

1 THE HONORABLE JOHN C. COUGHENOUR

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6 UNITED STATES DISTRICT COURT
7 WESTERN DISTRICT OF WASHINGTON
8 AT SEATTLE

9 DAVID DEARINGER and GANNA
10 DEARINGER,

CASE NO. C21-0060-JCC

11 Plaintiffs,

ORDER

12 v.

13 ELI LILLY AND COMPANY ,

14
15 Defendant.

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17 This matter comes before the Court on Defendant Eli Lilly and Company's second
18 motion for summary judgment (Dkt. No. 86) and Plaintiffs' motion for reconsideration (Dkt. No.
19 87). Having thoroughly considered the briefing and the relevant record, and finding oral
20 argument unnecessary, the Court hereby GRANTS Defendant's motion (Dkt. No. 86), DENIES
21 Plaintiffs' motion (Dkt. No. 87), and DISMISSES Plaintiffs' Second Amended Complaint
22 ("SAC") (Dkt. No. 37) with prejudice for the reasons explained below.

23 **I. BACKGROUND**

24 In 2018, Plaintiff David Dearinger suffered an intracranial brain hemorrhage, *i.e.*, a
25 stroke, resulting in the permanent loss of "sensory and motor function of the left side of his
26 body." (Dkt. No. 37 at 2–3.) The SAC states that Defendant's prescription erectile dysfunction

1 drug Cialis was the cause. (*Id.*) Accordingly, it asserts Washington’s Product Liability Act
2 (“WPLA”) claims, along with fraudulent concealment and loss of consortium. (*See generally id.*)

3 On December 18, 2023, the Court granted in part Defendant’s motion for summary
4 judgment, dismissing Plaintiffs’ failure-to-warn claim (Counts 2 and 3) and fraudulent
5 concealment claim (Count 4). (Dkt. No. 84.) However, summary judgment was denied on
6 Plaintiffs WPLA design defect claim (Count 1) and loss of consortium claim (Count 5). (*Id.*)
7 Defendant now moves for summary judgment on those claims. (Dkt. No. 86.) Separately,
8 Plaintiff moves to amend the Court’s order (Dkt. No. 84) dismissing the failure to warn and
9 fraudulent concealment claims. (Dkt. No. 87.)

10 **II. DISCUSSION**

11 **A. Motion for Summary Judgment**

12 “The court shall grant summary judgment if the movant shows that there is no genuine
13 dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R.
14 Civ. P. 56(a). In making such a determination, the Court must view the facts in the light most
15 favorable to the nonmoving party and draw justifiable inferences in that party’s favor. *Anderson*
16 *v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Ultimately, summary judgment is appropriate
17 against a party who “fails to make a showing sufficient to establish the existence of an element
18 essential to that party’s case, and on which that party will bear the burden of proof at trial.”
19 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

20 **B. Federal Preemption**

21 Defendant argues that Plaintiffs’ design defect claim is preempted because federal law
22 forbids Defendant from changing Cialis’s label design without prior Food and Drug
23 Administration (“FDA”) approval. (Dkt. No. 86 at 12.) FDA regulations provide that once a
24 drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making
25 any major changes to the “qualitative or quantitative formulation of the drug product, including
26 inactive ingredients, or in the specifications provided in the approved application.” 21 C.F.R.

1 § 314.70(b)(2)(i).¹ Federal regulation defines three classes of changes: “major changes,”
2 “moderate changes,” and “minor changes.” 21 C.F.R. § 314.70(b)–(d). Major changes “include,
3 but are not limited to[,] . . . changes in the qualitative or quantitative *formulation* of the drug
4 product.” *Id.* § 314.70(b)(2)(i) (emphasis added.)

5 Here, it is uncontroverted that Cialis is an FDA-approved prescription medication which,
6 under federal law, Defendant is prohibited from altering its formulation without prior FDA
7 approval. Based on the plain meaning of the regulation, Defendant could not alter the medication
8 without submission to the FDA for “approval *prior* to distribution of the product made using the
9 change.” *See id.* (emphasis added). Consequently, to the extent Plaintiffs’ design defect claim is
10 based on Cialis’s formulation, it is preempted. *See Yates v. Ortho-McNeil Pharm., Inc.*, 808 F.3d
11 281, 296–300 (6th Cir. 2015) (“[T]o the extent Yates argues that defendants should have altered
12 the formulation of ORTHO EVRA® after the FDA had approved the patch, we find this claim
13 clearly preempted.”) Accordingly, all that remains of Plaintiffs’ defective design claim is a claim
14 sounding in defective *labeling*.

15 C. Defective Labeling under the WPLA

16 Defendant now seeks summary judgment on the remainder of Plaintiffs’ WPLA claim for
17 defective labeling, arguing that, without any evidence supporting proximate cause, the claim fails
18 as a matter of law. (*See* Dkt. No. 86 at 6–18.)²

19 Under Washington law, “[i]n a products liability suit alleging inadequate warnings, the
20 plaintiff must show that his or her injury was *proximately caused* by a product that was not

21 ¹ Moderate changes must be reported to the FDA “at least 30 days *prior to* distribution of
22 the drug product made using the change.” *Id.* § 314.70(c) (emphasis added). Minor changes need
23 only be reported in an annual report to the FDA. *Id.* § 314.70(d)(3). Major changes require
24 FDA’s “approval prior to distribution of the product made using the change.” *Id.* § 314.70(b).

25 ² Defendant also argues that Plaintiffs’ design defect claim is barred under comment k to
26 section 402A of the Restatement (Second) of Torts. (*Id.* at 14–15.) But that is not so. By the
comment’s express terms, proper preparation, marketing, and warnings are *prerequisites* to a
manufacturer being able to qualify for immunity from strict liability. *See Taylor v. Intuitive
Surgical, Inc.*, 389 P.3d 517, 528 (2017).

1 reasonably safe because adequate warnings or instructions were not provided.” *Ayers By &*
2 *Through Ayers v. Johnson & Johnson Baby Prod. Co., a Subsidiary of Johnson & Johnson Co.*,
3 818 P.2d 1337, 1339 (1991) (emphasis added) (citations omitted). To establish proximate
4 causation, the plaintiff must show both cause in fact and legal causation. *Id.* (citation omitted).
5 “Cause in fact refers to the actual connection between the act and an injury—but for the act, the
6 injury would not have occurred.” *Sherman v. Pfizer, Inc.*, 8 Wash. App.2d 686, 687 (2019). A
7 warnings-based design defect claim requires proof that a different warning would have caused a
8 different outcome. *See Rodman v. Ethicon, Inc.*, 2021 WL 2434521, slip op. at 5 (W.D. Wash.
9 2021) (proximate cause requires proof that a different warning would have “avoided the harm.”).

10 According to Plaintiffs, the Cialis dose at issue was, in fact, prescribed by Dr. Bardin.
11 (Dkt. Nos. 60-5 at 6–7, 60-7 at 8.) And Dr. Bardin testified that (a) he was aware of Cialis’s risk
12 of hemorrhagic strokes and (b) even if he had received a stronger warning of the risk(s), such as
13 the one which Plaintiffs later suggest is adequate, Dr. Bardin would not have “changed [his]
14 decision to prescribe Cialis [to Mr. Dearing].” (Dkt. Nos. 60-1 at 17, 26, 27, 60-7 at 15.)
15 Plaintiffs fail to provide any evidence rebutting this testimony.

16 Accordingly, the Court finds that Plaintiffs fail to establish a genuine issue of fact on the
17 issue of proximate cause. And without this, Plaintiffs cannot proceed to trial on these claims.
18 Accordingly, summary judgment is GRANTED.

19 **D. Loss of Consortium**

20 As Plaintiffs’ predicate causes of action are dismissed, their loss-of-consortium claim *a*
21 *fortiori* fails, because such claims cannot independently stand. *See Carter v. Ethicon Inc.*, 2021
22 WL 1893749, slip op. at 3 (W.D. Wash. 2021) (dismissing loss-of-consortium claim because all
23 of plaintiff’s statutory claims were dismissed).

24 Accordingly, Plaintiffs’ loss of consortium claim is DISMISSED.
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1 **E. Motion for Reconsideration**

2 Plaintiffs’ motion for reconsideration (Dkt. No. 87) is premised on a *new* factual
3 allegation that Dr. Horst was “the actual prescriber” of the Cialis, not Dr. Bardin. (*Id.* at 2–7.)
4 But this flies in the face of Plaintiffs’ earlier sworn testimony to the contrary. (Dkt. Nos. 60-5 at
5 6–7, 60-7 at 8) (stating that Dr. Bardin prescribed the Cialis). “A party cannot create an issue of
6 fact by an affidavit contradicting his prior deposition testimony.” *Kennedy v. Allied Mut. Ins.*
7 *Co.*, 952 F.2d 262, 266 (9th Cir. 1991). Accordingly, the Court will not permit contradictory
8 testimony from creating an issue of fact sufficient to survive summary judgment. *Russell v. Pac.*
9 *Motor Trucking Co.*, 672 F. App’x 629, 630 (9th Cir. 2016) (“The district court did not abuse its
10 discretion in disregarding those portions of the affidavit that directly contradicted [plaintiff’s]
11 former deposition testimony.”)

12 Plaintiffs’ motion for reconsideration (Dkt. No. 87) is therefore DENIED.

13 **III. CONCLUSION**

14 For the foregoing reasons, Defendant’s motion for summary judgment (Dkt. No. 86) is
15 GRANTED and Plaintiffs’ motion for reconsideration (Dkt. No. 87) is DENIED. The Court
16 DISMISSES Plaintiffs’ complaint (Dkt. No. 37) with prejudice.

17 DATED this 5th day of February 2024.

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21 John C. Coughenour
22 UNITED STATES DISTRICT JUDGE