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. 48, 49

This case involves a generic heart medication, Amiodarone. Plaintiff Raymond Collette was prescribed the drug, took it, and later developed pulmonary fibrosis. 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) ingested by plaintiff. Defendants move to dismiss plaintiff's first amended complaint. Dkt. Nos. 48, 49. It is dismissed with leave to amend most, but not all, of the alleged claims.

DISCUSSION

The complaint asserts seven claims: (1) strict products liability -- failure to warn; (2) negligence -- failure to warn; (3) negligence -- marketing and sale; (4) negligence per se; (5) fraud and deceit; (6) violation of California Business & Professions Code § 17200 et seq. (Unfair Competition Law or "UCL"); and (7) violation of California Civil Code § 1750 et seq. (Consumer Legal Remedies Act or "CLRA"). Dkt. No. 33 ¶¶ 104-63. The first claim is alleged against Sandoz and Eon only; the remainder are alleged against all defendants.

At this initial stage of the case, the Court focuses on the gatekeeping preemption issues raised by Sandoz and Eon, and discusses plaintiff's claims more broadly by type of allegation as the parties themselves do. Dkt. Nos. 48, 52, 55.

I. INADEQUATE CONTENTS OF WARNINGS/LABELING

All of plaintiff's claims in this diversity action are framed under state common and statutory law. Dkt. No. 33 ¶¶ 104-63. Several Supreme Court decisions have reviewed state laws for drug labeling, and they mandate the conclusion here that the claims going to the warnings and labeling for Amiodarone, an FDA-approved generic drug, are preempted under federal law. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 608-09 (2011) (state tort-law claims based on an alleged failure to provide adequate warning labels for a generic drug held to be preempted by federal drug regulations applicable to generic drug manufacturers); *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2470-76 (2013) ("As *PLIVA* made clear, federal law prevents generic drug manufacturers from changing their labels"; consequently holding that state-law design-defect claims that turn on the adequacy of a drug's warnings are also preempted under federal law under *PLIVA*).

Plaintiff appears to concede as much. *See* Dkt. No. 52 at 5 (stating that this is not "a situation where plaintiff is challenging the content of the Medication Guide" and "[p]laintiff does not allege defendants should 'change' or 'alter' the existing warning label"). But his complaint does indeed contain these types of allegations. *See, e.g.*, Dkt. No. 33 ¶¶ 27 (plaintiff was "not provided up to date warning labels"); 76 (Cordarone/Amiodarone was "unaccompanied by proper warnings" and "warnings given did not and do not accurately reflect" severity or duration of side effects); 86 (warnings for Cordarone/Amiodarone were "vague, incomplete, and/or otherwise wholly inadequate"). These types of allegations are preempted under *PLIVA*, are dismissed with prejudice for that reason, and must be removed from any amended complaint.

II. FAILURE TO PROVIDE MEDICATION GUIDES

Plaintiff also alleges a failure to warn in a different flavor -- he asserts that defendants failed to distribute with the drug the "Medication Guide" as required by the Food and Drug Administration. Dkt. No. 33 ¶ 18. This claim may or may not be preempted. On the one hand, "state-law fraud-on-the-FDA claims" are impliedly preempted by federal law, as "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001). On the other, our circuit has recognized that claims that assert violations of state-law duties that parallel duties under

federal law are not preempted. *See McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir. 2015) (door remains open to "state-law claims 'parallel' to federal requirements" and plaintiff's failure-to-warn claims not preempted where they "did not arise solely by virtue of the MDA"); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233-34 (9th Cir. 2013) (state-law claim not preempted where it was "independent of the FDA's pre-market approval process" and it rested on a "state-law duty that parallels a federal-law duty").

The Court cannot resolve the preemption question now because the claim in its current form is too cursory and vague to state a plausible cause of action. *See, e.g.*, Dkt. No. 33 ¶ 133 (along with California's Sherman Food, Drug and Cosmetic Act, pointing to "various FDA regulations" defendants violated by failing to supply Medication Guides). The Court notes for plaintiff's guidance that what he has said about this claim gives the Court some skepticism that it can be successfully re-stated. It appears to seek a change in labeling, *see id*. ¶ 132 (alleging failure to supply Medication Guides violated Sherman Act because the labeling is false or misleading, fails to include a warning required by law, and fails to include adequate warnings or directions for use), or to be based purely on duties arising from federal regulations. *See id*. ¶ 133 (pointing to FDA regulations); Dkt. No. 52 at 6 (asserting Sandoz/Eon's "actual and physical failure . . . to fulfill their federally mandated responsibility to ensure the Medication Guides are available for distribution"); *id*. at 9 ("[b]y failing to ensure plaintiff received a Medication Guide -- as defendants were required to do under federal law . . .").

Despite these doubts, Collette has leave to amend this claim. The amendment will need to be stated in a way that avoids preemption, and with sufficient factual detail to meet 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). His current allegations, which do not even identify the pharmacy at which he filled his prescription, do not suffice.

III. OFF-LABEL MARKETING

Another central assertion in plaintiff's complaint is that defendants engaged in "off-label" marketing, promoting Cordarone/Amiodarone for the treatment of atrial fibrillation and as a "first line anti-arrhythmic therapy," even though it had been approved by the FDA "only as a drug of

last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." Dkt. No. 33 ¶ 18.

This claim is Collette's strongest in terms of avoiding federal preemption. There is no question that defendants had a state common law duty not to engage in fraud and deceit in the way that they marketed and sold their drugs. That duty arises wholly separately from federal law and does not necessarily conflict with defendants' specific labeling and disclosure requirements under the FDA's regulations. This consequently states the germ of a cognizable legal claim. *See* Dkt. No. 33 ¶¶ 135-48.

As allegations sounding in fraud, however, plaintiff also needed to meet the heightened particularity standard under Federal Rule of Civil Procedure 9(b) for this claim, and this he failed to do. Plaintiff's off-label marketing allegations in their current form are too generalized. In the next iteration he will need to say much more about what, specifically, each defendant said and did, and how those statements and actions (or lack thereof) relate to plaintiff personally and to his physician, Dr. James Yhip. Plaintiff has leave to amend to try to add those more specific allegations. And while the Court does not find at this time that defendants' statute of limitations arguments can be granted as a matter of law, Dkt. Nos. 49, 48, defendants may renew those arguments in response to a further amended complaint and the Court will take a closer look at plaintiff's amended allegations for issues of timeliness.

CONCLUSION

The motions to dismiss are granted. Plaintiff may file an amended complaint that is consistent with this order by **April 2, 2018**.

IT IS SO ORDERED.

Dated: March 12, 2018

JAMES DONATO
United States District Judge