UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

RAYMOND J COLLETTE,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC., et al.,

Defendants.

Case No. 16-cv-01034-JD

ORDER RE MOTIONS TO DISMISS

Re: Dkt. Nos. 95, 96

The pending motions to dismiss go to the third amended complaint, Dkt. No. 94 ("TAC"), which is plaintiff Collette's fourth attempt to state a plausible complaint.[1] Collette compounded the burden on defendants and the Court by making amendments that violated the prior dismissal order. The TAC again falls below the plausibility required by Rule 8 of the Federal Rules of Civil Procedure. Defendants' motions to dismiss the TAC, Dkt. Nos. 95, 96, are granted, this time with prejudice in light of Collette's many opportunities to plead an actionable claim.

DISCUSSION

I. OFF-LABEL MARKETING: SECOND, THIRD AND FOURTH CLAIMS

The parties' familiarity with the record is assumed, and the background and discussion in the prior motion to dismiss orders will not be repeated here. Dkt. Nos. 76, 93. In summary, the Court dismissed Collette's off-label marketing allegations because the claim was vague and "too generalized," and Collette was directed to "say much more about what, specifically, each

[1] The third amended complaint states that Raymond Collette is now deceased, and that "a motion to substitute Jeanne Collette, as personal representative and executrix of the estate of Raymond Collette as named plaintiff will be filed contemporaneously with this amended complaint or shortly thereafter." Dkt. No. 94 at 1 n.1. No motion has been filed as of the date of this order, and so "plaintiff" refers to Raymond Collette, who is the person alleged to have been harmed in the complaint.

defendant said and did, and how those statements and actions (or lack thereof) relate[d] to plaintiff personally and to his physician, Dr. James Yhip." Dkt. No. 93 at 3-4 (quoting Dkt. No. 76 at 4). The Court concluded that "[w]hether measured under Rule 9(b) or Rule 8, Collette did not adequately allege facts for each element of his claims against each defendant for the off-label marketing portion of his case." *Id*. After the second order of dismissal, Collette was given "one last chance to amend these allegations and claims only." *Id*.

The second, third and fourth claims in the TAC are focused on the off-label marketing allegations. *See* TAC ¶ 68 (alleging, for second cause of action for "negligence – failure to warn," that Wyeth breached its duties "by overpromoting the drug [Amiodarone/Cordarone] for unapproved uses, in particular for the treatment of atrial fibrillation" as well as "engaged in a lengthy campaign to promote the use of Amiodarone/Cordarone as a first line treatment for a-fib"); ¶¶ 73-82 (alleging, as third cause of action, "negligence – off-label marketing and sale" against all defendants); ¶¶ 83-90 (alleging, as fourth cause of action, "fraud and deceit – off-label marketing and sale").

The problem is that the TAC again fails to plead actionable claims "by this plaintiff for a specific injury attributable to these defendants." Dkt. No. 93 at 4. Although the TAC alleges that Wyeth illegally "instituted and maintained an aggressive marketing plan positioning Amiodarone as a 'first line anti-arrhythmic'" as far back as the late 1980s, TAC ¶ 28, it still fails to contain any factual allegations that connect the dots between that general allegation and plaintiff Raymond Collette himself. The allegations about plaintiff and his physician, Dr. James Yhip, remain far too general and conclusory to plausibly allege a claim under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), or to meet the heightened particularity standard under Federal Rule of Civil Procedure 9(b). For example, although the TAC alleges that "[a]s a direct and proximate result of defendant Wyeth's overpromotion of Amiodarone/Cordarone, Decedent's physician prescribed him Amiodraone for the treatment of his atrial fibrillation," TAC ¶ 71, it still lacks any factual allegations that explain which, if any, promotional activities and sales efforts Dr. James Yhip was subject to, when, and from whom, to mention just a few of the missing details.

For a claim to have facial plausibility, a plaintiff must plead "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). That remains missing. Instead, the TAC contains only general, vague and conclusory allegations. *See In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008) (court need not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences"). The second, third and fourth claims in the TAC are consequently dismissed under Federal Rule of Civil Procedure 12(b)(6). And after four attempts, the Court declines to provide another try. *See Chodos v. West Publishing Co.*, 292 F.3d 992, 1003 (9th Cir. 2002).

II. THE STRICT LIABILITY CLAIMS: FIRST AND FIFTH CAUSES OF ACTION

Collette added the first and fifth causes of action in violation of the prior dismissal order. The first cause of action alleges "strict products liability – failure to warn," and is based on defendants' failure to disclose "to the FDA all adverse drug events related to Amiodarone use." TAC ¶ 60 (citing 21 C.F.R. § 314.80(c); 21 C.F.R. § 314.98). The fifth cause of action alleges "strict liability – manufacturing defect," and is based on allegations that "the Manufacturer Defendants failed to comply with the FDA's Good Manufacturing Practices with regard to Packaging and Labeling Control as set forth in the FDA's Good Manufacturing Practice for Finished Pharmaceuticals, 21 C.F.R. § 211 et seq." *Id.* ¶ 92.

These claims are well beyond the scope of what the Court permitted Collette to amend in the last go-around. The Court granted plaintiff leave to amend "limited to claims based on his off-label marketing allegations only." Dkt. No. 93 at 4. The Court stated that plaintiff may not "add any new claims or defendants without express leave of Court," and warned that a "[f]ailure to amend . . . in a manner consistent with the Court's order will result in a dismissal under Federal Rule of Civil Procedure 41(b)." *Id.* Collette simply ignored these directives and filed new claims without even asking for leave in advance. The fair and efficient administration of justice demands that parties follow judicial orders. When a party unilaterally flouts them, as Collette did here, they impose unnecessary and unjustifiable costs on opposing parties, and the courts. Plainly put, it

gums up the works and makes litigation unduly burdensome. The first and fifth claims are dismissed under Rule 41(b).

Dismissal is particularly warranted because the unauthorized claims are also implausible. The fifth claim is clearly directed toward enforcing FDA regulations, and as such, is subject to the same preemption principles discussed previously. "[T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration," and claims resting purely on duties arising from federal regulations are preempted. Dkt. No. 76 at 2-3 (quoting *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001)).

While some California cases might be read to offer a possibility of non-preemption for a claim alleging a failure to report adverse events, *see Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 427-30 (2014), the claim must still be plausibly alleged. Plaintiff again offers only vague and conclusory allegations that defendants "failed to report thousands of serious adverse medical events in their exclusive possession to the FDA, health care professionals, and consumers, including plaintiff," without pleading any facts about the nature or timing of those alleged events, or otherwise indicating that this actually ever happened. TAC ¶ 61. The TAC is devoid of any factual allegations showing that "if [defendants] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent his injuries." *Coleman*, 223 Cal. App. 4th at 430 (citation omitted). And in the context of the off-label marketing claims, Collette has repeatedly failed to follow the Court's directive that he plead facts rather than conclusions about his physician's decision to prescribe Amiodarone to him.

Collette is not entitled to amend the first and fifth claims. They were made in contravention of the Court's order and without leave to proceed, which is more than enough to deny further amendment. *See Carvalho v. Equifax Information Services, LLC*, 629 F.3d 876, 892 (9th Cir. 2010) ("district court may exercise its discretion to deny leave to amend due to 'undue delay, bad faith or dilatory motive on part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . , [and] futility of amendment.'"). Permitting amendment of unauthorized claims made in violation of a court order

would reward conduct that has already imposed undue burdens. It is also worth noting that Collette had plenty of opportunities to develop these allegations in the multiple prior complaints, and did not do that.

CONCLUSION

The defendants' motions to dismiss are granted, and plaintiff's third amended complaint is dismissed with prejudice.

IT IS SO ORDERED.

Dated: June 22, 2020

JAMES DONATO
United States District Judge

United States District Court
Northern District of California