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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

9 Susan Fischer,

10 Plaintiff,

11 v.

12 Bayer Healthcare Pharmaceuticals
13 Incorporated, et al.,

14 Defendants.

No. CV-18-1778-PHX-DGC

ORDER

15 Plaintiff Susan Fischer has filed a motion for leave to file a second amended
16 complaint. Doc. 43. Defendants oppose the motion. Doc. 47. The Court will grant the
17 motion in part and deny it in part.

18 **I. Legal Standard.**

19 The Court “should freely give leave [to amend] when justice so requires.”
20 Fed. R. Civ. P. 15(a)(2). This policy must not only be heeded, *see Foman v. Davis*, 371
21 U.S. 178, 182 (1962), it must be applied with extreme liberality, *see Owens v. Kaiser*
22 *Foundation Health Plan, Inc.*, 244 F.3d 708, 880 (9th Cir.2001). A court may deny leave
23 when it would prejudice the opposing party, produce an undue delay in the litigation, or
24 result in futility for lack of merit. *See Foman*, 371 U.S. at 182.

25 **II. Analysis.**

26 **A. Undue Delay and Prejudice.**

27 The Court does not agree with Defendants’ assertion that the motion to amend is
28 untimely. The motion was filed within the time allowed in the Court’s case management

1 order, and relatively early in the discovery period. Nor does the Court agree that the motion
2 is untimely because it is not based on recently discovered information. Defendants'
3 reliance on *Vicente v. City of Prescott*, No. CV11-08204-PCT-DGC, 2014 WL 1346075,
4 at *1 (D. Ariz. Apr. 3, 2014), is misplaced. *Vicente* concerned a motion to amend filed
5 after the deadline set in the case management order and was governed by Rule 16(b)(4)'s
6 good cause standard, not the liberal amendment standard of Rule 15. *Id.* at 1-2.

7 The Court also disagrees with Defendants' claim that they will be prejudiced by the
8 amendment. Ample time remains for discovery in this case, and the causation issue to be
9 addressed by the Court on an expedited basis likely applies to each of Plaintiff's proposed
10 new claims.

11 **B. Futility.**

12 Defendants argue that several of Plaintiff's proposed causes of action (referred to in
13 this order as "counts") are futile because they fail to state a claim for relief.

14 **1. Count 2 – Design Defect.**

15 Count 2 asserts a claim for strict liability based on design defect. Defendants assert
16 that once a drug is approved by the FDA, the manufacturer is prohibited from making major
17 changes to the drug. Defendants argue that Count 2 asserts that Defendants should have
18 changed their drug after it was approved, and therefore is preempted by federal law.
19 Defendants present a one-paragraph argument that relies on *Yates v. Ortho-McNeil-*
20 *Janssen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015). Doc. 47 at 13. Plaintiff provides an
21 even shorter reply that does not address this preemption issue at all. Doc. 48 at 9.

22 The Court notes that at least one case has declined to follow the holding in *Yates*
23 that all design defect claims against drug manufacturers are preempted. *See Guidry v.*
24 *Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187, 1205 (E.D. La. 2016). *Guidry* agreed with
25 *Yates* that design defect claims based on a failure to change a drug *after* FDA approval are
26 preempted, but held that claims based on a defective design that occurred *before* FDA
27 approval are not preempted. *Id.* at 1205-09. The Court finds this preemption issue far too
28 complex to be decided on the basis of six sentences in Defendants' opposition and four

1 sentences in Plaintiff’s reply. *See* Doc. 47, 48. Given the liberal standard for amendments
2 under Rule 15, the Court will permit Count 2 to proceed. Defendants can present a more
3 detailed preemption argument (addressing *Guidry* and other relevant case law) at the
4 summary judgment stage. If Defendants wish to brief the issue earlier, they may schedule
5 a conference call with the Court to discuss whether earlier briefing is warranted.

6 **2. Count 4 – Breach of Implied Warranty.**

7 Plaintiff concedes that her breach of implied warranty claim is unfounded. Doc. 48
8 at 9. The Court will not grant leave to add Count 4.

9 **3. Count 5 – Breach of Express Warranty.**

10 Defendants claim that Plaintiff has failed to specify when or how an express
11 warranty was communicated to her, and has failed to allege facts showing that the warranty
12 became the basis of the bargain between her and Defendants. Defendants do not claim,
13 and cannot claim, that this count is subject to the heightened pleading standards of
14 Rule 9(b), like some of the claims discussed below.

15 Count 5 alleges that Defendants expressly warranted the safety of their drugs in
16 labels, advertisements, and brochures, and that Plaintiff read and relied on the warranties.
17 Doc. 43-2 at 24. The Court’s task is not to determine the truthfulness of these allegations
18 now, and the Court finds that the allegations satisfy the notice pleading requirements of
19 Rule 8. The Court therefore will permit the addition of this claim. Defendants may attack
20 the factual basis for these allegations in summary judgment briefing, if warranted.

21 **4. Counts 6 and 7 – Negligent Misrepresentation and Fraud.**

22 Rule 9(b) requires a party alleging fraud to “state with particularity the
23 circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). The complaint “must
24 state the time, place, and specific content of the false representations as well as the
25 identities of the parties to the misrepresentation.” *Schreiber Distrib. Co. v. Serv-Well
26 Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986) (citations omitted). The complaint
27 must specify “the who, what, when, where, and how” of the alleged misconduct. *Vess v.
28 Ciba-Geigy Corp.*, 317 F.3d 1097, 1106 (9th Cir. 2003). The same standard applies to

1 claims for negligent misrepresentation. *Gould v. M & I Marshall & Isley Bank*, 860 F.
2 Supp. 2d 985, 988 n. 2 (D. Ariz. 2012).

3 Counts 6 and 7 do not satisfy these heightened pleading requirements, and Plaintiff
4 does not argue otherwise. Doc. 48 at 8-9. The counts fail to identify when, where, or by
5 whom the alleged misrepresentations were made. Doc. 43-2 at 25-31. The motion to
6 amend will not be granted with respect to these counts.

7 **5. Count 8 – Fraud by Suppression or Concealment.**

8 Citing authority, Defendants contend that Arizona does not recognize an action for
9 fraud by omission in the absence of some affirmative duty to disclose. Doc. 47 at 12-13.
10 Defendants argue that Count 8 fails to allege the source of any such duty. Doc. 47 at 12-
11 13. Plaintiff does not address this argument. Doc. 48 at 8. The Court agrees that Count 8
12 fails to identify the source of any duty Defendants had to disclose the facts allegedly
13 omitted, and therefore fails to state a claim with the particularity required by Rule 9(b).
14 The motion to amend will not be permitted with respect to this count.

15 **6. Count 9 – Consumer Fraud.**

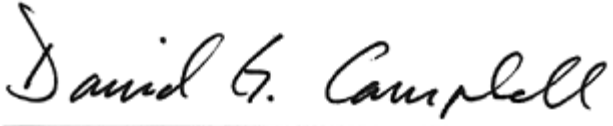
16 “A claim for consumer fraud is subject to Rule 9(b).” *Wilkinson v. Wells Fargo*
17 *Bank, N.A.*, No. CV11-02467-PHX-DGC, 2012 WL 1880610, at *2 (D. Ariz. May 22,
18 2012). Defendants contend that Count 9 fails to plead a claim with particularity under the
19 Arizona consumer fraud statute. Doc. 47 at 11-12. Plaintiff does not respond. Doc. 48.
20 The Court agrees with Defendants. Count 9’s bare-bones allegations do not provide the
21 time, place, and specific content of the false representations that allegedly violated the
22 Arizona statute.

23 **IT IS ORDERED** that Plaintiff’s motion for leave to file a second amended
24 complaint (Doc. 43) is **granted in part and denied in part**. Plaintiff may file the proposed
25 amended complaint without the claims set forth in Counts 4, 6, 7, 8, and 9. Other than
26 deleting these claims, the amended complaint should not be altered from the version
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presented to the Court. Doc. 43-2. The amended complaint shall be filed within 10 days of this order.

Dated this 4th day of February, 2019.



David G. Campbell
Senior United States District Judge