UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ROBIN HOGG-JOHNSON,

Plaintiff,

v.

MERZ NORTH AMERICA, et al.,

Defendants.

Case No.: 3:20-cv-00884-BEN-BLM

ORDER GRANTING MOTION TO DISMISS

[ECF No. 14]

Before the Court is Defendant Merz North America's ("Merz") Motion to Dismiss Plaintiff Robin Hogg-Johnson's First Amended Complaint ("FAC"). ECF No. 14. For the reasons that follow, the motion is granted.

I. BACKGROUND[1]

Plaintiff Robin Hogg-Johnson was prescribed Belotero Balance, a prescription dermal filler manufactured by Merz that is intended to smooth moderate to severe nasolabial folds. FAC, ECF No. 12, ¶ 4. After using Belotero Balance, Hogg-Johnson suffered a severe adverse reaction, which included "granulomatous hypersensitivity as a

[1] The following overview of the facts is drawn from Plaintiff's FAC, ECF No. 14, which the Court assumes true in analyzing Merz's motion to dismiss. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). The Court is not making factual findings.

reaction to the modified hyaluronic acid found in [Belotero Balance.]" *Id.* at ¶¶ 5-6. This adverse reaction caused a "breakdown of her immunity" and required at least three emergency room visits. *Id.* at ¶ 7. She continues to suffer adverse reactions to the Belotero Balance injections that have required her to meet with numerous medical specialists. *Id.* at ¶ 18.

Hogg-Johnson's FAC alleges a strict products liability claim on a failure to warn theory and a negligence claim arising from the "preparation, design, research, manufacture, inspection, label[ing], marketing, and sale of the dermal fillers." *Id.* at ¶¶ 10, 21.

Hogg-Johnsons's failure to warn claim alleges Belotero Balance's labeling "did not contain sufficient warnings to alert consumers, including Plaintiff, of the dangerous risks involved in the product, including but not limited to the risk of a granulomatous hypersensitivity reaction to hyaluronic acid." *Id.* at ¶ 10. She alleges Merz knew of these defects, nonetheless failed to warn her or members of the medical community, and that had Merz provided adequate warnings she would not have used the product. *Id.* at ¶¶ 11-13. She further alleges that Merz "had a continuing duty to warn Plaintiff and physicians of the dangers associated with Belotero Balance." *Id.* at ¶ 14.

Hogg-Johnson's negligence claim alleges Merz "had a duty to warn health care providers and consumers of the risks, dangers, and adverse side effects of the dermal fillers." *Id.* at ¶ 22. Her claim specifically cites Belotero Balance's "use of artificial cross-linking to modify the hyaluronic acid used in dermal fillers" as the potential source of her adverse reactions. *Id.* at ¶ 23. Hogg-Johnson alleges Merz breached this duty by "unreasonably and carelessly failing to properly warn of the potential risks associated with the dermal fillers, specifically with its potential adverse reaction with the immune system." *Id.* at ¶ 25.

Merz asks the Court to take judicial notice that the Food and Drug Administration (FDA) approved Belotero Balance through the premarket approval process in 2011. Pursuant to Federal Rule of Evidence 201, the Court may take judicial notice of matters

of public record when ruling on a motion to dismiss. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001). The Court may also take judicial notice of documents where the plaintiff's complaint necessarily relies on those documents and the documents' authenticity is not questioned. *Id.* at 688. Merz has provided an authenticated copy of Belotero Balance's premarket approval documentation and its FDA approved labels. Decl., ECF No. 14-1, Exs. A-C. Hogg-Johnson does not question the authenticity of these documents. Moreover, the Court finds the FAC necessarily relies on these documents because Hogg-Johnson alleges Belotero Balance's warning labels were inadequate. FAC, ECF No. 12, ¶ 10. Accordingly, the Court takes judicial notice of the FDA's premarket approval of Belotero Balance and the FDA approved label for the product. *See Bryant v. Apotex, Inc.*, Case No. 12-CV-1377-LJO, 2013 WL 394705, at *6 (E.D. Cal. Jan 30, 2013) (taking judicial notice of prescription drug warning labels) *and In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) (same).

II. LEGAL STANDARD

A dismissal under Rule 12(b)(6) may be based on the lack of a cognizable legal theory or on the absence of sufficient facts alleged under a cognizable legal theory. *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1121 (9th Cir. 2008); *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). When considering a Rule 12(b)(6) motion, the court "accept[s] as true facts alleged and draw[s] inferences from them in the light most favorable to the plaintiff." *Stacy v. Rederite Otto Danielsen*, 609 F.3d 1033, 1035 (9th Cir. 2010). A plaintiff must not merely allege conceivably unlawful conduct but must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (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.'" *Zixiang Li v. Kerry*, 710 F.3d 995, 999 (9th Cir. 2013) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do

not suffice." *Iqbal*, 556 U.S. at 678.

If a court dismisses a complaint, it may grant leave to amend unless "the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc.*, 911 F.2d 242, 247 (9th Cir. 1990).

III. ANALYSIS

Merz argues Hogg-Johnson's claims are "preempted by federal law and also still fail to include sufficient factual allegations to make her claims plausible." Mot., ECF No. 14, 1. The Court does not reach the second argument, as it finds the claims as pleaded to be preempted.

Hogg-Johnson's FAC contains one products liability claim alleging Merz failed to warn of known defects, as well as one generalized negligence claim. ECF No. 12, ¶¶ 10, 21-26. Merz argues these claims are preempted because "Belotero Balance is a Class III prescription injection that was approved via the premarketing approval process," which "impose[s] specific requirements on Merz, including that Merz must use the design and labeling approved as part of that [premarket approval]." Mot., ECF No. 14, 6. Merz reasons that if it used FDA approved labeling and otherwise obtained premarket approval for Belotero Balance, Hogg-Johnson's state law claims for failure to warn and negligence are preempted and thus must fail. *Id.*

The Supreme Court established a two-part test for whether a claim is preempted by the Medical Device Amendment to the Federal Food, Drug, and Cosmetic Act. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008). First, the Court must determine whether "the Federal Government . . . established requirements applicable to [the medical device]." *Id.* at 321. If so, it then determines whether the common law claims are "based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)). If these conditions are met, the state law claim is preempted and is dismissed. *Id.* at 330.

Here, the first element is met. Hogg-Johnson's FAC alleges that Belotero Balance's label "did not contain sufficient warnings to alert consumers, including Plaintiff, of the dangerous risks involved with the Product." FAC, ECF No. 12, ¶ 10. She also alleges Merz was negligent "in their preparation, design, research, manufacture, inspection, label[ing], marketing, and sale" of the product. *Id.* at ¶ 21. However, Hogg-Johnson does not dispute that Belotero Balance was accepted by the FDA through the premarket approval process. Opp'n, ECF No. 15, 2.

The premarket approval process is "rigorous." *Riegel*, 552 U.S. at 317. During the process, the FDA conducts a "risk-benefit assessment of the device and an analysis of the adequacy of the manufacturer's label." *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1110 (9th Cir. 2019). Once a device receives premarket approval, the FDA must sign off on any changes "in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319. Accordingly, Belotero Balance's labeling, manufacture, and sale were clearly subject to federal requirements through the premarket approval process.

The question then is whether Hogg-Johnson's claims are based on state requirements that are "different from, or in addition to" the FDA's requirements. 21 U.S.C. § 360k(a)(1). The Court concludes the claims are, causing them to be preempted.

Hogg-Johnson alleges that Belotero Balance "did not contain sufficient warnings," FAC, ECF No. 12, ¶ 10, but the product's warning labels were approved by the FDA and could not be changed without FDA's approval. *Riegel*, 552 U.S. at 319. Merz could not comply with both federal law through the FDA's approved labeling for Belotero Balance *and* provide the allegedly appropriate warnings Hogg-Johnson seeks to impose. This claim presents a classic case of preemption, and thus is dismissed.

Hogg-Johnson's negligence claim suffers the same fate. Her negligence claim references a standard of "reasonable care" and alleges breach of that standard. Congress, however, through the Medical Device Amendment and the FDA's premarket approval process, imposes its own requirements on medical device manufacturers before a new

product can be introduced into the market. *Weber*, 940 F.3d at 1110. The FAC flatly ignores those requirements in favor of common law negligence standards. ECF No. 12, ¶¶ 21-26. Accordingly, as pleaded, the common law negligence claim is preempted. *See Riegel*, 552 U.S. at 327-28 (also finding medical device negligence claim preempted).

To state a claim that is not preempted, Hogg-Johnson would have to allege Merz violated an FDA requirement, not a common law duty of care. *Weber*, 940 F.3d at 1111. The FAC does not do so. Hogg-Johnson seemingly acknowledges this in her opposition, where she argues that Merz failed to notify the FDA of adverse incidents that occurred after Belotero Balance received premarket approval. Opp'n, ECF No. 15, 5. However, Hogg-Johnson cannot amend her FAC in her opposition. *See Doe v. Wolf*, 432 F. Supp. 3d 1200, 1215 (S.D. Cal. 2020) (stating it "is axiomatic that the complaint may not be amended by the briefs"). The Court therefore declines to consider these arguments.

The Court finds Hogg-Johnson's negligence claim is preempted because the FDA's premarket approval process regulates the activity at issue and because her claims would impose different requirements than those imposed by federal law. Accordingly, it grants the motion to dismiss this claim.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion to Dismiss is **GRANTED**. ECF No. 14. Plaintiff has once again requested leave to file an amended complaint and the Court, considering the above, will grant the request. *See* Fed. R. Civ. P. 15(a)(2). Accordingly, Plaintiff may file a Second Amended Complaint within fourteen (14) days of this Order.

IT IS SO ORDERED.

DATED: November 18, 2020

HON. ROGER T. BENITEZ
United States District Judge