

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

United States District Court  
Northern District of California

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

<p>JOSHUA ROSEWOLF, Plaintiff,  v. MERCK &amp; CO., INC., et al., Defendants.</p>
<p>MARK STARR, Plaintiff,  v. MERCK &amp; CO., INC., et al., Defendants.</p>
<p>TYLER SKINNER, Plaintiff,  v. MERCK &amp; CO., INC., et al., Defendants.</p>
<p>SHAUNA GIBSON, Plaintiff,  v. MERCK &amp; CO., INC., et al., Defendants.</p>

Case Nos. [22-cv-2072](#), [22-cv-02138-JSW](#),  
[22-cv-02260](#), and [22-cv-2263](#)

**ORDER GRANTING, IN PART, AND DENYING, IN PART, MOTIONS TO DISMISS AND SETTING DEADLINES AND CASE MANAGEMENT CONFERENCE**

Re: Dkt. Nos. 18 (Rosewolf), 8 (Starr and Skinner), and 9 (Gibson)

1 Now before the Court for consideration are motions to dismiss filed by Defendants Merck  
2 & Co., Inc., Merck Sharp & Dohme Corp., Organon & Co., and Organon, LLC (“Defendants”).  
3 The Court has considered the parties’ papers, relevant legal authority, and the record in this case,  
4 and it HEREBY GRANTS, IN PART, AND DENIES, IN PART, Defendants’ motions.

### 5 BACKGROUND<sup>1</sup>

#### 6 A. Regulatory Background for New and Generic Drugs.

7 In order to place Plaintiffs’ claims in context, the Court begins with some background of  
8 the law and regulations relating to the manufacture and sales of new and generic drugs. When a  
9 drug manufacturer wants to market a new drug, it must submit a New Drug Application (“NDA”)  
10 to the FDA and then “undergo a long, comprehensive, and costly testing process[.]” *FTC v.*  
11 *Activis, Inc.*, 570 U.S. 136, 141 (2013). When a manufacturer wants to market a generic version  
12 of an FDA approved new drug, it can file an Abbreviated New Drug Application (“ANDA”) and  
13 “piggy-back” on the brand-name manufacturer’s NDA by “show[ing] that the generic drug has the  
14 same active ingredients as, and is biologically equivalent to, the brand-name drug.” *Caraco*  
15 *Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. §§  
16 355(j)(2)(A)(ii), (iv)).

17 As part of the NDA process, the manufacturer of the new drug must submit and the FDA  
18 must approve “the exact text in the proposed label.” *Wyeth v. Levine*, 555 U.S. 555, 568 (2009);  
19 *see also* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b). Under the ANDA process, the manufacturer of  
20 a generic drug must “show that the safety and efficacy labeling proposed ... is the same as the  
21

---

22 <sup>1</sup> In addition to the captioned cases, the Court has related four other cases that involve  
23 identical, or nearly identical claims, against Defendants. (*See Rosewolf*, Dkt. Nos. 28, 30, 36, 50.)  
24 On August 9, 2022, the Court granted Defendants’ motion to sever and denied the Plaintiffs’  
25 cross-motion to consolidate in *Rosewolf* and *Gibson*. (*Id.*, Dkt. No. 46.) On August 16, 2002, the  
26 Court granted Defendants’ motion to dismiss *Rosewolf*’s claims, with leave to amend, on the basis  
27 that his claims were time barred. (*Id.*, Dkt. No. 47.)

28 The substance of Defendants’ pending motions to dismiss also are identical or nearly so,  
although Defendants did not move to dismiss *Rosewolf*’s claims for lack of personal jurisdiction.  
In their opposition briefs, Starr, Skinner, and Gibson incorporated by the arguments *Rosewolf*  
raised in his opposition brief on Defendants’ challenges to the substance of Plaintiffs’ claims.  
Accordingly, that is the brief on which the Court has relied to resolve Defendants’ Rule 12(b)(6)  
motions.

1 labeling approved for the brand-name drug.” *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612-13  
 2 (2011) (internal alterations and quotations omitted). Thus, “[a] brand-name manufacturer seeking  
 3 new drug approval is responsible for the accuracy and adequacy of its label[,]” whereas a generic  
 4 manufacturer “is responsible for ensuring that its warning label is the same as the brand name’s”  
 5 label. *Id.* at 613 (citations omitted). Although any drug manufacturer can apply to the FDA to  
 6 change an existing drug label, only the manufacturer of the branded drug can “add or strengthen a  
 7 contraindication, warning, precaution, or adverse reaction” warning without waiting for FDA  
 8 approval. *Wyeth*, 555 U.S. at 568 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)).

9 **B. Factual Background.**

10 Defendants manufacture and sell the brand-name drug “Singulair,” and each Plaintiff  
 11 alleges that Singulair’s active ingredient, montelukast, causes neuropsychiatric injury by crossing  
 12 the blood-brain barrier. Plaintiffs also allege that Defendants knew montelukast could cause these  
 13 types of injuries but failed to warn of those risks and failed to maintain the accuracy and adequacy  
 14 of Singulair’s warning label. (*See, e.g., Starr* Compl. ¶¶ 32-85.) Defendants held patent rights on  
 15 montelukast until August 2012, when the patent expired. (*Id.* ¶¶ 2, 27.) At that point, other  
 16 companies began to manufacture and sell generic montelukast. (*Id.* ¶ 86.) Plaintiffs allege that  
 17 Defendants “engaged in an extensive campaign to educate physicians in California about the  
 18 alleged benefits of Singulair” but misrepresented its safety in that campaign. (*Id.* ¶ 19.)

19 Plaintiffs also allege that on March 4, 2020, the FDA required Defendants to add a Black  
 20 Box Warning to Singulair’s label and required a new medication guide. (*Id.* ¶ 3.) The Black Box  
 21 Warning states:

22 Serious neuropsychiatric events have been reported in patients  
 23 taking Singulair. These include:

24 agitation, aggressive behavior or hostility, anxiousness, depression,  
 25 disorientation, disturbance in attention, dream abnormalities,  
 26 dysphagia (stuttering), hallucinations, insomnia, irritability, memory  
 impairment, obsessive-compulsive symptoms, restlessness,  
 somnambulism, suicidal thoughts and behavior (including suicide),  
 tic, and tremor ...

27 Psychiatric disorders: agitation including aggressive behavior or  
 28 hostility, anxiousness, depressions, disorientation, dream  
 abnormalities, hallucinations, insomnia, irritability, restlessness,

1 somnambulism, suicidal thinking and behavior (including suicide),  
2 tremor [*see Warnings and Precautions (5.4)*].

3 (*Id.* ¶ 4 (emphasis in original)). The Black Box Warning also states that “the benefits of Singulair  
4 may not outweigh the risks, and the FDA issued a press release in which it stated that “many  
5 patients and health care professionals are not fully aware of these risks.” (*Id.*)

6 Plaintiffs allege they were prescribed Singulair during various periods after 2012, which  
7 “were filled with branded and/or generic Singulair.”<sup>2</sup> (*Starr* Compl. ¶¶ 7-8; *Skinner* Compl. ¶¶ 7-  
8 8; *Gibson* Compl. ¶¶ 7-8.) According to Plaintiffs, if they or their physicians had known that  
9 Singulair “could cause [them] to suffer neuropsychiatric events, [their physicians] would not have  
10 prescribed Singulair,” and they would not have ingested it. (*Starr* Comp. ¶ 11; *Skinner* Compl. ¶  
11 10; *Gibson* Compl. ¶ 11.) Based on these and other allegations that the Court shall address as  
12 necessary, Plaintiffs assert the following claims for relief: Count I - strict liability (design defect);  
13 Count II – strict liability (failure to warn); Count III – negligence; Count IV – negligent  
14 misrepresentation; Count V – breach of express warranty; and Count VI – breach of implied  
15 warranty.

16 The Court will address additional facts as necessary in its analysis.

## 17 ANALYSIS

### 18 A. The Court Concludes It Has Personal Jurisdiction Over Defendants.

#### 19 1. Applicable Legal Standards.

20 Defendants move to dismiss Plaintiffs’ claims for lack of personal jurisdiction, under  
21 Federal Rule of Civil Procedure 12(b)(2). Due process requires that a defendant have “minimum  
22 contacts” with the forum state “such that the maintenance of the suit does not offend ‘traditional  
23 notions of fair play and substantial justice.’” *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316  
24 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). The Court’s focus when evaluating  
25 personal jurisdiction is on the “nature and extent of ‘the defendant’s relationship to the forum  
26

---

27 <sup>2</sup> Unlike *Starr*, *Skinner*, and *Gibson*, *Rosewolf* alleges he was prescribed Singulair before  
28 Defendants’ patent expired.

1 state.” *Ford Motor Co. v. Montana Eighth Judicial Dist. Ct.*, -- U.S. --, 141 S.Ct. 1017, 1024  
 2 (2021) (quoting *Bristol-Myers Squibb Co. v. Super. Ct. of California*, 582 U.S. --, 137 S. Ct 1773,  
 3 1779 (2017)) (“*Ford*”); *see also Walden v. Fiore*, 577 U.S. 277, 290 (2014) (“The proper question  
 4 is not where the plaintiff experienced a particular injury or effect but whether the defendant’s  
 5 conduct connects him to the forum in a meaningful way.”).

6 Plaintiffs argue the Court has specific jurisdiction over Defendants, which requires them to  
 7 show: (1) Defendants purposefully directed their activities at California or purposefully availed  
 8 themselves of California’s laws; (2) Plaintiffs’ claims arise out of or relate to Defendants’  
 9 activities in California; and (3) exercising jurisdiction would be reasonable. *See, e.g.*,  
 10 *Schwarzenegger v. Fred Martin Motor Co.*, 374 F.3d 797, 802 (9th Cir. 2004). In *Ford*, the Court  
 11 addressed the meaning of the phrase “arise out of or relate to” and concluded that

12 [t]he first half of that standard asks about causation; but the back  
 13 half, after the “or,” contemplates that some relationships will  
 14 support jurisdiction without a causal showing. That does not mean  
 15 anything goes. In the sphere of specific jurisdiction, the phrase  
 16 “relate to” incorporates real limits, as it must to adequately protect  
 17 defendants foreign to a forum. But again, we have never framed the  
 18 specific jurisdiction inquiry as always requiring proof of  
 19 causation—*i.e.*, proof that the plaintiff’s claim came about because  
 20 of the defendant’s in-state conduct.

21 *Ford*, 141 S.Ct. at 1026.

22 Plaintiffs bear the burden of proving the first two prongs. *Schwarzenegger*, 347 F.3d at  
 23 802. If Plaintiffs meet their burden, “the burden then shifts to [Defendants] to present a  
 24 compelling case that the exercise of jurisdiction would not be reasonable.” *Id.* (internal quotation  
 25 marks omitted).

## 26 **2. Analysis.**

27 Defendants challenge Plaintiffs’ allegations on the second prong of the specific jurisdiction  
 28 test, and the parties dispute what contacts are jurisdictionally relevant in light of Plaintiff’s  
 theory of warning label liability. The California Supreme Court has reasoned that because a  
 brand-name manufacturer is responsible for the content of a drug’s warning label, it “knows to a  
 legal certainty ... that any deficiencies in the label for its drug will be perpetrated in the label for  
 its generic bioequivalent.” *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145, 166 (2017). Thus,

1 California has extended liability for failure to warn to a brand-name manufacturer of a prescription  
2 drug “regardless of whether the consumer is prescribed the brand-name drug or its generic  
3 bioequivalent.” *Id.* at 165 (internal quotations and citations omitted).

4 Defendants argue that because they made decisions about the contents of Singulair’s label  
5 either in New Jersey or in Pennsylvania, there are no contacts in California that give rise to or  
6 relate to Plaintiffs’ claims. (*See Starr* Dkt. No. 8-2, Declaration of Shannon Beamer, ¶ 3, Ex. 1  
7 (Declaration of Margaret McCann, ¶¶ 3-4).) Plaintiffs counter by arguing the Court can, and  
8 should, consider a broader range of activities, including research Defendants conducted in  
9 California, sales of Singulair in California, and Defendants’ marketing and advertising to  
10 consumers and physicians in California. The parties each have authority to support their positions.

11 Defendants argue the Court should follow *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 546  
12 F. Supp. 3d 1192, 1213 (S.D. Fla. 2021) (“*Zantac*”). In that case, the court dismissed California  
13 plaintiffs’ claims for negligent misrepresentation, which related to the safety of ranitidine, the  
14 active ingredient in Zantac. *Id.* at 1199. It found plaintiffs’ allegations regarding the defendant’s  
15 sales and marketing were sufficient to establish the defendants purposefully availed themselves of  
16 a California forum. *Id.* at 1211-12. It also acknowledged that, under *Ford*, the plaintiffs were not  
17 required to show “but for” causation to establish jurisdiction. *Id.* at 1198 n.5, 1203-04. However,  
18 it reasoned that any misrepresentations the defendants made about Zantac’s safety in sales and  
19 marketing material were not necessary to state a claim under warning label liability. Thus, it held  
20 that those contacts were not jurisdictionally relevant. *Id.* at 1212-13.

21 Defendants also rely on *R.S.B. v. Merck & Co.*, and argue that, unlike the defendants in  
22 *Ford*, they did not benefit from the contacts on which Plaintiffs rely. No. 20-C-1402-WCG, 2021  
23 WL 6113765, at \*3 (E.D. Wis. Dec. 27, 2021). In *R.S.B.*, the court concluded the plaintiffs’  
24 negligent misrepresentation claim was barred under Wisconsin’s product liability statute, which  
25 requires a plaintiff to show a defendant, *inter alia*, “promotes” a product. The court rejected the  
26 plaintiffs’ argument that, by being responsible for Singulair’s label, Defendants promoted the  
27 generic version of the drug. “A company, no matter what precarious position it may be in, does  
28 not intend to promote a competitor’s product to the detriment of its own sales.” *Id.*, at \*5. *R.S.B.*

1 is not a case about personal jurisdiction, and that court was not called upon to construe California  
2 law, which has accepted warning label liability as a viable theory. For those reasons, the Court  
3 does not find Defendants' reliance on *R.S.B.* persuasive.

4 *T.H.* also is not a case about personal jurisdiction. However, the defendant argued that  
5 warning label liability claims are unfair to brand-name manufacturers because they would hold  
6 them liable for harm caused by a competitor's product, from which they "derive[] no revenue or  
7 profit." 4 Cal. 5th at 172. The California Supreme Court was not persuaded. It reasoned the  
8 plaintiffs' claim was not about whether the generic drug was defectively designed or inherently  
9 dangerous. "It is that [the drug's] warning label failed to mention the risk ... and Novartis was  
10 responsible for the deficient label. So the alleged fault here lies with Novartis, not with its generic  
11 competitors." *Id.* The court also reasoned that any burden falling on brand-name manufacturers  
12 would be "more than offset by the substantial benefits federal law confers on the brand-name  
13 manufacturer" for the life of its patents. *Id.*

14 Plaintiffs, in turn, rely on *Whaley v. Merck & Co., Inc.*, in which the court considered and  
15 rejected many of the same arguments Defendants raise in this case. 21-cv-01985-H-BLM, 2022  
16 WL 1153151 (S.D. Cal. Apr. 12, 2022). In *Whaley*, the court reasoned that adopting Defendants'  
17 argument would require a court to find "a causal link between the activity and the cause of action,"  
18 a requirement rejected by the Supreme Court in *Ford*. *Id.* at \*5. The court also noted that  
19 Defendants' marketing and sales activities would encompass both the drug and the label. "Federal  
20 law combines these two parts into the same product and California law recognizes a cause of  
21 action concerning the warning label part." *Id.*, at \*6. The court also reasoned that, like the  
22 defendant in *T.H.*, Defendants misconstrued the nature of the plaintiffs' claims by casting the  
23 claims as related only to generic montelukast, not Singulair. The court determined the plaintiffs'  
24 claim was "not that [montelukast] is defectively designed or inherently dangerous. It is that  
25 [montelukast's] warning label failed to mention the risk ... and that [Merck] was responsible for  
26 the deficient label. So the alleged fault here lies with [Merck], not with its generic competitors."  
27 *Id.* (quoting *T.H.*, 4 Cal. 5th at 172 (brackets as in *Whaley*)); see also *Bueno v. Merck & Co., Inc.*,  
28 No. 22-cv-522-H-BLM, 2022 WL 4125231, at \*5 (S.D. Cal. Sept. 8, 2022) ("Defendants' forum-

1 based advertising, marketing, and selling of Singulair – the product that is at the heart of  
2 Plaintiffs’ claim – are jurisdictional activities under *Ford* that are within the ‘real limits’ of the  
3 ‘relates to’ element of the specific jurisdiction test,” even if they “only ingested generic  
4 montelukast.”)

5 The Court finds *Whaley* and *Bueno* more persuasive than *Zantac* and agrees that  
6 Defendants’ jurisdictional challenge is, in actuality, a challenge “aimed at California’s warning  
7 label liability law.” *Whaley*, 2022 WL 1153151, at \*8; *see also Bueno*, 2022 WL 4125231, at \*5.  
8 Even if Plaintiffs received and ingested generic montelukast, Defendants’ activities selling and  
9 promoting Singulair “count because California law assigns liability to Defendants for the label on  
10 their Singulair product;” that label is part and parcel of the drug Defendants have marketed and  
11 sold within California. *Whaley*, 2022 WL 1153151, at \*8; *cf. T.H.*, 4 Cal. 5th at 172 (stating that  
12 federal law “bundles – and indeed, only makes available – benefits” associated with a new drug  
13 “along with the responsibility to maintain an adequate warning label”).

14 Defendants also argue that if the Court follows *Whaley*, it should still grant the motion  
15 because Plaintiffs fail to include specific facts showing their doctors were exposed to any of the  
16 alleged marketing activities and also failed to provide detail about the nature of Defendants’  
17 advertising and marketing campaigns. In *Bueno*, the court noted that the plaintiffs’ allegations  
18 were less detailed than in *Whaley*. It still found them sufficient and concluded that “maintenance  
19 of the suit does not offend traditional notions of fair play and substantial justice.” *Bueno*, 2022  
20 WL 4125231. at \*5, n.6.<sup>3</sup> The Court concludes the allegations here also are sufficient to allege the  
21 Court has jurisdiction over Defendants.

22 Accordingly, the Court DENIES Defendants’ motions to dismiss on this basis.  
23  
24

---

25 <sup>3</sup> Plaintiffs have also alleged far more contacts than the plaintiff in *Henry v. Angelini*  
26 *Pharma, Inc.*, No. 17-cv-2593-TLN-KJN, 2020 WL 1532174, at \*4 (E.D. Cal. Mar. 31, 2020), on  
27 which Defendants rely, and the Court finds that case distinguishable. *Cf. Whaley*, 2022 WL  
28 1153151, at \*8. The Court also finds *LNS Enter. LLC v. Cont’l Motors, Inc.* distinguishable. 22  
F.4th 852 (9th Cir. 2022). There, the Ninth Circuit did not address the theory of warning label  
liability. Further, unlike the defendant in that case, when Defendants marketed and sold Singulair  
in California, they marketed and sold a warning label which, by law, generic manufacturers were  
bound to include on their products.



1 **B. Plaintiffs Have Stated Claims for Relief, in Part.**

2 **1. Applicable Legal Standards.**

3 Defendants also move to dismiss for failure to state a claim under Federal Rule of Civil  
4 Procedure 12(b)(6). Under Rule 12(b)(6), the Court’s inquiry generally “is limited to the  
5 allegations in the complaint, which are accepted as true and construed in the light most favorable  
6 to the plaintiff.” *Lazy Y Ranch Ltd. v. Behrens*, 546 F.3d 580, 588 (9th Cir. 2008). Even under the  
7 liberal pleading standard of Federal Rule of Civil Procedure 8(a)(2), “a plaintiff’s obligation to  
8 provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and  
9 a formulaic recitation of the elements of a cause of action will not do.” *Bell Atl. Corp. v.*  
10 *Twombly*, 550 U.S. 544, 555 (2007) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).  
11 Pursuant to *Twombly*, a plaintiff must not merely allege conduct that is conceivable but must  
12 instead allege “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570. “A  
13 claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw  
14 the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*,  
15 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

16 A plaintiff must state fraud based claims with particularity but can plead intent,  
17 knowledge, and other matters relating to state of mind generally. Fed. R. Civ. P. 9(b). A claim is  
18 “grounded in fraud” if the plaintiff alleges a unified course of fraudulent conduct and relies  
19 entirely on that course of conduct as the basis of his or her claim.” *Vess v. Ciba-Geigy Corp. USA*,  
20 317 F.3d 1097, 1104 (9th Cir. 2003). Rule 9(b)’s particularity requirements must be read in  
21 harmony with Rule 8, which requires a “short and plain” statement of the claim. The particularity  
22 requirement is satisfied if the complaint “identifies the circumstances constituting fraud so that a  
23 defendant can prepare an adequate answer from the allegations.” *Moore v. Kayport Package Exp.,*  
24 *Inc.*, 885 F.2d 531, 540 (9th Cir. 1989). Accordingly, “[a]verments of fraud must be accompanied  
25 by ‘the who, what, when, where, and how’ of the misconduct charged.” *Vess*, 317 F.3d at 1107  
26 (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)).

27 If the allegations are insufficient to state a claim, a court should grant leave to amend,  
28

1 unless amendment would be futile. *See, e.g., Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th  
2 Cir. 1990); *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc.*, 911 F.2d 242, 246-47 (9th  
3 Cir. 1990).

4 **2. Analysis.**

5 **a. Plaintiffs' Concessions.**

6 Plaintiffs concede that Count I and the portion of Count III that is not based on a failure to  
7 warn should be dismissed. Accordingly, the Court GRANTS, IN PART, the motions on that  
8 basis.

9 **b. Plaintiffs' allegations on the failure to warn claims are adequate.**

10 Counts II, III, and IV are premised on Plaintiffs' allegations that Defendants failed to  
11 include adequate warnings on Singulair's label regarding the likelihood that it could cause  
12 neuropsychiatric injuries. In California, "in the case of prescription drugs, the duty to warn runs to  
13 the *physician*, not to the patient." *Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1116 (1996) (emphasis in  
14 original). In *Bueno*, the court considered the three cases on which Defendants rely to support their  
15 position: *Fisher v. Boston Sci. Corp.*, No. SACV 19-02106 JVS (DFM), 2020 WL 2300138 (C.D.  
16 Cal. Mar. 25, 2020), *Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152 (E.D. Cal. 2019), and *Tapia*  
17 *v. Davol, Inc.*, 116 F. Supp. 3d 1149 (S.D. Cal. 2015). It concluded that although the plaintiffs did  
18 not include the names of their physicians, the allegations were directed to the plaintiffs in  
19 particular, rather than to patients and physicians in general, and were sufficient to state a claim.  
20 *Bueno*, 2022 WL 4125231, at \*6; *see also Whaley*, 2022 WL 1153151, at \*12 (finding allegations  
21 sufficient to state a claim).

22 Unlike the plaintiff in *Tapia*, Plaintiffs do not make "allegations as to 'physicians' in  
23 general, and the 'healthcare community.'" *Tapia*, 116 F. Supp. 3d at 1158. Plaintiffs' allegations  
24 here also are distinguishable from the allegations in *Fischer*. There the plaintiff alleged the  
25 defendant failed to warn her "and/or her physician" of alleged defects in the product but also  
26 included allegations about numerous safety issues. The plaintiff did not, however, clearly specify  
27 which of those allegations applied to her. *Fisher*, 2020 WL 2300138, at \*3. Finally, in  
28 *Marroquin*, the court concluded the plaintiff's allegations were not sufficient, in part, because the

1 plaintiff alleged that ““ordinary consumers’ could not have recognized the potential risks of the”  
 2 drug and did not include facts to show “how or why the warnings provided were inadequate. ...  
 3 Merely stating that the Defendants failed to ‘adequately warn’” of the alleged risks “is a bare legal  
 4 conclusion.” *Marroquin*, 367 F. Supp. 3d at 1161-62. Here, although Plaintiffs do not provide the  
 5 names of their physicians, they have included facts that describe the information available to  
 6 Defendants about the risk of severe neuropsychotic events and the likelihood that montelukast  
 7 crossed the blood-brain barrier, as well as facts to show why Singulair’s label allegedly did not  
 8 adequately warn of those dangers.

9 Accordingly, the Court concludes Plaintiffs’ allegations pass muster under Rule 8. *Cf.*  
 10 *Whaley*, 2022 WL 1153151, at \*12. The Court DENIES, IN PART, Defendants’ motions on this  
 11 basis as well.<sup>4</sup>

12 **c. Plaintiffs’ allegations on the negligent misrepresentation claims are**  
 13 **adequate.**

14 Defendants argue that Plaintiffs’ claims for negligent misrepresentation fail to comply with  
 15 Rule 9(b) because Plaintiffs do not describe with particularity the statements contained in media or  
 16 advertisements, do not identify what individuals made statements on Defendants’ behalf, and do  
 17 not provide the dates on which Plaintiffs and/or their physicians saw these statements. Plaintiffs  
 18 did not directly address this argument in their opposition.

19 Plaintiffs allege why Singulair’s label (what) failed to describe the risks associated with the  
 20 Drug. Plaintiffs allege that Defendants created Singulair’s label (who), and at this stage the Court  
 21 will not fault them for being unable to specifically identify the particular employees who may  
 22 have made those decisions. Finally, Plaintiffs allege the time period during which they were  
 23 prescribed Singulair or a generic equivalent and allege they were prescribed and ingested Singulair  
 24 or its equivalent in California (when and where). Finally, Plaintiffs provided detailed allegations  
 25 about why and how Singulair’s label failed to sufficiently disclose the risks involved and allege  
 26 their physicians would not have prescribed Singulair had those risks been disclosed.

27 \_\_\_\_\_  
 28 <sup>4</sup> The Court does not reach Plaintiffs’ alternative argument that Defendants also could be held liable based on direct marketing to consumers.

United States District Court  
Northern District of California

1 The Court concludes Plaintiffs' allegations are sufficient under Rule 9(b) and DENIES  
2 Defendants' motion to dismiss on this basis as well.

3 **d. Plaintiffs' allegations on their breach of warranty claims are adequate.**

4 Defendants also argue the Court should dismiss Plaintiffs' claims for breach of express or  
5 implied warranty because they have failed to adequately allege their physicians relied on any  
6 purported warranties. For the reasons set forth in Section B.2.b and B.2.c, the Court concludes  
7 Plaintiffs' allegations are sufficient to withstand Defendants' motions. Accordingly, the Court  
8 DENIES Defendants' motions to dismiss on this basis as well.

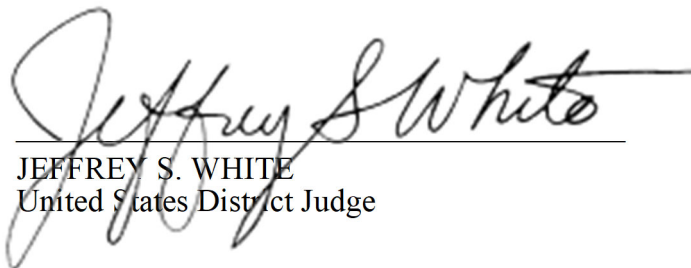
9 **CONCLUSION**

10 For the foregoing reasons, the Court GRANTS, IN PART, and DENIES IN PART,  
11 Defendants' motions to dismiss. Pursuant to the Court's Order granting Defendants' motion to  
12 dismiss Rosewolf's claims, with leave to amend, Rosewolf shall file an amended complaint by no  
13 later than November 2, 2022. Defendants shall respond to Rosewolf's amended complaint by no  
14 later than November 23, 2022, and shall respond to the remaining Plaintiffs' complaints by  
15 November 2, 2022.

16 The parties shall appear on December 9, 2022 at 11:00 a.m. for a case management  
17 conference in these cases, and they shall file a joint case management conference statement by  
18 December 2, 2022.

19 **IT IS SO ORDERED.**

20 Dated: October 12, 2022

21   
22 JEFFREY S. WHITE  
23 United States District Judge

24  
25  
26  
27  
28