IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

KEVIN D. BRYANT,

Plaintiff,

vs.

APOTEX, INC., et al.,

Defendants.

_____/

CASE NO. 1:12-CV-01377 LJO JLT

ORDER ON DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS

(Doc. 39)

Defendants Apotex, Inc., AmeriSource Health Services Corporation, The Harvard Drug Group LLC d/b/a Major Pharmaceuticals, Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals Inc., and Mylan Institutional Inc. (herein collectively "Defendants"[1]) have filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c). Plaintiff Kevin D. Bryant ("Mr. Bryant" or "Plaintiff"), who is proceeding *pro se*, has filed an opposition to the motion, and Defendants have filed a reply. Having considered the parties' submissions, the Court GRANTS IN PART and DENIES IN PART Defendants' motion for judgment on the pleadings.

I. BACKGROUND

A. Plaintiff's Allegations

Plaintiff is a California state prisoner currently housed in Kern Valley State Prison ("KVSP"). Defendants manufacture and distribute prescription drugs, including Gabapentin and Tramadol, which are at issue in this case.

[1] In addition to Defendants, Plaintiff includes 250 "Doe" defendants in this action. Plaintiff also refers to several named individuals as "defendant" in the body of his complaint; however, it appears that Plaintiff references these named individuals as defendants only because they are (or were) defendants in a separate suit filed by Plaintiff in state court. See Bryant v. CDCR,, Case No. S-1500-CV-272692 (Kern County Superior Court).

In November or December 2009, Plaintiff was instructed by medical staff at KVSP to take his pain medications, which included Gabapentin and Tramadol, in crushed form. The medications were crushed and floated in small cups of water as part of a prison policy to prevent inmates from hoarding, selling, and overdosing on medication. Within one month of the policy's implementation, however, Plaintiff experienced severe pain in his stomach, vomited black blood frequently, and observed blood in his stool. These symptoms persisted over the next six months.

On July 7, 2010, Plaintiff was admitted to Mercy Hospital for leg surgery. The next morning, Plaintiff vomited black blood. In response, Plaintiff underwent an emergency procedure wherein 1.6 liters of blood, food, and other gastric content were removed from his stomach. Plaintiff's physician diagnosed Plaintiff's condition as severe erosive esophagitis with slow hemorrhages in the esophagus. Plaintiff's physician also indicated that this condition was probably caused by taking Gabapentin and Tramadol in crushed form.

Ms. Markman, a nurse at KVSP, informed Plaintiff that the "crush and float" policy at KVSP was implemented after several meetings between prison officials and KVSP medical staff. According to Ms. Markman, prison officials and KVSP medical staff were aware that administering Gabapentin and Tramadol in crushed form was contrary to the manufacturers' instructions, acknowledged the risks posed to prisoners, and yet decided to implement the "crush and float" policy regardless. In fact, some prison officials even claimed that they had obtained express permission and approval from Defendants to administer Gabapentin and Tramadol to prisoners in crushed form.

B. Procedural History

Plaintiff filed suit in the Kern County Superior Court. Plaintiff asserted claims for negligence, strict products liability, breach of express warranty, breach of implied warranty, and fraud. The action was then removed to this Court on August 21, 2012, based on the Court's diversity jurisdiction under 28 U.S.C. § 1332(a).

On November 28, 2012, Defendants filed the pending motion for judgment on the pleadings. The Court deemed the matter to be suitable for decision without oral argument pursuant to Local Rule 230(g), vacated the hearing, and set a briefing schedule for this matter. Plaintiff filed an opposition on January 17, 2013, and Defendants filed a reply on January 25, 2013.

II. LEGAL STANDARD

A party may move for judgment on the pleadings after the pleadings are closed so long as there is no delay to trial. Fed. R. Civ. P. 12(c). Where, as here, a motion for judgment on the pleadings is used to raise the defense of failure to state a claim, the motion "faces the same test as a motion under [Federal Rule of Civil Procedure] 12(b)(6)[.]" McGlinchy v. Shell Chemical Co., 845 F.2d 802, 810 (9th Cir. 1988).

To survive a motion to dismiss under Rule 12(b)(6), a 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). In making this determination, courts follow a "two-pronged approach." Id. at 679. First, the court identifies those allegations that are not presumed to be true. See id. at 680. This includes allegations that are mere conclusions or allegations that are contradicted by matters properly subject to judicial notice or exhibit. Sprewell v. Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001). Second, the court determines whether the factual allegations that are presumed to be true give rise to a claim that is plausible on its face when construed in the light most favorable to the opposing party. See Iqbal, 556 U.S. at 681; Sprewell, 266 F.3d at 988. Although the plausibility standard is not akin to a probability requirement, it asks for more than a sheer possibility that the defendant has acted unlawfully. Iqbal, 556 U.S. at 678.

If the court concludes that the complaint fails to state a claim that is plausible on its face, the court should dismiss the complaint with leave to amend unless the deficiencies in the complaint could not be cured by amendment. See Cook, Perkiss & Liehe, Inc. v. Northern California Collection Serv. Inc., 911 F.2d 242, 246-47 (9th Cir. 1990); In re Dynamic Random Access Memory Antitrust Litig., 516 F. Supp. 2d 1072, 1084 (N.D. Cal. 2007) (courts have discretion to grant Rule 12(c) motions with leave to amend and should generally do so unless amendment would be futile or would result in prejudice to the moving party).

III. DISCUSSION

A. Construction of Plaintiff's Claims

As a preliminary matter, the Court finds it necessary to construe Plaintiff's claims because it is apparent that the parties disagree on this issue. Defendants argue that Plaintiff's claims are essentially

"failure to warn" claims under state tort law, which seek to impose liability on Defendants for failing to provide *additional warnings* (i.e., warnings beyond those already contained in the drug's approved warning label) to prison officials and to Plaintiff regarding the dangers of ingesting Gabapentin and/or Tramadol in crushed form. Plaintiff, on the other hand, asserts that the essence of this case is not any failure to warn, but rather his allegation that Defendants gave prison officials express permission and approval to administer Gabapentin and Tramadol to him and other prisoners in crushed form, *despite being aware that this directly contradicted Defendants' own instructions regarding the administration of the two drugs*. In other words, Plaintiff claims that Defendants told prison officials that they could disregard Defendants' own drug warning labels, which specifically caution against ingesting the drugs in crushed form.

Although Plaintiff's complaint is not a model of clarity, it does contain allegations that support Plaintiff's position. For example, Plaintiff alleges:

> [P]rison officials now claim that [Defendants] gave them permission and approval to administer them to human beings crushed and floated and *contrary to the administering directions of the drugs*, and that they knew all along that they were giving it to human beings here at KVSP and throughout CDCR this same way.

(Doc. 1, Ex. A ("Compl.") at ¶ 32) (emphasis added). Similarly:

> [Defendants] gave CDCR express permission and approval to administer these two drugs in question to Me [sic] and all CDCR inmates crushed and floated contraindicative of the dosing and administration directions and are liable and responsible for My [sic] damages and injuries[.]

(Id. at ¶ 48.)

Because Plaintiff is the master of his complaint, and the complaint's allegations are susceptible to the interpretation advanced by Plaintiff, the Court will construe Plaintiff's allegations accordingly. See Eldridge v. Block, 832 F.2d 1132, 1137 (9th Cir. 1987) (however inartful, the pleadings of *pro se* litigants must be construed liberally). The gravamen of this case is the allegation that Defendants told prison officials that they could administer Gabapentin and Tramadol to Plaintiff and other prisoners in crushed form, despite being aware that this was contrary to the drugs' warning label and administration instructions. With this in mind, the Court turns to the merits of Defendants' substantive arguments for judgment on the pleadings.

B. Federal Preemption

Defendants argue that Plaintiff's state law claims are impliedly preempted by federal law. As support for its position, Defendants rely on PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011). In that case, the Supreme Court held that federal law preempted state law torts seeking to hold generic drug manufacturers liable for failing to adequately warn consumers of dangers associated with their drug. The Supreme Court explained that federal regulations that were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Amendments"), Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984),[2] require generic drug manufacturers to provide the same warning label as that provided by the brand name drug. See Mensing, 131 S. Ct. at 2574. This federally imposed duty of "sameness" precludes generic drug manufacturers from taking unilateral steps to warn consumers of dangers not already disclosed by the brand name drug. Thus, to the extent that state law seeks to impose liability on generic drug manufacturers for failing to do so (e.g., failing to unilaterally strengthen its label; failing to send additional warnings to prescribing physicians and other healthcare professionals; or failing to propose stronger warning labels to the U.S. Food and Drug Administration ("FDA")), it is preempted by federal law. See id. at 2575-81.

The Court is not persuaded by Defendants' preemption argument. Defendants' argument rests on the assumption that Plaintiff seeks to impose state tort liability on Defendants for failing to warn him of a danger not already disclosed by the brand name versions of Gabapentin and Tramadol.[3] However, as discussed above, this is not the focus of Plaintiff's claims. Instead, Plaintiff asserts that the danger of ingesting Gabapentin and Tramadol in crushed form *is* included in Defendants' warning labels and instructions, but Defendants told prison officials that they could disregard those warnings. The Court is unaware of any federal law or regulation that requires Defendants to tell healthcare professionals to disregard drug warnings and instructions that have been approved by the FDA. If anything, federal and state law are in accord that this is prohibited.

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[2] The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et. seq*. The amendments sought to promote competition in the prescription drug market by establishing a process for approving generic drugs in a more efficient manner. See AstraZeneca Pharms. LP v. FDA, 872 F. Supp. 2d 60, 84 (D. D.C. 2012).

[3] The Court takes judicial notice that Gabapentin is generic for Neurontin and Tramadol is generic for Ultram. See The Merck Manual at 3511, 3518 (19th ed.) (2011).

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. As such, where state and federal law conflict, state law is preempted and is "without effect." Maryland v. Louisiana, 451 U.S. 725, 746 (1981). State and federal law conflict when it is impossible for a party to meet its obligations under both state and federal law. See Freightliner Corp v. Myrick, 514 U.S. 280, 287 (1995). Here, Defendants have failed to show any tension or impossibility between its state and federal law obligations. Accordingly, the Court concludes that Plaintiff's state law claims are not preempted by federal law.

C. Sufficiency of Plaintiff's Allegations

1. Claims Related to Fraud

Defendants maintain that Plaintiff's state law claims relating to fraud are not sufficiently pled under Rule 9(b). Here the Court agrees.

State law claims grounded in fraud are subject to the heightened pleading standard under Rule 9(b). Vess v. Ciba-Geity Corp. USA, 317 F.3d 1097, 1103-04 (9th Cir. 2003). See Neilson v. Union Bank of Cal., N.A., 290 F. Supp. 2d 1101, 1141 (C.D. Cal. 2003) ("It is well-established in the Ninth Circuit that both claims for fraud and negligent misrepresentation must meet Rule 9(b)'s particularity requirements."). Under Rule 9(b), the circumstances constituting the alleged fraud must be pled with "particularity." Fed. R. Civ. P. 9(b). In other words, the party claiming fraud must set forth specific facts establishing the "who, what, when, where, and how" of the alleged fraudulent activity. Vess, 317 F.3d at 1006. Even where the party claiming fraud cannot be expected to have personal knowledge of all the facts, the party must provide a sufficient factual basis for its allegations and beliefs. Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993).

Here, Plaintiff only makes two substantive allegations with respect to his claims for fraud: (1) Defendants gave prison officials permission and approval to administer Gabapentin and Tramadol in crushed form despite being aware of the dangers of ingesting the drugs in that way; and (2) Defendants instructed prison officials to tell any prisoner who asked that it was safe to ingest the drugs in crushed form. (Compl. at 12.) This falls well short of establishing the "who, what, when, where, and how" of Defendants' alleged fraudulent activity. Vess, 317 F.3d at 1106. For example, there is no indication

when or where Defendants had these conversations with prison officials; nor is there any indication as to who specifically was involved.

Moreover, Plaintiff fails to establish a sufficient factual basis for his allegation/belief that these conversations took place. Plaintiff states that prison medical officials told him that such conversations occurred.[2] (See Compl. ¶ 25.) But, there is no indication who these officials are or on what basis they made their statements. Such vague, naked accusations cannot serve as the sole foundation on which a claim for fraud rests. Accord Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009) (one of the purposes of Rule 9(b) is to prohibit plaintiffs from unilaterally imposing upon the court, the parties, and society enormous social and economic costs associated with a claim for fraud absent a firm factual basis). Accordingly, the Court concludes that Plaintiff's claims sounding in fraud are not sufficiently pled under Rule 9(b) and must be dismissed.

2. Other Claims

Defendants also appear to argue that Plaintiff's other claims (i.e., strict products liability, breach of express warranty, and breach of implied warranty) are insufficiently pled under Rule 8. (See Doc. 39 ("Defs.' Mot. for J. on the Pleadings") at 13-14.) Yet, beyond reciting the legal standard for a motion to dismiss, Defendants offer no specific argument. Accordingly, the Court concludes that dismissal of Plaintiff's other claims is not warranted at this time. See Kehr Packages, Inc. v. Fidelcor, Inc., 926 F.2d F.2d 1406, 1409 (3d Cir. 1991) ("[U]nder Rule 12(b)(6) the defendant has the burden of showing no claim has been stated."); see also Gallardo v. DiCarlo, 203 F. Supp. 2d 1160, 1165 (C.D. Cal. 2002) ("It is the burden of the party bringing a motion to dismiss for failure to state a claim to demonstrate that the requirements of Rule 8(a)(2) have not been met.").

3. Leave to Amend

Plaintiff will be given an opportunity to amend his allegations relating to fraud. If, however, Plaintiff elects to file an amended complaint he is cautioned that he may not change the nature of this suit by adding new and unrelated claims. See George v. Smith, 507 F.3d 605, 607 (7th Cir. 2007) (no "buckshot" complaints). In addition, Plaintiff is advised that once he files an amended complaint his

[2] It should be noted that Plaintiff does not allege that every prison medical officials agrees that such conversations took place. According to Plaintiff, some prison officials have explicitly indicated that they did not have permission from Defendants to administer Gabapentin and Tramadol in crushed form. (Compl. at ¶ 25.)

original complaint is superceded and no longer serves any function in this case. See Loux v. Rhay, 375 F.2d 55, 57 (9th Cir. 1967). Thus, Plaintiff's amended complaint must be "complete in itself without reference to the . . . superceded pleading." Local Rule 220. A cause of action alleged in the original complaint but not re-alleged in the amended complaint will be deemed to have been waived. King v. Atiyeh, 814 F.2d 565, 567 (9th Cir. 1987).

D. Defendants' Reply Arguments

Finally, the Court notes that Defendants maintain in their reply that there is no private right of action under the FDCA. At first blush, the Court does not see the relevance of this argument. In any event, the Court need not reach this argument because it was not raised in Defendants' initial motion. See Zamani v. Carnes, 491 F.3d 990, 997 (9th Cir. 2007) (district court need not consider arguments raised for the first time in a reply brief).

Defendants also seek judicial notice of the warning labels for Neurontin and Ultram. Although the Court GRANTS Defendants' requests, see, e.g., In re Epogen & Aransep Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1286 (2008) (taking judicial notice of FDA approved warning labels), the Court struggles to see how this is helpful to Defendants' position. Presumably, Defendants argue that, contrary to Plaintiff's assertions, Gabapentin and Tramadol do not actually have warnings against ingesting the drugs in crushed form. Yet, this appears to be untrue. The FDA approved label for Gabapentin provides:

> **How should I take NEURONTIN [Gabapentin]?**
>
> - Take NEURONTIN [Gabapentin] exactly as prescribed. Your healthcare provider will tell you how much NEURONTIN [Gabapentin] to take.
>
> - Do not change your dose of NEURONTIN [Gabapentin] without talking to your healthcare provider. If you break a tablet in half the unused half of the tablet should be taken at your next scheduled dose. Half tablets not used within several days of breaking should be thrown away. If taking capsules, *always swallow them whole* with plenty of water.

(Doc. 51 ("Reply") at 43) (italics and brackets added).[3] With respect to Tramadol, the matter appears to be less clear. The FDA approved label for Ultram does not contain a warning against ingesting the

[3] For the entire label see FDA Drug Database, http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020235s050,020882s035,021129s033lbl.pdf.

drug in crushed form.[4] However, the warning label for Ultram ER (extended release) tablets do.[5] See FDA Drug Database, http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021692s005s007lbl.pdf ("ULTRAM ER must be swallowed whole and must not be chewed, crushed, or split . . . ."). In any event, whether Defendants actually manufacture and distribute Tramadol extended release tablets and whether Plaintiff actually ingested such tablets are factual matters that the Court cannot resolve at this stage of the litigation.

IV. CONCLUSION

For all the reasons set forth above, the Court GRANTS IN PART and DENIES IN PART the motion for judgment on the pleadings as follows:

1. Plaintiff's claims relating to fraud are DISMISSED with leave to amend. Plaintiff will not be given another opportunity to amend. If Plaintiff believes he is unable to file an adequate claim for fraud, he need only file a pleading stating he will stand on the original pleading and the Court will then strike the fraud allegations and move forward. Plaintiff may file an amended complaint by no later than February 19, 2013.
2. Defendants' motion for judgment on the pleadings is DENIED in all other respects.

IT IS SO ORDERED.

Dated: January 30, 2013 **/s/ Lawrence J. O'Neill**
UNITED STATES DISTRICT JUDGE

[4] For the entire label see FDA Drug Database, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020281s032s033lbl.pdf.

[5] The Court takes judicial notice of the FDA approved label for Ultram ER. See Fed. R. Evid. 201(c)(1).