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. 78, 79

This case involves a generic heart medication, Amiodarone, which is used to treat irregular heartbeat. Plaintiff Raymond Collette took Amiodarone and developed pulmonary fibrosis. He alleges a causal connection between the drug and his lung illness. Defendants are Wyeth Pharmaceuticals, Inc., which makes the brand-name version of the drug (Cordarone), and Sandoz, Inc. and its subsidiary Eon Labs, Inc., which manufacture the generic version (Amiodarone) used by Collette.

The Court granted defendants' motions to dismiss the first amended complaint with leave to amend most, but not all, of the alleged claims. Dkt. No. 76. Collette filed a second amended complaint that largely ignored the pleading deficiencies that he was advised to address. Dkt. No. 77. Defendants ask to dismiss the second amended complaint. Dkt. Nos. 78, 79. It is dismissed with a limited and likely final opportunity to amend.

DISCUSSION

The second amended complaint repeats the same seven claims from the prior iteration: (1) strict products liability -- failure to warn; (2) negligence -- failure to warn; (3) negligence -- sale and marketing; (4) negligence per se; (5) violation of California Business & Professions Code § 17200 et seq. (Unfair Competition Law or "UCL"); (6) violation of California Civil Code § 1750

et seq. (Consumer Legal Remedies Act or "CLRA"); and (7) fraud and deceit. Dkt. No. 77. This time, the "strict products liability -- failure to warn" claim is alleged "against all defendants," Dkt. No. 77 at 35, but plaintiff's brief in response to Wyeth's motion to dismiss clarifies that this was an error. Dkt. No. 86 at 5 ("every claim but Count I (Strict Products -- Failure to Warn) is asserted against Wyeth."). There are consequently no substantive changes in the second amended complaint to plaintiff's legal claims or the defendants against which each claim is alleged.

Because plaintiff's allegations are identical to the previous version of the complaint, the Court also follows the same approach it applied in its prior motion to dismiss order.

I. INADEQUATE CONTENTS OF WARNINGS / LABELING

The Court held in the prior order that "the claims going to the warnings and labeling for Amiodarone, an FDA-approved generic drug, are preempted under federal law," and "must be removed from any amended complaint." Dkt. No. 76 at 2 (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 608-09 (2011); *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2470-76 (2013)).

Collette clarifies in the pending complaint that he "does not allege that the warning label or package insert used by defendants is inadequate or should be changed" and that he "makes no allegations regarding the adequacy of the label." Dkt. No. 77 ¶ 114. Nevertheless, the second amended complaint still contains echoes of the warning and labeling claim the Court dismissed with prejudice. *See, e.g.*, *id*. ¶ 91 ("At all material times, the Cordarone/Amiodarone . . . was defective due to inadequate post-marketing warning and instruction."). These claims have already been dismissed and are not properly before the Court.

II. FAILURE TO PROVIDE MEDICATION GUIDES

For Collette's claim that defendants failed to distribute with the drug the "Medication Guide" as required by the Food and Drug Administration, the Court called for more detail because the claim as pled was too cursory and vague to state a plausible cause of action. Dkt. No. 76 at 3. The Court found, for example, that plaintiff did not even identify the pharmacy at which he filled his prescription. *Id*. The Court also noted that to the extent the claim was based only on duties arising from federal regulations, it was likely preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001). *Id*. at 2-3.

Collette has not supplied any of the additional factual detail called for by the Court. Surprisingly, he still does not even say at which pharmacy he filled the prescription, despite the fact that the particular pharmacy's failure to receive any Medication Guide would appear to be a critical piece of his claim. Instead, he continues to allege his claim only in a vague and conclusory outline fashion. *See, e.g.*, Dkt. No. 77 ¶ 31 ("[T]he Medication Guides were not provided by the defendants to the distributor and pharmacists for distribution to plaintiff with his prescription."). This is just one example of the ways in which plaintiff's claim continues to fail the plausibility requirements of Rule 8 as articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Preemption provides an alternative and independent basis for dismissal. From what the Court can make out about the claim, it does indeed appear to be based on federal regulatory duties only. *See, e.g.*, Dkt. No. 77 ¶ 39 (alleging plaintiff's "pharmacist was not provided a Medication Guide . . . as required by FDA regulations"). Collette has not, as directed by the Court, identified any parallel state duty that would have required defendants' distribution of the Medication Guide. Hanging his hat on FDA regulations only is impermissible. *See McDaniel v. Upsher-Smith Labs*., 893 F.3d 941, 944-48 (6th Cir. 2018) (where another Amiodarone plaintiff sought to "enforce the federal regulation requiring drug manufacturers to ensure the availability of Medication Guides for distribution to patients," finding the claim impliedly preempted and noting that "the majority of district courts to consider this very issue have found identical claims preempted").

The Court consequently dismisses plaintiff's Medication Guide claims without a further opportunity to amend. *See Chodos v. West Publishing Co.*, 292 F.3d 992, 1003 (9th Cir. 2002) (district court's discretion to deny amendment "particularly broad" when court has already granted plaintiff leave to amend).

III. OFF-LABEL MARKETING

The Court previously held that Collette's off-label marketing allegations sounded in fraud and consequently needed to meet the heightened particularity standard under Federal Rule of Civil Procedure 9(b). The Court dismissed the claim because it was too generalized as pled, and directed Collette, if he chose to amend, to "say much more about what, specifically, each

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. 76 at 4.

Collette has wholly failed to do so. Whether 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. Collette mentions enforcement actions instituted by the Food and Drug Administration against defendant Wyeth dating as far back as October 1986, Dkt. No. 77 ¶ 50, but he does not tie any of this in any concrete way to himself "and/or his prescribing physician." *Id.* ¶ 115. The complaint reads much more like a general investigative report than an actionable complaint by this plaintiff for a specific injury attributable to these defendants. Again, plaintiff's off-label marketing allegations have failed the requirements of *Twombly*, 550 U.S. 544; *Iqbal*, 556 U.S. 662; Rule 8 and Rule 9(b).

The Court will nevertheless grant plaintiff one last chance to amend these allegations and claims only.

CONCLUSION

The defendants' motions to dismiss are granted, and plaintiff's second amended complaint is dismissed. Plaintiff may file an amended complaint by July 10, 2019, limited to claims based on his off-label marketing allegations only. Plaintiff may not amend or re-allege his previously dismissed claims; nor may he add any new claims or defendants without express leave of Court. Failure to amend by the deadline in a manner consistent with the Court's order will result in a dismissal under Federal Rule of Civil Procedure 41(b).

IT IS SO ORDERED.

Dated: June 25, 2019

JAMES DONATO
United States District Judge