UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HARRY H. DAVALLOU,

Plaintiff,

v.

GLENMARK PHARMACEUTICALS US HEAD QUARTERS, a business of unknown form,

Defendant.

Case No.: 20-cv-00619-DMS-MDD

ORDER GRANTING MOTION TO DISMISS

Pending before the Court is Defendant Glenmark Pharmaceuticals Inc.'s motion to dismiss Plaintiff Harry H. Davallou's Complaint for failure to state a claim. Plaintiff, proceeding *pro se*, filed two separate responses to Defendant's motion, and Defendant filed a reply. For the reasons given herein, the Court grants Defendant's motion to dismiss without prejudice.

I.

BACKGROUND

On March 3, 2020, Plaintiff filed a Complaint based on products liability in the Superior Court of California, County of San Diego. (ECF No. 1 at 11). Plaintiff alleges that in November of 2019, his previously mild Parkinson's disease worsened and he

experienced "general weakness in [his] body." (*Id.* at 14). Plaintiff alleges that at the same time, he received a letter from CVS Pharmacy indicating that the prescription drug he had been taking—ranitidine, the generic version of the brand-name Zantac heartburn and ulcer medication—was recalled. (*Id.* at 14, 17). Plaintiff connected the progression of his Parkinson's disease[1] to the recall of ranitidine. (*Id.* at 14). Based on these alleged facts, Plaintiff brought suit against the manufacturer of ranitidine, Glenmark Pharmaceuticals Inc., seeking punitive damages of $20,000,000. (*Id.* at 13). On March 31, 2020, Defendant removed the case to this Court, asserting diversity jurisdiction under 28 U.S.C. § 1332(a). (*Id.* at 1).

On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation ("JPML") centralized all actions involving consumers alleging physical injuries in the form of liver, bladder, and other types of cancer as a result of their purchase of ranitidine products. The case is captioned *In Re Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924 ("Zantac MDL"). On April 1, 2020, Defendant filed a notice of potential tag-along action to the Zantac MDL pursuant to Rule 7.1(a) of the JPML and moved to stay this action, pending the JPML's decision. (ECF No. 12-1 at 9). On April 8, 2020, the JPML determined without opinion that this action was not appropriate for inclusion in the Zantac MDL. (*Id.*).

Defendant then withdrew its motion to stay the action and filed a motion to dismiss Plaintiff's complaint under Federal Rules of Civil Procedure 8 and 12(b)(6). Defendant argues that Plaintiff fails to adequately allege his products liability claim.

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[1] In his responses to Defendant's motion, Plaintiff discusses other medical conditions that he believes his consumption of ranitidine caused. These conditions include weight loss and eczema. Because Plaintiff's additional allegations were not included in his Complaint, the Court cannot consider them in ruling on Defendant's motion to dismiss. *Twombly*, 550 U.S. at 570 (noting that a motion to dismiss should be granted if a plaintiff's complaint fails to contain "enough facts to state a claim to relief that is plausible").

II.

LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 12 (b)(6) is read in conjunction with Rule 8(a), which requires only "a short and plain statement of the claim showing that pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). While Rule 8 does not require detailed factual allegations, at a minimum, a complaint must allege enough facts to provide "fair notice" of both the particular claims being asserted and "the grounds upon which [those claims] rests." *Bell Atlantic Corp. v. Twombly*, 556 U.S. 544, 555 & n.3 (2007).

In deciding a motion to dismiss, all material factual allegations of the complaint are accepted as true, as well as all reasonable inferences to be drawn from them. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 338 (9th Cir. 1996). A court, however, need not accept all conclusory allegations as true. Rather it must "examine whether conclusory allegations follow from the description of facts as alleged by the plaintiff." *Holden v. Hagopian*, 978 F.2d 115, 1121 (9th Cir. 1992). A motion to dismiss should be granted if a plaintiff's complaint fails to contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads 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 (citing *Twombly*, 550 U.S. at 556).

Pro se complaints are "held to a less stringent standard than formal pleadings drafted by lawyers." *Hebbe v. Pliler*, 627 F.3d 338, 342 (9th Cir. 2010). A pro se plaintiff's complaint must be construed liberally to determine whether a claim has been stated. *See Zichko v. Idaho*, 247 F.3d 1015, 1020 (9th Cir. 2001). However, a pro se litigant's pleadings still must meet some minimum threshold in providing the defendants with notice of what it is that they allegedly did wrong. *See Brazil v. U.S. Dep't of Navy*, 66 F.3d 193, 199 (9th Cir. 1995).

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III.

DISCUSSION

A. Plaintiff Does Not Adequately Allege A Products Liability Claim

A plaintiff may seek recovery in a products liability case either on the theory of strict liability in tort or on the theory of negligence. *See Merrill v. Navegar, Inc.*, 28 P.3d 116, 124 (Cal. 2001). Plaintiff checked the 'products liability' box in his state court Complaint. As such, the Court will consider his allegations under both theories of liability.

Under California law, a manufacturer of prescription drugs may only be strictly liable for injuries if its product is either: (1) defectively manufactured; or (2) distributed without adequate instructions or warnings as to its potential for harm. *Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589, 591 (Cal. Ct. App. 1994); *see also Brown v. Superior Court*, 751 P.2d 470, 482–83 (Cal. 1988) (holding that drug manufacturers cannot be held strictly liable for design defects in prescription drugs, but may be held liable for defective manufacturing or defective warnigns). To prevail on a defective manufacturing claim, a plaintiff must demonstrate that the product caused a plaintiff's injury because it deviated from the manufacturer's intended result or from other ostensibly identical units of the same product line. *See Morris v. Parke, Davis & Co.*, 667 F. Supp. 1332, 1335 (C.D. Cal. 1987). This theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." *In re Coordinated Latex Glove Litigation*, 121 Cal. Rptr. 2d 301, 316 (Cal. Ct. App. 2002).

Here, Plaintiff does not allege that his tablets of ranitidine were any different from other ranitidine tablets manufactured by Defendant. In fact, Plaintiff appears to allege the opposite. His claim appears to rely on the recall of ranitidine. As such, Plaintiff alleges that his ranitidine did not deviate from Defendant's intended design, instead it contained the same impurities as all other ranitidine tablets. Plaintiff, therefore, cannot successfully plead a manufacturing defect.

Plaintiff also fails to allege causation. Specifically, Plaintiff does not allege that the ranitidine caused his Parkinson's disease to worsen. Instead, Plaintiff alleges that his

consumption of ranitidine and the worsening of his Parkinson's were simultaneous. In support of this allegation, Plaintiff provides the two letters he received—one from CVS Pharmacy and one from Blue Shield of California—informing him of ranitidine's recall and the possibility of it containing carcinogens. Neither letter, however, indicates the plausibility of ranitidine aggravating a nervous system disorder like Parkinson's disease. To prevail on a manufacturing defect theory of liability, Plaintiff would need to demonstrate a plausible connection between the ranitidine he ingested and the worsening of his specific medical condition.

To prevail on a defective warnings claim, a plaintiff must "identify which danger was not warned against, explain that the danger was substantial, and that the danger was known or reasonably knowable, or explain how any warning that was given was inadequate." *Marroquin v. Pfizer, Inc.*, 367 F. Sup. 3d 1152, 1160–61 (E.D. Cal. 2019) (citing *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1156 n.1 (E.D. Cal. 2010)). Furthermore, "in the case of prescription drugs, the duty to warn runs *to the physician*, not the patient." *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996); *see also Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) ("In the case of medical prescriptions, if adequate warnings of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed."). A plaintiff, therefore, must allege that the defendant failed to warn or inadequately warned his or her doctor about the specific danger and that "a different warning would have changed the prescribing physician's decision." *Thompson v. Janssen Pharm., Inc.*, No. CV 16-2628, 2017 WL 5135548, at *8 (C.D. Cal. Oct. 23, 2017); *see also Georges v. Novartis Pharm., Corp.*, 988 F. Supp. 2d 1152, 1157 (C.D. Cal. 2013) ("If the plaintiff would have taken the drugs and suffered the same injuries, even with an adequate warning, the defendant's failure to warn cannot have caused her injury.").

Furthermore, state law claims involving generic drugs labels or warning are preempted by federal law. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). "Federal law . . . demand[s] that generic drug labels be the same at all times as the corresponding

brand-name drug labels." *Id.* (citing 21 C.F.R. § 314.150(b)(10)). Because it would be "impossible for the [m]anufacturers to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same[,]" state law claims concerning generic drug warnings are preempted. *Id.*; *see also Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 486 (2013) ("As *PLIVA* made clear, federal law prevents generic drug manufacturers from changing their labels.").

Here, Plaintiff does not allege that Defendant failed to warn or inadequately warned his doctor about the risk of ranitidine aggravating his Parkinson's disease. As explained above, although Plaintiff includes the recall letters in his Complaint, those letters indicate ranitidine may contain carcinogens—they do not contain any information connecting ranitidine to the worsening of nervous system disorders. As such, if Plaintiff's claim concerns Defendant's failure to warn of ranitidine's possible carcinogenic effect, Plaintiff fails to allege proximate cause. In other words, Plaintiff does not demonstrate how Defendant's failure to warn that ranitidine causes cancer caused his ultimate injury: the progression of his Parkinson's disease.

Plaintiff's claim may also be preempted by federal law. Because ranitidine is a generic drug, Defendant is bound by federal law to use the same label, warnings, and design approved by the Federal Drug Administration ("FDA") in connection with Zantac. Therefore, if Plaintiff alleges that Defendant should have included additional warnings on ranitidine's label, Plaintiff's claim is preempted.

Finally, the Court considers Plaintiff's products liability claim under a negligence theory. To prevail on a negligence claim, a plaintiff must show that the defendant "owed her a legal duty, breached the duty, and that the breach was a proximate or legal cause of her injury." *Gonzalez v. Autoliv ASP, Inc.*, 64 Cal. Rptr. 3d 908, 919 (Cal. Ct. App. 2007). A plaintiff must also demonstrate that "the defect in the product was due to negligence of the defendant." *Id.* (quoting *Merrill v. Navegar, Inc.*, 28 P.3d 116, 125 (Cal. 2001)).

Plaintiff does not allege duty, breach, or causation. Again, if Plaintiff's claim is that Defendant breached its duty by marketing ranitidine, despite the drug being impure or

potentially carcinogenic, then Plaintiff fails to show how this breach caused his specific injuries. Without factual allegations connecting his harm to Defendant's actions or inactions, Plaintiff fails to state a claim.

B. Leave To Amend

Generally, leave to amend is granted "even if no request to amend the pleading was made, unless [the court] determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir. 2000) (en banc) (internal citation omitted). Here, Plaintiff should be afforded an opportunity to attempt to cure the deficiencies in his Complaint. Accordingly, the Court grants Plaintiff leave to amend his Complaint.

IV.

CONCLUSION AND ORDER

For the foregoing reasons, Defendant's motion to dismiss is granted. Plaintiff may file a First Amended Complaint within 30 days of this order.

IT IS SO ORDERED.

Dated: July 27, 2020

Hon. Dana M. Sabraw
United States District Judge