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IN THE UNITED STATES DISTRICT COURT

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FOR THE DISTRICT OF ARIZONA

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Beatrice Mills,

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CV 11-00968-PHX-FJM

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Plaintiff,

)

**ORDER**

11

vs.

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Bristol-Myers Squibb Co.; Sanofi-Aventis  
U.S. LLC; Sanofi-Aventis U.S. Inc.;  
Sanofi-Synthelabo Inc.,

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Defendants.

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The court has before it plaintiff's motion for leave to file an amended complaint (doc. 30) and defendants' response (doc. 34). Plaintiff did not reply.

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In January 2009, plaintiff was prescribed Clopidogrel (branded as "Plavix") by Dr. Xavier for the treatment of peripheral vascular disease. Plavix is an antiplatelet agent that is designed to prevent blood clots from forming. Between January 7 and January 12, 2009, each day plaintiff ingested one tablet of Plavix along with aspirin pursuant to Dr. Xavier's instructions. On January 12, 2009, plaintiff began bleeding extensively from her rectum. She was brought by ambulance to Mercy Gilbert Medical Center that day. Her bleeding continued, and on January 13, 2009 plaintiff underwent surgery to stop the bleeding. Plaintiff was discharged on January 20, 2009. On January 25, 2009, plaintiff returned to the hospital due to respiratory distress. She was treated for bilateral pulmonary embolism and thrombocytopenia, and was released on January 30, 2009. Plaintiff initiated this action in

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1 the Superior Court of Arizona in Maricopa County and filed a first amended complaint (the  
2 "FAC") on January 19, 2011. Defendants timely removed the action on May 16, 2011. This  
3 court granted defendants' motion to dismiss all counts without prejudice on August 12, 2011  
4 (doc. 25).

5 Plaintiff now moves to file a Second Amended Complaint (the "SAC"). The SAC  
6 asserts six counts: (1) strict products liability (failure to warn); (2) strict products liability  
7 (pursuant to Restatement Second of Torts § 402(a)); (3) negligence; (4) negligent  
8 misrepresentation; (5) breach of express warranty; and (6) breach of implied warranty.  
9 Defendants argue that leave to amend should be denied as futile.

10 Rule 15(a), Fed. R. Civ. P. instructs that leave to amend "shall be freely given when  
11 justice so requires." If amendment would be futile, however, we deny leave to amend.  
12 AmerisourceBergen Corp. v. Dialysist W., Inc., 465 F.3d 946, 951 (9th Cir. 2006). A  
13 proposed amendment is futile if it would be subject to immediate dismissal. Steckman v.  
14 Hart Brewing, Inc., 143 F.3d 1293, 1298 (9th Cir. 1998). The appropriate test to apply when  
15 assessing a proposed amended complaint is the same used to assess the sufficiency of a  
16 pleading under Rule 12(b)(6), Fed. R. Civ. P. Nordyke v. King, 644 F.3d 776, 788 n.12 (9th  
17 Cir. 2011). To do so, we assess whether plaintiff's proposed SAC contains "well-pleaded  
18 factual allegations" that "plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal,  
19 \_\_ U.S. \_\_, \_\_, 129 S.Ct. 1937, 1950 (2009).

20 Plaintiff's allegation of strict products liability is premised on two theories: failure to  
21 warn, and design defect. Plaintiff also premises her negligence claim on these theories. For  
22 plaintiff to prevail under both theories she must show that the product left the defendants'  
23 hands in a defective condition, the defect rendered the product unreasonably dangerous, and  
24 the defect was a proximate cause of plaintiff's injuries. Sw Pet Prods., Inc. v. Koch Indus.,  
25 Inc., 273 F. Supp. 2d. 1041, 1051 (D. Ariz. 2003) (internal citations omitted).

26 Plaintiff alleges that the chemical structure of Plavix is defective because it carries a  
27 higher risk of adverse events for patients who carry the genetic variant CYP, who are poor  
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1 metabolizers of the drug.<sup>1</sup> Plaintiff contends that Plavix is the proximate cause of her injuries  
2 because, "[u]pon information and belief," she is a CYP carrier. SAC at 10. Twombly does  
3 not prevent a plaintiff from pleading facts on information and belief when the information  
4 is either "peculiarly" within a defendant's control or where a belief is based on facts that  
5 make an inference of liability plausible. Arista Records, LLC v. Doe 3, 604 F.3d 110, 120  
6 (2d Cir. 2010); see also Strand v. John C. Lincoln Health Network, Inc., CV-10-02112-PHX-  
7 NVW, 2011 WL 1253408 at \*3 (D. Ariz. Mar. 31, 2011) (applying Arista). This is not a case  
8 where the facts are in the sole possession of the defendants. Plaintiff's genetic makeup is a  
9 fact solely within her control. Tests are available that can reveal whether plaintiff in fact  
10 possesses CYP.<sup>2</sup> See Response, ex. D. Neither does her belief that she carries the CYP  
11 variant make an inference plausible. According to plaintiff, approximately thirty percent of  
12 Caucasians possess the CYP variant. This means that about seventy percent do not.  
13 Plaintiff's claim has not moved from the realm of possible to plausible.

14 Next, plaintiff alleges that Plavix is defective because, when combined with aspirin,  
15 it creates a heightened risk of bleeding complications for patients with peripheral vascular  
16 disease. To support this allegation, plaintiff first cites the Chan study. Plaintiff asserts that  
17 this study found that patients who had previously had stomach ulcers that had healed had  
18 higher incidents of stomach bleeding when they took a combination of Plavix and aspirin.  
19 Plaintiff, however, does not allege that she had a previously healed stomach ulcer when she  
20 took Plavix, and she alleges she experienced rectal, not stomach, bleeding. Thus, the Chan

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21  
22 <sup>1</sup> Plavix works less effectively in people with the CYP variant. This genetic variation  
23 diminishes Plavix's ability to inhibit platelets. In other words, the drug does not prevent  
24 blood clots from forming as well for those with the CYP variation. Higher rates of death  
25 from cardiovascular causes, heart attack, and stroke among CYP carriers using Plavix have  
26 been observed. Jessica L. Mega, M.D., M.P.H., *et al.*, Cytochrome P-450 Polymorphisms  
27 and Response to Clopidogrel, 360 *New Eng. J. Med.* 354 (2009). We may consider  
28 documents referenced in the complaint, like this one, when ruling on a Rule 12(b)(6) motion.  
See Swartz v. KPMG LLP, 476 F.3d 756, 763 (9th Cir. 2007).

<sup>2</sup> We may consider the Plavix label as it is a matter of public record. See Lee v. City  
of Los Angeles, 250 F.3d 668, 689 (9th Cir. 2001).

1 study does not show what may be defective about Plavix. Plaintiff also cites the  
2 CHARISMA study and "subsequent studies" to support her claim that there is a heightened  
3 risk of bleeding complications when patients with her vascular condition ingest Plavix and  
4 aspirin. SAC at 9. Viewing the pleading in the light most favorable to plaintiff, Plavix is  
5 allegedly defective when ingested along with aspirin by people who have peripheral vascular  
6 disease.

7         However, simply pleading a defect is not enough. To prevail on a design defect claim,  
8 a plaintiff must also show that the defective product is unreasonably dangerous. Sw Pet  
9 Prods., 273 F. Supp. 2d at 1051. Although plaintiff's design defect claim is pled pursuant to  
10 Restatement (Second) of Torts § 402(a), this no longer appears to be the correct standard for  
11 design defect claims in Arizona. Although Arizona has not officially adopted the  
12 Restatement (Third) of Torts, it "has demonstrated a willingness to look to [it] as the current  
13 statement of the law." Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 (D. Ariz. 1999). See  
14 Sw Pet Prods., 273 F. Supp. 2d at 1052 n.17 (collecting cases applying the Restatement  
15 (Third) of Torts in Arizona and noting the state's "longstanding policy to look to the  
16 Restatement absent contrary precedent"). Courts in this District apply the Restatement  
17 (Third) of Torts' definition of an unreasonably safe prescription drug or medical device to  
18 Arizona design defect claims. See Gebhardt, 191 F.R.D. at 185; Harrison v. Howmedica  
19 Osteonics Corp., CV-06-0745-PHX-RCB, 2008 WL 906585 at \*21-22 (D. Ariz. Mar. 31,  
20 2008). Section 6(c) of the Restatement (Third) of Torts declares that

21             A prescription drug or medical device is not reasonably safe due to defective  
22 design if the foreseeable risks of harm posed by the drug or medical device are  
23 sufficiently great in relation to its foreseeable therapeutic benefits that  
24 reasonable health-care providers, knowing of such foreseeable risks and  
therapeutic benefits, would not prescribe the drug or medical device for any  
class of patients.

25 Although plaintiff alleges that no reasonable health-care provider would prescribe Plavix  
26 for plaintiff knowing of the risks to "Caucasian patients who carry the genetic variant  
27 allele CYP who are poor metabolizers of Plavix, and who are diagnosed with peripheral  
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1 vascular disease and concomitantly ingest Aspirin," SAC at 24, nowhere does plaintiff  
2 allege that Plavix would not be prescribed for any class of patients. See Restatement  
3 (Third) of Torts: Prod. Liab., § 6, cmt. b ("Under Subsection (c) a drug is defectively  
4 designed only when it provides no net benefit to any class of patients.").

5 We note that even under a traditional risk/benefit analysis used to determine  
6 whether a product is unreasonably dangerous based on the Restatement (Second) of Torts,  
7 plaintiff's pleading does not state a plausible claim. See Dart v. Wiebe Mfg., Inc., 147  
8 Ariz. 242, 245-46, 709 P.2d 876, 879-80 (1985) (listing the risk/benefit factors as 1)  
9 usefulness of the product, 2) availability of safer products to "meet the same need," 3)  
10 "likelihood of injury", 4) obviousness of danger, 5) public expectation of danger, 6)  
11 avoidability of injury through due care, and 7) ability to eliminate danger without  
12 "seriously impairing the usefulness" of the product or making it too expensive). Plaintiff  
13 offers statements including "Plavix was not more efficacious than aspirin" and the risks of  
14 bleeding, colectomy, thrombocytopenia, hypotension, and cardiovascular problems "far  
15 outweigh any potential benefit to patients," SAC at 8, the risk of respiratory disorders "is  
16 greater" than listed on the label, Id. at 12, the risk of "thromboycentica [sic]" is listed on  
17 the label as rare, but this risk is "more frequent," Id. at 13, and "there were practical and  
18 feasible alternative designs that would have prevented and/or significantly reduced the  
19 risk" of plaintiff's injuries and were "economically and technologically feasible." Id. at  
20 31-32. Although detailed factual allegations are not necessary in pleadings, "labels and  
21 conclusions" are insufficient. Bell Atlantic Corp v. Twombly, 550 U.S. 544, 555, 127  
22 S.Ct. 1955, 1965 (2007). In sum, plaintiff has failed to plead that Plavix was defectively  
23 designed.

24 For plaintiff to establish proximate cause on her failure to warn claim, she needs to  
25 show that had a proper warning been given, the injury would not have happened. See  
26 Gosewisch v. Am. Honda Motor Co., Inc., 153 Ariz. 400, 403, 737 P.2d 376, 379 (1987)  
27 (superceded by statute on other grounds); see also Gebhardt, 191 F.R.D. at 184-85  
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1 (granting summary judgment to defendant on failure to warn claim when plaintiff failed  
2 to show that a doctor would not have used a medical device on plaintiff if alternative  
3 warnings were given). Here, plaintiff pleads "on information and belief" that Dr. Xavier  
4 would not have prescribed Plavix had he known of its true risks for patients like plaintiff.  
5 SAC at 24. We noted in our dismissal of the FAC that plaintiff "could have contacted her  
6 physician" to determine facts that were not solely in the control of defendants. Order at 2.  
7 Plaintiff has not done so. In addition, plaintiff's statements regarding the Plavix label's  
8 alleged failure to adequately disclose risks of her injury ignores relevant portions  
9 describing the risks of major bleeding.<sup>3</sup> See Sprewell v. Golden State Warriors, 266 F.3d  
10 979, 988 (9th Cir. 2001) (we need not "accept as true allegations that contradict matters  
11 properly subject to judicial notice or by exhibit"). Thus, plaintiff has not shown that  
12 Plavix was defective due to a failure to warn.

13 Because plaintiff has not pled a plausible strict liability claim, her negligence  
14 claim is insufficient. The breach of implied warranty claim also fails. See Hearn v. R.J.  
15 Reynolds Tobacco Co., 279 F. Supp. 2d 1096, 1103 (D. Ariz. 2003) (theories of strict  
16 liability and breach of implied warranty merge for product liability claims in Arizona).  
17 Similarly, plaintiff's express breach of warranty claim is deficient. As in the FAC, the  
18 SAC pleads conclusory assertions that "[d]efendants made representations to Plaintiff  
19 about the quality or characteristics of P[lavix] by affirmation of fact, promise and/or  
20 description." SAC at 39. We explained in our dismissal of the FAC that plaintiff "must  
21 actually identify what representations were made to her and how they became the basis of  
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23 <sup>3</sup> For example, plaintiff complains that language in the precautions section only  
24 addresses the risk of major bleeding in patients "with recent TIA or stroke who are at high  
25 risk of recurrent ischemic events." SAC at 12 (emphasis deleted). However, directly under  
26 that section, the label contains information about the rate of "major gastrointestinal bleeding"  
27 for patients taking a combination of Plavix and aspirin. See Response, ex. C at 18. Plaintiff's  
28 complaint that the label only warns about bleeding from puncture sites is also contradicted  
by the label, which warns about "an excess in major bleeding in patients receiving Plavix  
plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture  
sites." Id. at 20 (emphasis added).

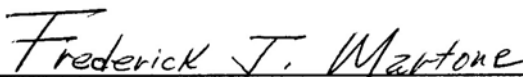
1 the bargain." Order at 4 n.3. Plaintiff has not identified any representations.

2 Finally, plaintiff's negligent misrepresentation fails to satisfy the heightened  
3 pleading requirement of Rule 9(b), Fed. R. Civ. P. Plaintiff alleges that the defendants  
4 "negligently misrepresented material facts" about Plavix to plaintiff, who, along with her  
5 "healthcare providers," "justifiably relied on [d]efendants' misrepresentations." SAC at  
6 38. Plaintiff fails to identify any specific representations that were made, to which of her  
7 healthcare providers these were made, and when they were made. Such general  
8 allegations do not satisfy Rule 9(b), Fed. R. Civ. P.'s requirement to plead with  
9 particularity.

10 Because plaintiff's allegations in the SAC would not withstand a Rule 12(b)(6)  
11 motion to dismiss, amendment would be futile. **IT IS ORDERED DENYING** plaintiff's  
12 motion for leave to amend (doc. 30).

13 The August 26, 2011 Rule 16 scheduling order (doc. 29) noted that no further  
14 motions to amend the complaint would be considered after September 2, 2011.  
15 Therefore, **IT IS ORDERED DISMISSING** this case with prejudice. The clerk shall  
16 enter judgment.  
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18 DATED this 7<sup>th</sup> day of October, 2011.

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22 Frederick J. Martone  
23 United States District Judge  
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