UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

SHERIDAN ALLO	CIVIL ACTION
v.	NO. 19-12493
ALLERGAN USA, INC.	SECTION "F"

ORDER AND REASONS

Before the Court is Allergan's Rule 12(b)(6) motion to dismiss Sheridan Allo's complaint. For the reasons that follow, the motion is GRANTED IN PART and DENIED IN PART.

Background

This products-liability action arises from injuries Sheridan Allo says she suffered when an Allergan-manufactured breast implant partially collapsed.

Allergan manufactured a breast implant product called the "Natrelle Style 410 FX." Allo had two of them implanted following a bilateral mastectomy. Three years later, Allo saw her doctor, complaining of pain in her right breast. An MRI revealed that the right implant showed signs of rupture. One month later, Allo had both implants removed. Her doctor examined them and concluded that the right one had partially collapsed. This lawsuit followed.

Allo sues Allergan under the Louisiana Products Liability Act, LA. REV. STAT. §§ 9:2800.51 — 9:2800.60, and the Louisiana Civil Code's redhibition articles, LA. CIV. CODE arts. 2520, 2545. She says Allergan is liable because its implants (1) were unreasonably dangerous in construction or composition, (2) lacked an adequate warning, (3) violated an express warranty, and (4) suffered from redhibitory defects.

Now, Allergan moves to dismiss under Rule 12(b)(6), contending that Allo's claims are expressly preempted and inadequately pleaded.

I.

A complaint must contain a short and plain statement of the claim showing that the pleader is entitled to relief. FED. R. CIV. P. 8(a)(2). A party may move for dismissal of a complaint that fails this requirement. See FED. R. CIV. P. 12(b)(6). Such motions are rarely granted because they are viewed with disfavor. Leal v. McHugh, 731 F.3d 405, 410 (5th Cir. 2013) (quoting Turner v. Pleasant, 663 F.3d 770, 775 (5th Cir. 2011)).

In considering a Rule 12(b)(6) motion, the Court "accept[s] all well-pleaded facts as true and view[s] all facts in the light most favorable to the plaintiff." Thompson v. City of Waco, Tex., 764 F.3d 500, 502 (5th Cir. 2014) (citing Doe ex rel. Magee v. Covington Cty. Sch. Dist. ex rel. Keys, 675 F.3d 849, 854 (5th

Cir. 2012) (en banc)). Conclusory allegations are not well pleaded and, consequently, are not accepted as true. See Thompson, 764 F.3d at 502-03 (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

To overcome a Rule 12(b)(6) motion, "'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" Gonzalez v. Kay, 577 F.3d 600, 603 (5th Cir. 2009) (quoting Iqbal, 556 U.S. at 678). A claim is facially plausible if it contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678.

"A complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations[.]" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). But it must contain "more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Id. at 555. Ultimately, the Court's task is "to determine whether the plaintiff stated a legally cognizable claim that is plausible, not to evaluate the plaintiff's likelihood of success." Thompson, 764 F.3d at 503 (citation omitted).

II.

Before turning to the merits, the Court considers a procedural objection. Allo says the Court should convert the motion into one for summary judgment because Allergan invokes material outside the pleadings. See FED. R. CIV. P. 12(d). Allergan rejoins that Rule 12(d) conversion is unwarranted. The Court agrees.

A.

A court ruling on a Rule 12(b)(6) motion may consider "documents incorporated into the complaint by reference and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007). A fact is judicially noticeable if it is not subject to reasonable dispute because (1) it is "generally known within the trial court's territorial jurisdiction," or (2) it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b). For example, a court may take judicial notice of a premarket approval the Food and Drug Administration (FDA) grants to a medical device manufacturer. Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011). Judicial notice of "publicly-available documents and transcripts produced by the FDA" is likewise appropriate. Id. at 783 (citing Norris v. Hearst Trust, 500 F.3d 454, 461 n.9 (5th Cir. 2007)).

B.

Allergan invokes four items outside the pleadings: (1) a February 20, 2013 letter from the FDA granting premarket approval to the breast implant product; (2) the FDA's summary of "safety and effectiveness data" for the product; (3) the FDA-approved product label for physicians; and (4) the FDA-approved product label for patients. Each is judicially noticeable.

The first item, the February 20, 2013 letter, is a publicly-available[1] document produced by the FDA. Its accuracy "cannot reasonably be questioned." FED. R. EVID. 201(b). So too with the second item, the FDA safety summary.[2] See Funk, 631 F.3d at 783. The third[3] and fourth[4] items are publicly-available product labels approved by the FDA; their accuracy is not —— and cannot reasonably be —— questioned. See Cooper v. Pfizer, Inc., No. 14-3705, 2015 WL 2341888, at *1 (S.D. Tex. May 13, 2015) (taking judicial notice of the contents of an FDA-approved label).

[1] The letter is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046a.pdf

[2] The summary is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046b.pdf

[3] The FDA-approved physician label is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046c.pdf

[4] The FDA-approved patient label is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040046c.pdf#page=100

Accordingly, because the Court may take judicial notice of the factual content of each outside-the-pleadings item Allergan invokes, and the Court may consider judicially-noticeable facts in its Rule 12(b)(6) analysis, the Court need not convert Allergan's motion into one for summary judgment. See Funk, 631 F.3d 777. The procedural objection resolved, the Court turns to the merits.

III.

Allergan contends that Allo's claims are expressly preempted by the Medical Device Amendments of 1976 (MDA). Allo rejoins that hers are permissible "parallel" claims premised on violations of federal law.

A.

The MDA imposes "a regime of detailed federal oversight" over the introduction of medical devices into the market. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Its express preemption provision is at issue here. See 21 U.S.C. § 360k(a).

Section 360k(a) preempts state-law tort claims to recover for injuries caused by a medical device if: "(1) 'the Federal Government has established requirements applicable to the device'; and (2) the claims are based on state-law requirements that are 'different from, or in addition to, the federal ones, and that relate to safety and effectiveness.'" Bass v. Stryker Corp., 669

F.3d 501, 507 (5th Cir. 2012) (quoting Riegel, 552 U.S. at 321-22).

Preemption is not plenary. Section 360k(a) "allows 'parallel' state actions —— state-law claims that are based on federal regulations." Funk, 631 F.3d at 779. So, for example, a failure-to-warn claim that is based on a failure to comply with FDA regulations is "parallel" and not expressly preempted. See Hughes v. Boston Scientific Corp., 631 F.3d 762, 769 (5th Cir. 2011). To plead a parallel claim successfully, "a plaintiff's allegations that the manufacturer violated FDA regulations must meet the Twombly plausibility standard." Bass, 669 F.3d at 509.

B.

Applied here, § 360k(a) preempts Allo's claims if two prongs are met. First, the federal government must have established requirements applicable to Allergan's breast implant device. See Bass, 669 F.3d at 507. Second, Allo's claims must be based on state-law requirements that differ from, or add to, federal requirements relating to safety and effectiveness. Id.

1.

Allergan says the first prong is met because its implant product received premarket approval. Allo appears to concede the point.

Devices that have received premarket approval "automatically satisfy" the first prong. Bass, 669 F.3d at 407 (citing Riegel, 552 U.S. at 322). Allergan's implant product, the Natrelle Style 410 FX, is a Class III medical device that has received premarket approval. So, the first prong is met, and the Court turns to the second. See Bass, 669 F.3d at 407 (citing Riegel, 552 U.S. at 322).

2.

Allergan says the second prong is met because Allo's state-law claims seek to impose safety and effectiveness requirements that differ from, or add to, federal ones. Allo disagrees. She says she alleges "parallel claims" based on Allergan's violation of federal requirements. The Court disagrees with both sides.

The allegations in Allo's complaint are sparse and conclusory. As to each cause of action, Allo merely recites the relevant statutory or codal elements.

Consider her construction-defect claim. See LA. REV. STAT. § 9:2800.55. Allo fails to allege any facts showing how Allergan's implant product "deviated in a material way" from "specifications or performance standards." In fact, she fails even to identify the "standards" from which the product allegedly deviated.

Her inadequate-warning claim is equally unadorned. See LA. REV. STAT. § 9:2800.57. Allo alleges no facts showing how, exactly, Allergan's warning was inadequate. Instead, she simply concludes

that the implant product "was unreasonably dangerous because an adequate warning about the product was not provided[.}" Rule 8(a) requires more. See Twombly, 550 U.S. at 555.

Consider next the breach-of- warranty claim. See LA. REV. STAT. § 9:2800.58. Allo concludes that the product was "unreasonably dangerous because it did not conform to an express warranty[.]" She does not identify the express warranty or allege any facts showing how Allergan's product breached it.

Finally, consider the redhibition claim. See LA. CIV. CODE arts. 2520, 2545. Allo says Allergan's implant product had a redhibitory defect "because it was not manufactured and marketed in accordance with industry standards." She again fails to identify the "industry standards" or explain how, exactly, the product's manufacture or marketing was out-of-sync with them.

Allo's complaint contains only labels, conclusions, and formulaic recitations of the elements of causes of action. See Twombly, 550 U.S. at 555. Her allegations are so conclusory that the Court cannot discern whether the second preemption prong is met. Specifically, the Court cannot determine whether any of her claims seeks to impose safety and effectiveness requirements that differ from, or add to, federal ones. But the Court can determine one thing: Allo's allegations fall well below Twombly's plausibility standard. The Court therefore grants Allergan's motion to dismiss Allo's claims as inadequately pleaded under Rule

12(b)(6); one question remains: whether dismissal should be with or without leave to amend.

IV.

Allo requests leave to amend her complaint to state "parallel" claims. Allergan counters that amendment would be futile.

A.

The Court should grant leave to amend freely when justice so requires. FED. R. CIV. P. 15(a). Rule 15(a) "evinces a bias in favor of granting leave to amend." Jones v. Robinson Prop. Grp., L.P., 427 F.3d 987, 994 (5th Cir. 2005) (citation omitted). Although leave to amend is not "automatic," the Court "must possess a substantial reason to deny a request for leave to amend." Id. at 994. In deciding whether to allow amendment, the Court may consider "undue delay, bad faith or dilatory motive on the part of the movant, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of amendment." Id.

B.

The Court lacks a "substantial" reason to deny Allo leave to amend at this early stage. See Jones at 994. Allo has not unduly delayed; she sought leave to amend once Allergan challenged the

sufficiency of her allegations. Nor has she repeatedly failed to cure deficiencies: She has filed one complaint and has not amended it. Critically, she has not yet had an opportunity to correct the deficiencies identified in this Order and Reasons. And it is not clear that she has pleaded her "best case." See Geter v. Fortenberry, 849 F.2d 1550, 1559 (5th Cir. 1988). On this record, then, the Court cannot conclude that amendment would be futile. The Court grants Allo 14 days to amend her complaint to attempt to state plausible claims.

V.

Accordingly, IT IS ORDERED: that Allergan's Rule 12(b)(6) motion to dismiss is GRANTED IN PART, insofar as it requests dismissal of Allo's claims, and DENIED IN PART, insofar as it requests dismissal *with* prejudice. Allo is GRANTED 14 days to amend her complaint to attempt to state plausible claims. If she fails to timely amend, the Court will dismiss her complaint *with* prejudice and without further notice.

New Orleans, Louisiana, January 2, 2020

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE