffs did not allege precisely how the dangers of Belviq's design outweighed the defendants' burden in creating a similar, less-dangerous drug, that would not doom their claim at the motion-to-dismiss stage. *Flagg,* 647 F. App'x at 318 ("Although [the plaintiff] does not plead . . . that the danger of the damage outweighs the burden of adopting the design, those very detailed and specific allegations are not required to plead a plausible claim at this stage."); *Donald v. AstraZeneca Pharms., LP*, No. 16-17753, 2017 WL 1079186, at *3 (E.D. La. Mar. 22, 2017) (Feldman, J.) (holding that omission of the risk-burden element "is not so fatal to give rise to dismissal under 12(b)(6) at this stage in the litigation") (citing *Flagg*, 647 F. App'x at 316).

[53] R. Doc. No. 20, at 21 ¶ 133.
[54] *See* R. Doc. No. 26-1, at 5–7; R. Doc. No. 32, at 3–4.

Regardless, the plaintiffs allege facts from which it can be reasonably inferred that they could prove the second element. *See Iqbal*, 556 U.S. at 678. Specifically, they allege that pre-clinical studies of Belviq in rodents indicated that the drug posed a cancer risk,[55] and Belviq's human trials showed that Belviq had modest weight-loss benefits.[56] One could reasonably infer from these allegations that the cancer risk of Belviq was at least notable and the utility of Belviq was marginal. The plaintiffs must plead enough only to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *Guidry*, 206 F. Supp. 3d at 1198. The Court finds that they have. Accordingly, the Court will not dismiss the design-defect claim.

B. Manufacturing Defect

To succeed on a manufacturing defect claim under the LPLA, a plaintiff must show that "at the time the product left [the] manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La. Stat. § 9:2800.55. "This is a narrow and demanding test" because the plaintiff must show "that the *particular* product used by the plaintiff deviated from its intended design." *Guidry*, 206 F. Supp. 3d at 1197–98 (emphasis in original). In other words, the plaintiff must show "what a manufacturer's specifications or performance standards are for a particular product" *and* "how the

[55] R. Doc. No. 20, at 7–9 ¶¶ 52–57.
[56] *Id.* at 9 ¶¶ 58–60. Further, the plaintiffs allege a study conducted by the European Medicines Agency concluded that "Belviq was not approvable [(presumably, for use in Europe)] due to major objections regarding its carcinogenicity and efficacy." *Id.* at 12 ¶ 74.

product [used by the plaintiff] materially deviated from those standards so as to render it unreasonably dangerous." *Lyles v. Medtronic Sofamor Danek, USA, Inc.*, 871 F.3d 305, 311 (5th Cir. 2017) (citation omitted). "A [plaintiff] must also show that the alleged defect was the cause-in-fact of his injury, as well as the 'most probable cause.'" *Rhodes*, 2019 WL 2162845, at *3 (quoting *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 342 (5th Cir. 1994)).

Defendants argue that the plaintiffs' manufacturing defect claim "is merely a recitation of the elements of a claim under the LPLA . . . and is therefore inadequate to state a claim for relief."[57] Defendants cite *Aucoin*, 2012 WL 2990697, at *10 (rejecting a manufacturing defect claim where the plaintiff "merely recite[d] the elements of this cause of action"), and *Cooper v. Wyeth, Inc.*, No. 09-929, 2012 WL 733846, at *9 (M.D. La. Mar. 6, 2012) (same).

The Court finds that the plaintiffs merely repeat the elements of the manufacturing-defect cause of action. They allege only that Belviq "deviated in a material way from the manufacturer's" production standards or from the manufacturer's "otherwise identical products."[58] Such conclusory allegations are insufficient. *See Aucoin*, 2012 WL 2990697, at *10. "Rule 8 does not require 'detailed factual allegations but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.'" *Gulf Coast Hotel-Motel Ass'n v. Miss. Gulf Coast Golf Course Ass'n*, 658 F.3d 500, 504 (5th Cir. 2011) (quoting *Iqbal*, 556 U.S. at 662);

[57] R. Doc. No. 26-1, at 7.
[58] R. Doc. No. 20, at 23 ¶¶ 147–48.

see also Parra v. Coloplast Corp., No. 16-14696, 2017 WL 24794, at *3 (E.D. La. Jan. 3, 2017) (Vance, J.) (dismissing manufacturing defect claim where the plaintiff "ma[de] no mention of anything that went wrong in the manufacturing process").

The plaintiffs do not allege sufficient facts for the Court to reasonably conclude that a manufacturing defect occurred—let alone that the specific doses of Belviq taken by Fuller were defectively manufactured. *Cf. Flagg*, 647 F. App'x at 318 (holding that the plaintiff sufficiently pleaded a manufacturing defect by alleging "precisely how the product failed and how that failure caused [the plaintiff's] injury"). Accordingly, the Court grants defendants' motions as to this count.

C. Breach of Express Warranty

A product can also be unreasonably dangerous under the LPLA if the manufacturer breached an express warranty that it made about the product. Under this theory, a plaintiff must show that "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." *Guidry*, 206 F. Supp. 3d at 1199 (quoting *Caboni v. General Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002)).[59]

[59] The LPLA provides that a product is unreasonably dangerous "when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." La. Stat. § 9:2800.58.

"An 'express warranty' is a representation or statement about a product that affirms the product possesses specified characteristics or qualities." *Id.* (citing La. Stat. § 9:2800.53(6)).[60] But an express warranty does not include a "general opinion" or "general praise" of a product. *Id.* (quoting La. Stat. § 9:2800.53(6)). Put another way, "[t]he plaintiff must allege the content of the warranty and explain how the warranty was not true." *Donald,* 2017 WL 1079186, at *4.

Eisai argues, and Arena adopts by reference,[61] that the plaintiffs' claim for breach of express warranty should be dismissed because the amended complaint "does not offer any factual allegations regarding which warranties were supplied by Eisai, how those statements induced Plaintiff's doctor to prescribe and Plaintiff to use [Belviq], or how [Belviq]'s failure to conform to those statements caused Plaintiff's

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[60] The LPLA defines "[e]xpress warranty" as:

> a representation, statement of alleged fact or promise about a product . . . that represents, affirms or promises that the product . . . possesses specified characteristics or qualities or will meet a specified level of performance. "Express warranty" does not mean a general opinion about or general praise of a product. A sample or model of a product is an express warranty.

La. Stat. § 9:2800.53(6).

[61] R. Doc. No. 27-1, at 1. Separately, Arena also argues that the plaintiffs' claim against it for breach of express warranty should be dismissed because it neither distributed nor sold Belviq in the United States; therefore, as a matter of law, it cannot be held liable for a breach of any express warranty. *Id.* at 1–2 (citing Belviq product labels available on the FDA's website stating that Belviq was "Distributed by Eisai Inc"). The Court questions whether a manufacturer must distribute or sell a product in the United States to be held liable under the LPLA. *See Stahl*, 283 F.3d at 261 (stating that a plaintiff must prove only "that the defendant is a manufacturer of the product"); *see also* La. Stat. § 9:2800.53 (defining "manufacturer"). Ultimately, however, the Court need not decide now whether Arena is a "manufacturer" under the LPLA because it concludes that the plaintiffs have insufficiently pleaded their breach-of-warranty claim.

injuries."[62] Instead, the allegations "make only a general reference to an alleged express warranty . . . [and therefore] are not specific enough to state a claim under the LPLA."[63]

The plaintiffs respond that the defendants generally "knew and/or should have known, primarily based on their own clinical trials, that Belviq . . . was not safe because it could cause cancer."[64] But they do not identify any specific warranty made by the defendants, instead averring that "[a] party asserting a breach of express warranty claim does not have to cite to a specific express warranty in the Complaint to satisfy its pleading obligations."[65] In rebuttal, the defendants argue that that "argument puts the cart before the horse . . . [a] plaintiff must first 'specify the warranty in question.'"[66] The defendants are correct—plaintiffs "need not point to specific language offered by a manufacturer," *Huffman*, 2016 WL 6024532, at 3 (citation omitted), but they "must 'specify the warranty in question.'" *Robertson*, 2015

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[62] R. Doc. No. 26-1, at 5.
[63] *Id.*
[64] R. Doc. No. 28, at 12 (citing R. Doc. No. 20, at 2 ¶ 5; *id.* at 7–9 ¶¶ 52–60; *id.* at 9–11 ¶¶ 62–70; *id.* at 12–13 ¶¶ 73–74; *id.* at 13–14 ¶¶ 78–80; *id.* at 18 ¶ 107; *id.* at 18–19 ¶¶ 110–115).
[65] *Id.* at 11. For support, the plaintiffs cite *Baudin v. AstraZeneca Pharms., LP*, 413 F. Supp. 3d 498, 511 (W.D. La. 2019), which stated that "it is unnecessary for Plaintiff to cite to a specific express warranty" to survive a motion to dismiss. Plenty of cases in the Eastern District, however, have required more. *See Rivers*, 2018 WL 746392, at *4 (dismissing warranty claim because the plaintiff did not "allege what warranty, if any, was made to him"). At the very least, courts require plaintiffs to allege the "content" of the warranty. *Flournoy v. Johnson & Johnson*, No. 15-5000, 2016 WL 6474142, at *3 (E.D. La. Nov. 2, 2016) (Lemelle, J.) (dismissing claim for not "identify[ing] the contents of any warranty"); *Donald,* 2017 WL 1079186, at *4 (same); *Robertson*, 2015 WL 5823326, at *5 (same).
[66] R. Doc. No. 29-2, at 3 (quoting *Robertson*, 2015 WL 5823326, at *5).

WL 5823326, at *5 (quoting *Becnel v. Mercedes-Benz USA, LLC*, No. 14-0003, 2014 WL 4450431, at *4 (E.D. La. Sept. 10, 2014) (Barbier, J.) (citation omitted)). In other words, the plaintiff must "make more than a general reference to" the alleged warranty. *Id.*

Nothing in the amended complaint is more than a general reference to a warranty. The most the plaintiffs point to is the fact that Belviq was approved by the FDA for certain patients (but they allege no specific warranties that defendants made *to* the FDA),[67] and conclusory allegations like "Belviq did not conform to Defendants' express warranties that Belviq was safe to use" and "effective to use."[68] The plaintiffs argue that such "representations regarding the efficacy and safety of Belviq constitute express warranties under the LPLA,"[69] but they cite no cases holding as much. This is unsurprising because many courts have held to the contrary. *See, e.g.*, *Lewis v. Baxter Int'l Inc.*, No. 16-16391, 2017 WL 661324, at *5 (E.D. La. Feb. 17, 2017) (Fallon, J.) (finding warranty insufficiently alleged where plaintiff pointed only to defendant's statement that product was "suitable and safe for use").[70]

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[67] R. Doc. No. 28, at 12 (citing R. Doc. No. 20, at 7 ¶¶ 46, 48, and R. Doc. No. 20 at 19, ¶¶ 113–16). The amended complaint also alleges that (1) the defendants "skewed" the results of the working-group report that reassessed the rat data toward "a finding that [Belviq] was not a carcinogen" and (2) that they then submitted that skewed report to the FDA. *See* R. Doc. No. 20, at 11 ¶¶ 69–70. The plaintiffs offer no factual allegations to support that. And even if the Court construes that as a warranty, the plaintiffs admit that the FDA itself did the same thing—it "disregarded as irrelevant to [Belviq's] risk of carcinoma" the data on non-cancerous rat tumors. *Id.* at 11 ¶ 69.

[68] R. Doc. No. 20, at 19 ¶¶ 113–14.

[69] R. Doc. No. 28, at 12.

[70] *See also Aucoin*, 2012 WL 2990697, at *11 (finding warranty insufficiently alleged where defendant made no "representations other than those contained in the [product's] labeling" and concluding that "Plaintiff has not alleged that Defendant

Put differently, the plaintiffs fail to "allege facts that the warranty was made to a specific audience." *Lewis,* 2017 WL 661324, at *5. Other than repeatedly reciting the words "express warranties," the plaintiffs fail to identify the audience to whom the alleged warranties were made. Was it the FDA? Was it Fuller's physician? Was it physicians generally? Was it Fuller herself? The plaintiffs apparently say it was 'all of the above.'[71] And that underscores just how vague their warranty allegation is. If there was a warranty that made Fuller take Belviq, or her physician to prescribe it, Fuller could likely allege the warranty with specificity. But she has not. Without those specifics, the Court cannot reasonably infer that (1) Fuller or her physician were exposed to the alleged warranty, and (2) therefore induced to use or prescribe Belviq—both of which are necessary to ultimately prevail on a breach of warranty claim. *See Guidry*, 206 F. Supp. 3d at 1200.[72]

Fuller also fails to adequately allege that the warranties—whatever they were—induced her to take Belviq. Her inducement allegations are boilerplate and conclusory.[73] Although they "contain[] the magic word 'induce,'" *Guidry*, 206 F. Supp.

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advertised its product, detailed its product to doctors, or made any other forms of communication regarding Tramadol"); *Robertson*, 2015 WL 5823326, at *5 (finding statements that drug was "safe" and "effective," made on the manufacturer's "website or in its marketing materials[,] were not warranties" and that plaintiff failed "to specify the 'materials presented to the FDA' in which the alleged warranties appear").

[71] *See* R. Doc. No. 28, at 12–15 (plaintiffs' opposition).

[72] In *Guidry*, the court dismissed a warranty claim because the plaintiff "never specifically state[d] that she was induced by the marketing materials or even directly exposed to them." 206 F. Supp. 3d at 1200. Here, as there, "[t]he plaintiff must do more than elusively 'suggest' essential facts to raise her right to relief above the speculative level." *Id.*

[73] Fuller alleges that "[t]he express warranties made by Defendants induced Plaintiff . . . to use the product and/or her prescribing physician to prescribe the product," R.

3d at 1200, they fall short of alleging that Fuller was even "exposed to" the alleged warranty—which is an obvious predicate to concluding that the warranty induced her to use Belviq. *See id.* Absent an allegation that Fuller was exposed to the warranty, the Court cannot reasonably conclude that she was induced by it to use Belviq.

Without more as to the content of the warranty, to whom it was conveyed, or whether Fuller was exposed to it and therefore induced by it, the Court cannot reasonably conclude that the plaintiffs have a plausible breach-of-warranty claim.

IV. CONCLUSION

Accordingly,

IT IS ORDERED that Eisai's and Arena's motions to dismiss are **GRANTED IN PART** and **DENIED IN PART**. The motions are **GRANTED** with respect to the manufacturing-defect and breach-of-warranty claims; those claims are **DISMISSED**.The motions are **DENIED** with respect to the design-defect claim.

New Orleans, Louisiana, January 15, 2021.

LANCE M. AFRICK
UNITED STATES DISTRICT JUDGE

Doc. No. 20, at 19 ¶ 118, and that "[h]ad Defendants not made these express warranties, Plaintiff . . . would not have used the product and/or her prescribing physician would not have prescribed the product." *Id.* at 19 ¶ 119.