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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDWIN STREED, et al., Plaintiffs, v. EON LABS, INC., et al., Defendants.	Case No. 17-cv-02609-MMC ORDER GRANTING PLAINTIFFS’ MOTION TO REMAND; DENYING PLAINTIFFS’ REQUEST FOR ATTORNEYS’ FEES AND COSTS Re: Dkt. No. 60
JOHN W. BLACKFORD, et al., Plaintiffs, v. WYETH PHARMACEUTICAL, INC., et. al., Defendants.	Case No. 17-cv-03825-MMC ORDER GRANTING PLAINTIFFS’ MOTION TO REMAND; DENYING PLAINTIFFS’ REQUEST FOR ATTORNEYS’ FEES AND COSTS Re: Dkt. No. 20

Before the Court are two motions to remand: (1) plaintiffs’ Motion to Remand Action to Alameda County Superior Court, filed May 31, 2017, in Case No. 17-2609; and (2) plaintiffs’ Motion to Remand Action to Sonoma County Superior Court, filed July 7, 2017, in Case No. 17-3285. Both motions have been fully briefed. Having considered the parties’ written submissions, the Court rules as follows.¹

BACKGROUND

Plaintiffs are 113 individuals who allege they have been injured by their, or their spouses or decedents’, use of products “manufactured, promoted, supplied and/or distributed by” defendants. (See First Amended Compl., Case No. 17-2609 (hereinafter “Streed FAC”) ¶¶ 1-39; Compl., Case No. 17-3825 (hereinafter “Blackford Compl.”) ¶¶ 1-

¹ By order filed August 14, 2017, the Court took the matter under submission.

1 36). In particular, plaintiffs allege they were “diagnosed as suffering from atrial
2 fibrillation” and were prescribed and thereafter “purchased and ingested” amiodarone
3 hydrochloride, a “drug commonly referred to as [a]miodarone,” and, “as a proximate
4 cause thereof,” developed various “life-threatening and debilitating” conditions, including,
5 but not limited to, pulmonary fibrosis, lung disease, and vision loss. (See Streed FAC ¶¶
6 1-39; Blackford Compl. ¶¶ 1-36.).²

7 Defendant Wyeth Pharmaceuticals, Inc. (“Wyeth”) is named as the initial
8 manufacturer of amiodarone in the United States; defendant McKesson Corporation
9 (“McKesson”) is named as the primary distributor of amiodarone; and the remaining
10 defendants (collectively, “Generic Defendants”) are named as manufacturers of generic
11 formulations of amiodarone. (See Streed FAC ¶ 50, 66, 70; Blackford Compl. ¶ 47, 63,
12 67.)

13 In 1985, the Food and Drug Administration (“FDA”) approved Wyeth’s application
14 to “market and sell” the brand name version of amiodarone. (See Streed FAC ¶ 66;
15 Blackford Compl. ¶ 63.) Plaintiffs allege amiodarone “was approved by the FDA only as
16 a drug of last resort for patients suffering from documented recurrent life-threatening
17 ventricular fibrillation and ventricular tachycardia,” but that Wyeth “instituted and
18 maintained an aggressive marketing plan positioning [a]miodarone as a ‘first-line’
19 treatment “for atrial fibrillation, . . . and failed to warn prescribing physicians of the
20 potential dangers associated with [a]miodarone toxicity and danger to atrial fibrillation
21 patients.” (See Streed FAC ¶¶ 67-68; Blackford Compl. ¶¶ 64-65.) Plaintiffs further
22 allege Generic Defendants “took advantage of Wyeth’s aggressive marketing plan” and
23 “actively promoted their generic [a]miodarone in the stream of commerce for the ‘off-label’
24 uses openly promoted by Wyeth.” (See Streed FAC ¶¶ 71, 118; Blackford Compl. ¶¶ 68,
25

26 ² The operative complaints refer to all named plaintiffs, whether a patient, spouse,
27 or estate, collectively as “plaintiffs.” (See, e.g., Streed FAC ¶ 73 (alleging “[p]rior to being
28 prescribed [a]miodorane, [p]laintiffs were diagnosed with atrial fibrillation”); Blackford
Compl. 73 (same).) For ease of reference, the Court does so as well herein.

1 115.)³

2 Additionally, plaintiffs allege, the FDA required that “any person who was
3 prescribed [amiodarone] was to first receive a ‘Medication Guide,’” the distribution of
4 which “was the responsibility of all [d]efendants,” and that defendants failed “to provide
5 the Medication Guide,” or, “in the case of McKesson, to distribute it and ensure its
6 distribution.” (See Streed FAC ¶¶ 67, 74; Blackford Compl. ¶¶ 64, 71.)

7 According to plaintiffs, each of the defendants “continued to actively conceal and
8 understate the drug’s nature and adverse risks . . . , despite [its] duty to disclose such
9 information and the need to distribute and ensure distribution of the Medication Guides,”
10 failed to disclose “specific material adverse information” to “the FDA, healthcare
11 professionals, consumers, and [p]laintiffs,” and “continued [its] fraudulent marketing,
12 promotional, and sales practices,” in spite of “FDA warnings and thousands of adverse
13 patient experiences.” (See Streed FAC ¶¶ 108, 116, 120; Blackford Compl. ¶ 105, 113,
14 117.)

15 Based on the above allegations, plaintiffs assert eight Causes of Action, titled,
16 respectively: “Strict Product Liability – Failure to Warn,” “Negligence – Failure to Warn,”
17 “Negligence –Marketing and Sale,” “Negligence Per Se,” “Fraud and Deceit,” “Violation of
18 Cal. Bus. & Prof. Code §§ 17200,” “Violation of Cal. Civil Code §§ 1750, et seq.,” and
19 “Wrongful Death.”

20 On May 5, 2017 and July 5, 2017, respectively, Case No. 17-2609 and Case No.
21 17-3825 were removed from state court on the asserted basis of federal question
22 jurisdiction, namely, that plaintiffs’ claims are either “inherently federal in nature,” or “raise
23 questions that are, in and of themselves, both substantial and disputed questions of
24 federal law”. (See Not. Removal, Case No. 17-2609 (hereinafter “Streed Not. Removal”),
25

26 ³ As alleged by plaintiffs, “off-label” use is “[a]ny specifically prescribed use beyond
27 those approved by the FDA” and promotion of a drug for off-label use is subject to “strict
28 requirements” that Wyeth and the Generic Defendants did not follow. (See Streed
Compl. ¶ 69; Blackford Compl. ¶ 66.)

1 ¶ 18); Not. Removal (hereinafter “Blackford Not. Removal”), ¶ 18.)

2 By the instant motions, plaintiffs seek remand on the ground that they have
3 alleged no federal claims and that their state law claims do not raise federal issues
4 sufficiently significant to confer federal question jurisdiction.

5 **LEGAL STANDARD**

6 Where a case has been removed from state court and “at any time before final
7 judgment it appears that the district court lacks subject matter jurisdiction, the case shall
8 be remanded.” See 28 U.S.C. § 1447(c). The Court is required to “strictly construe the
9 removal statute against removal jurisdiction,” and “[f]ederal jurisdiction must be rejected if
10 there is any doubt as to the right of removal in the first instance.” See Gaus v. Miles, Inc.,
11 980 F.2d 564, 566 (9th Cir. 1992). The removing defendant “always has the burden of
12 establishing that removal is proper.” See id.

13 **DISCUSSION**

14 District courts have federal question jurisdiction over “all civil actions arising under
15 the Constitution, laws or treaties of the United States.” See 28 U.S.C. § 1331. There are
16 “two ways” in which a case can “‘arise under’ federal law” and thus be subject to federal
17 question jurisdiction. See Gunn v. Minton, 568 U.S. 251, 257 (2013) (alteration omitted).
18 First, and “[m]ost directly, a case arises under federal law when federal law creates the
19 cause of action asserted.” See id. Second, “even where a claim finds its origins in state
20 rather than federal law,” federal question jurisdiction will still lie where “a state law claim
21 necessarily raise[s] a stated federal issue, actually disputed and substantial, which a
22 federal forum may entertain without disturbing any congressionally approved balance of
23 federal and state judicial responsibilities.” See id. (quoting Grable & Sons Metal Prods.,
24 Inc. v. Darue Eng’g & Mfg., 545 U.S. 308, 314 (2005)).

25 Here, the parties dispute whether the instant cases “arise under” federal law in
26 either of the above-discussed ways.

27 **A. Federal Cause of Action as Basis for Jurisdiction**

28 As noted, the first way in which a case may “arise under” federal law is where

1 “federal law creates the cause of action asserted.” See Gunn, 568 U.S. at 275. Here,
2 defendants point out, each complaint “on its face expressly and repeatedly references
3 and incorporates federal law” (see Opp., Case No. 17-2609 (hereinafter “Streed Opp.”),
4 at 5:19-20; Opp., Case No. 17-3825 hereinafter “Blackford Opp.”), at 5:19-20), in
5 particular, the federal Food Drug and Cosmetic Act (“FDCA”) and its implementing
6 regulations. Where, as here, however, a plaintiff has “chosen to seek relief” solely under
7 state statutory and common law, the fact that the complaint makes “repeated references
8 to” a federal statute “does not mean [such statute] creates the cause of action under
9 which [he/she] sues.” See ARCO Env’tl. Remediation, L.L.C. v. Dep’t Health & Env’tl.
10 Quality Mont., 213 F.3d 1108, 1133 (9th Cir. 2000).

11 Nevertheless, as defendants also point out, a plaintiff “cannot compel a remand
12 simply because they disclaim having specifically pled a federal cause of action” (see
13 Streed Opp. at 6:3-4; Blackford Opp. at 6:6-8), i.e., where they engage in “artful
14 pleading,” see ARCO, 213 F.3d at 1114.

15 Accordingly, the Court next turns to defendants’ second argument in support of
16 removal.

17 **B. Federal Issues within State Law Claims as Basis for Jurisdiction**

18 As set forth by the Supreme Court in Gunn, federal jurisdiction “will lie” where a
19 state law claim raises a federal issue that is “(1) necessarily raised, (2) actually disputed,
20 (3) substantial, and (4) capable of resolution in federal court without disrupting the
21 federal-state balance approved by Congress.” See Gunn, 568 U.S. at 258. “Where all
22 four of these requirements are met, . . . jurisdiction is proper.” See id.

23 Here, defendants contend plaintiffs’ state law claims raise two federal issues that
24 meet the above four requirements: (1) violation of the FDCA and its implementing
25 regulations governing Medication Guides; and (2) violation of the FDCA by promotion of
26 off-label use.

27 The Court next addresses whether either issue meets the four requirements.

28 //

1 **1. Necessarily Raised**

2 As the Supreme Court observed in Merrell Dow Pharmaceuticals, Inc. v.
3 Thompson, 478 U.S. 804 (1986), “the mere presence of a federal issue in a state cause
4 of action does not automatically confer federal-question jurisdiction.” See id. at 813.
5 “[F]ederal law is not a necessary element” of a state law claim where the claim “can be
6 supported by alternative and independent theories—one of which is a state law theory
7 and one of which is a federal law theory.” See Rains v. Criterion Sys., Inc., 80 F.3d 339,
8 346 (9th Cir. 1996).

9 Here, plaintiffs allege claims for strict products liability, negligence, fraud, and
10 wrongful death, as well as claims under California’s Unfair Competition Law (“UCL”) and
11 Consumer Legal Remedies Act (“CLRA”), each of which can be supported by a theory
12 independent of any violation of federal law or regulation.

13 In particular, one independent theory on which plaintiffs’ fraud, UCL, and CLRA
14 claims are predicated is common law fraud, namely, defendants’ affirmative
15 misrepresentations as to the nature and intended use of amiodarone and failure to
16 disclose material facts about its side effects. (See, e.g., Streed FAC ¶¶ 116, 132, 135,
17 178-185, 193-95, 202-203; Blackford Compl. ¶¶ 113, 129, 132, 175-182, 190-92, 199-
18 200.) Similarly, an independent theory on which plaintiffs’ strict products liability,
19 negligence, and wrongful death claims are predicated arises under the common law,
20 namely, defendants’ breach of their duty to adequately warn of known risks and to market
21 and sell a safe product. (See Streed FAC ¶¶ 108, 149-52, 157-59, 165, 207; Blackford
22 Compl. ¶¶ 105, 146-49, 154-56, 162, 204.)⁴

23
24 ⁴ Although plaintiffs’ Fourth Cause of Action, titled “Negligence Per Se,” is based
25 on an alleged violation of a federal regulation governing distribution of Medication
26 Guides, negligence per se “is not a separate cause of action,” see Millard v. Biosources,
27 Inc., 156 Cal. App. 4th 1338, 1353 n.2 (2007), but, rather, a legal concept that “raises a
28 [rebuttable evidentiary] presumption that the violator was negligent,” see Jacobs
Farm/Del Cabo, Inc. v. Western Farm Serv., Inc., 190 Cal. App. 4th 1502, 1526 (2010)
(citing Quiroz v. Seventh Ave. Center, 140 Cal. App. 4th 1256, 1285-86 (2006)
(explaining negligence per se is an “evidentiary presumption” that “may be rebutted”));
see also Johnson v. Honeywell Int’l, Inc., 179 Cal. App. 4th 549, 558 (2009) (“Under the
doctrine of negligence per se, the plaintiff ‘borrows’ statutes to prove duty of care and

1 Consequently, the Court finds the first requirement has not been met.

2 **2. Actually Disputed**

3 The parties disagree as to the interpretation of 21 C.F.R. § 208.24, the regulation
4 governing distribution of the Medication Guides. Neither party has clarified whether there
5 is any dispute as to defendants’ alleged promotion of off-label uses.

6 Consequently, the Court finds the second requirement has been met as to at least
7 one federal issue.

8 **3. Substantial**

9 For a federal issue to be substantial, “it is not enough that [it] be significant to the
10 particular parties in the immediate suit”; rather, the issue must be important “to the
11 federal system as a whole.” See Gunn, 568 U.S. at 260.

12 In that regard, the Court notes that the two cases cited in Gunn as providing
13 examples of a substantial federal issue involved, respectively, a challenge to the actions
14 of a federal agency and the validity of a federal law. See Grable, 545 U.S. at 314-15
15 (finding, where case turned on whether Internal Revenue Service had provided plaintiff
16 with “adequate notice, as defined by federal law,” federal government had “a direct
17 interest in the availability of a federal forum to vindicate its own administrative action”);
18 Smith v. Kansas City Title & Trust Co., 255 U.S. 180, 201 (1921) (finding, where
19 shareholder challenged “validity” of securities issued by federal government,
20 “constitutional validity of an act of Congress” was “directly drawn into question”). Here,
21 plaintiffs challenge only the behavior of private parties, not the actions of the FDA or the
22 validity of the FDCA and/or its implementing regulations, and, consequently, have not
23 raised an issue of “importance . . . to the federal system as a whole.” See Gunn, 568
24 U.S. at 260; see also Carmine v. Poffanbarger, 154 F. Supp. 3d 309, 318 (E.D. Va. 2015)
25 (holding dispute as to “whether medical manufacturers designed, manufactured, and

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28 standard of care.”) (internal citation omitted). As such, it assists a plaintiff in proving a
negligence claim, but is not a required element thereof.

1 promoted an unreasonably dangerous product” does “not affect the operation of the
2 federal system in the way that was evident in Smith or in Grable”).

3 Additionally, as plaintiffs point out, the plaintiffs in Merrell Dow based their
4 negligence claim on an alleged violation of the FDCA, and the Supreme Court, noting
5 “there is no federal cause of action for FDCA violations,” see Merrell Dow, 478 U.S. at
6 810, held the absence of a “federal remedy for the violation of this federal statute is
7 tantamount to a congressional conclusion that the presence of a claimed violation of the
8 statute as an element of a state cause of action is insufficiently ‘substantial’ to confer
9 federal-question jurisdiction,” see id. at 814. Although, in Grable, the Supreme Court
10 later clarified that Merrell Dow should not be read as holding the absence of a federal
11 private right of action is dispositive, the Grable Court also acknowledged the potential
12 significance of such absence on the “assessment of substantiality.” See Grable, 545 U.S.
13 at 318. As Merrell Dow has made that assessment with respect to state law claims
14 alleging violations of the FDCA, the Court finds Merrell Dow “governs the present
15 question” as to the substantiality of the federal issues presented here.⁵ See In re.
16 Avandia Marketing, Sales Practices & Prods. Liab. Litig., 624 F. Supp. 2d 396, 415-16
17 (E.D. Pa. 2009) (citing Merrell Dow as controlling; finding, where plaintiffs alleged
18 “Negligence – Failure to Warn” claim that “explicitly refer[red] to the FDCA as well as
19 certain implementing administrative regulations,” federal issue was “not . . . sufficiently
20 substantial” to confer federal question jurisdiction).

21 Consequently, the Court finds the third requirement has not been met.

22 **4. Capable of Resolution Without Disrupting Federal-State Balance**

23 Lastly, even if all of the above three requirements had been met, defendants must
24 show the federal issues presented here are “capable of resolution in federal court without
25

26 ⁵ To the extent plaintiffs here allege noncompliance with regulations promulgated
27 under the FDCA, such allegations necessarily allege a violation of the FDCA itself,
28 namely, that such noncompliance constitutes “distribution of a mislabeled and illegal
drug.” (See Streed FAC ¶ 74; Blackford Compl. ¶ 71); see also 21 U.S.C. § 352(a)(1).

1 disrupting the federal-state balance approved by Congress.” See Gunn, 568 U.S. at 258.

2 In Merrell Dow, the Supreme Court addressed this requirement as well,
3 “empasiz[ing] . . . it would flout congressional intent to provide a private federal remedy
4 for the violation of the [FDCA],” and holding “it would similarly flout, or at least undermine,
5 congressional intent to conclude that the federal courts might nevertheless exercise
6 federal-question jurisdiction and provide remedies for violations of that federal statute
7 solely because the violation of the federal statute is said to be a ‘rebuttable presumption’
8 [of negligence] . . . under state law.” See Merrell Dow, 478 U.S. at 812; see also Grable,
9 545 U.S. at 318 (acknowledging “the combination of no federal cause of action and no
10 preemption of state remedies for misbranding as an important clue to Congress’s
11 conception of the scope of the jurisdiction to be exercised under § 1331”; noting,
12 “exercising federal jurisdiction over a state misbranding action would have attracted a
13 horde or original filings and removal cases raising other state claims with embedded
14 federal issues”).

15 The Supreme Court’s reasoning in Merrell Dow and Grable applies equally to the
16 issues presented here. The Court finds unpersuasive defendants’ argument that, to the
17 extent plaintiffs’ claims allege a failure to supply an accompanying Medication Guide,
18 there is little risk of disrupting the federal-state balance because such claims are rare.
19 Were the Court to find federal jurisdiction appropriate in this instance, such ruling
20 “arguably would apply further,” see Carmine, 154 F. Supp. at 319, and essentially would
21 “invite all similar claims involving FDA-approved drugs into federal courts across the
22 country,” see Arnold v. Baxter Healthcare Corp., 609 F. Supp. 2d 712, 718 (N.D. Ohio
23 2009) (noting “any products liability case involving FDA-approved drugs will likely involve
24 the FDCA”).

25 Consequently, the Court finds the fourth requirement, as with the first and third,
26 has not been met.

27 In sum, the Court lacks federal question jurisdiction over the above-titled cases
28 and, accordingly, remand is appropriate.

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C. Attorneys' Fees and Costs

Plaintiffs ask the Court for an award of the attorneys' fees and costs they incurred in seeking remand. An "order remanding the case may require payment of just costs and any actual expenses, including attorney fees, incurred as a result of the removal." See 28 U.S.C. § 1447(c). "[A]bsent unusual circumstances," however, "attorney's fees should not be awarded when the removing party has an objectively reasonable basis for removal." See Martin v. Franklin Capital Corp., 546 U.S. 132, 141 (2005). Here, the Court finds an award of fees is not warranted. Although, as discussed above, the Court was not persuaded by defendants' arguments, the Court does not find those arguments were objectively unreasonable, and plaintiffs have not shown defendants sought removal "for the purpose of prolonging litigation." See id. at 140.

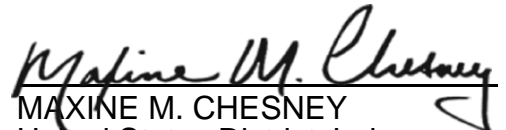
CONCLUSION

For the reasons set forth above, plaintiffs' motions to remand are hereby GRANTED, and plaintiffs' requests for fees and costs are hereby DENIED. In light thereof, Case No. 17-2609 is hereby REMANDED to the California Superior Court for the County of Alameda, and Case No. 17-3825 is hereby REMANDED to the California Superior Court for the County of Sonoma.

The Clerk shall close the files.

IT IS SO ORDERED.

Dated: August 23, 2017


MAXINE M. CHESNEY
United States District Judge