UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ERIN HEXUM AND NICK HEXUM,

Plaintiffs,

v.

ELI LILLY AND COMPANY, an Indiana Corporation,

Defendant.

CASE NO. 2:13-cv-02701-SVW-MAN

ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW AND JUDGMENT THEREON

I. INTRODUCTION

This products liability action arises from plaintiff Erin Hexum ("Hexum") alleged "discontinuation" symptoms upon ceasing to take Cymbalta—defendant Eli Lilly and Company's ("Lilly") serotonin norepinephrine reuptake inhibitor ("SNRI"). Hexum and her husband, plaintiff Nick Hexum ("Nick"), allege that Lilly failed to adequately warn of the risk and severity of discontinuation side effects upon discontinuing Cymbalta. In the First Amended Complaint ("FAC"), Hexum asserts claims for: (1) negligence[1]; (2) strict product

[1] Plaintiff's negligence claim includes several negligent failure-to-warn and negligent misrepresentation theories. At the pretrial conference held on August 10, 2015, Plaintiffs indicated that they are not pursuing their design defect theory. (Dkt. 344.)

liability—failure to warn; (3) negligent misrepresentation; and (4) fraud.

On August 11, 2015, the Court held the first day of a jury trial. On August 12, 2015, Plaintiffs finished presenting their case in chief. After Plaintiffs rested their case, Lilly orally moved for judgment as a matter of law. For the reasons discussed below, the Court GRANTS Lilly's motion and ENTERS JUDGMENT in Lilly's favor on all of Plaintiffs' claims.

II. STATEMENT OF FACTS[2]

A. Cymbalta's Background

The Cymbalta label that was in effect in February 2012 cited the risk of discontinuation symptoms in three sections—"Highlights of Prescribing Information," "Dosage and Administration," and "Warnings and Precautions." (Tr. Ex. 398.) The 2011 label included the following language in the "Highlights" section:

> **DOSAGE AND ADMINISTRATION**
> . . .
> Discontinuing Cymbalta: A gradual dose reduction is recommended to avoid discontinuation symptoms. (5.7)
> . . .
> **WARNINGS AND PRECAUTIONS**
> . . .
> Discontinuation: May result in symptoms, including dizziness, nausea, headache, paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis (5.7)

(Trial Ex. 398.) The 2011 Cymbalta label also included the following language in the "Dosage and Administration" section:

> Symptoms associated with discontinuation of Cymbalta and other SSRIs and SNRIs have been reported. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible (*see Warnings and Precautions (5.7)).*

(Trial Ex. 398.)

The 2011 Cymbalta label also included the following language in the "Warnings and Precautions" section:

> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients

[2] The Court used an unofficial version of the trial transcript for reference. The statements quoted and cited herein are consistent with the Court's recollection.

> compared to those discontinuing from placebo: dizziness, nausea, headache paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate. *[see Dosage and Administration (2.4)]*.

(Trial Ex. 398.)

Though Cymbalta's label recommends tapering, it does not provide specific parameters—such as timeframe or dosage increments— for designing an appropriate taper regime. (Trial Ex. 398.) The label also states that Cymbalta "should be swallowed whole and should not be chewed or crushed, nor should the capsule be opened and its contents be sprinkled on food or mixed with liquids." (Trial Ex. 398.)

B. Hexum's Diagnosis and Use of Cymbalta

In February of 2012 Dr. Sean Wollaston ("Wollaston"), a rheumatologist, diagnosed Hexum with fibromyalgia. (Aug. 12, 2015 A.M. Tr. ("Day 2 A.M. Tr.") 52:22–25; 55:11–56:15; 78:14–79:24; Trial Ex. 788.) According to Wollaston, fibromyalgia is a "diffuse musculoskeletal pain syndrome, a syndrom that causes . . . widespread diffuse pain, typically all over one's body.") (Day 2 A.M. Tr. 56:19–22.) Wollaston further described fibromyalgia as a condition that "can be a very disabling, difficult-to-treat condition." (*Id.* at 56:23–24.) Hexum was referred to Wollaston by another physician. (*Id.* at 56:8–9.) According to Hexum, her symptoms in early 2012 included being "really tired"—regardless of how much she slept she "didn't ever feel restored or refreshed," (*Id.* at 108:5–18.); tinging in her joints; and joint pain. (*Id.* at 108:16–22.)

1. Wollaston's Prescribing Practices and Knowledge of Cymbalta

Wollaston had prescribed Cymbalta for other fibromyalgia patients before Hexum. (*Id.* at 78:6–9.) Cymbalta was near the top of Wollaston's list "in terms of choosing a medicine for fibromyalgia." (*Id.* at 78:10–12.) Wollaston testified that alternative options for a patient such as Hexum with fibromyalgia include other drugs in the same class as Cymbalta (such as Effexor, Pristique, or Savella), anticonvulsant drugs (such as gabapentin, Lyrica, or Topamax), and antidepressants in different classes than Cymbalta (such as Prozac, Paxil, Zoloft, amitriptyline, and nortriptiline). (*Id.* at 64:21–65:5.) However, he stated that SNRIs (such as Cymbalta) are believed to work better for pain than the SSRI class. (*Id.* at 75:10–24.) He further testified that all SNRIs and SSRIs carry some degree of "discontinuation risk." (*Id.* at 76:4–6.) When asked if he could compare the discontinuation risks or other risks attendant to Lyrica, Cymbalta, and Savella, Wollaston stated that he could not; he also stated that he had no basis to say it is higher on Cymbalta than the other two. (*Id.* at 77:8–18.) Wollaston also acknowledged that there are nonprescription medication treatments for fibromyalgia, including physical therapy, exercise, and improvement on the quality of sleep. (*Id.* at 65:7–21.) According to Wollaston he has "[s]ometimes" had success with nonprescription alternatives to treating fibromyalgia. (*Id.* at 65:22-24.)

Wollaston testified that his prescription process is a joint decision-making process with the patient. (*Id.* at 54:16–19.) Generally, once Wollaston diagnoses a patient, he discusses "option for potential treatment or not treatment. If we decide on a particular treatment that I would suggest or multiple drugs as options, then typically we would discuss potential benefits, timeline to benefits, as well [as] common side-effects of that drug." (*Id.* at 55:2–7.) Wollaston testified that if he discloses the risks to a patient and the patient is resistant to the medication, then he never forces the medication on the patient. (*Id.* at 55:8–11.)

Wollaston said that when he prescribes a medicine he does what he feels is appropriate to education himself about the medicine he is prescribing. (*Id.* at 84:14–17.) One of the sources that Wollaston uses to educate himself about medications is *Up To Date*—which he described as a "common source for information that [he] would use as a medical text." (*Id.* at 61:19–25.) Wollaston testified that he likely reviewed the *Up to Date* publication on Cymbalta "[m]aybe in

the day before but at some point prior" to prescribing Cymbalta to Hexum. (*Id.* at 85:6–18.) Wollaston acknowledged that he understands that *Up to Date* is not a copy of the package insert. (*Id.* at 81:7–16.) He also admitted that *Up to Date* is not Lilly's warning. (*Id.* at 81:17–18.)

Wollaston also testified as follows:

> Q: You don't typically read the package inserts for the drugs that you prescribe, correct?
>
> A: I don't read the package inserts cover to cover certainly.
>
> Q: Do you have a specific recollection of ever reviewing a package insert [label] for Cymbalta?
>
> A: I don't have a specific recollection on that, no.
>
> Q: And you have no independent recollection of having reviewed it prior to prescribing Cymbalta to Ms. Hexum in 2012.
>
> A: I don't recall that, no.
>
> . . .
>
> Q: Did you see the one percent language in your deposition?
>
> A: In my deposition?
>
> Q: Yes. Was it pointed out you [*sic*] to?
>
> A: I believe so.
>
> Q: Can you tell me with certainly [*sic*] whether you saw it before that point in time, given your testimony on reviewing labels?
>
> A: No.

(*Id.* at 90:13–91:12.)

Wollaston also said it was "pretty common" in 2012 for him to meet with drug companies' sales representatives in his office. (*Id.* at 59:10–17.) According to Wollaston, the purpose of these visits was that the "sales rep was trying to present the pros of their drug for us to utilize, as well as enlightening us on any changes to the package insert, any adverse affects [*sic*] associated with the drug. Typically they bring a sample of the drug." (*Id.* at 59:16–22.) Wollaston further testified that "[f]rom time to time" he "[had] occasion to meet with sales reps from Eli Lilly and Company" specifically regarding Cymbalta. (*Id.* at 59:23–60:2.) Wollaston further testified:

> Q: When you met with sales reps from Eli Lilly and Company, did they

> bring, as you said, samples and sometimes package inserts?
>
> A: They certainly brought samples. When they bring samples, they—I believe they are required to bring package inserts with that.
>
> Q: When sales reps would come into your office, would you keep—did you have a practice of keeping track of any revisions or updates to the package insert by way of the materials that they brought you?
>
> A: We had no procedures for that, no.
>
> Q: Okay. But you personally?
>
> A: If they brought something to my attention and said there was a change in the package insert, they would usually give it to me, and I would read it.
> . . .
>
> Q: . . . If at any point in time you had been alerted by a sales rep as to a revision to the product label in the package insert, would that have prompted any further investigation on your part?
>
> A; It would depend on what the change was. Certainly, I would look at whatever they presented, and if I felt that more information from that was needed, then I would look further.

(*Id.* at 60:3–61:10.)

Wollaston admitted that he doesn't remember any specific discussions with sales representative prior to February 2012 about Cymbalta and the discontinuation risk. (*Id.* at 85:19–22.) When asked if he knows if that ever happened, Wollaston responded that he doesn't recall. (*Id.* at 85:23–24.) Finally, Wollaston testified that he would not rely on sales representatives to "do [his] education for [him]" about the medicines he prescribes. (*Id.* at 84:18–20.)

2. Hexum's Initiation on Cymbalta

Wollaston testified that he "discussed potential treatment options [with Hexum] and agreed to start her on Cymbalta." (*Id.* at 56:15–16.) At the time he initiated Hexum's Cymbalta treatment in February 2012, Wollaston understood that Hexum only intended to take Cymbalta temporarily because she wanted to have another baby and would stop Cymbalta before becoming pregnant. (*Id.* at 58:19–59:5.) According to Hexum, she started taking Cymbalta with the expectation that she and her husband would likely want to have another child "in the reasoanbly near future[.]" (Aug. 12, 2015 P.M. Tr. ("Day 2 P.M. Tr.") 20:25–21:4.) Hexum testified that Wollaston "told [her] not to quit it cold turkey, that [they] would taper when [she] needed to

come down. He knew [she] wanted to have more kids. It didn't seem like it would be a big deal to come off of it." (Day 2 A.M. Tr. 109:4–16.) When asked what Wollaston "[said] about discontinuation[,]" Hexum said she "[doesn't] really remember. [She] think it was two weeks. [She] couldn't tell you the exact conversation, but it was at some point we would go off and [*sic*] be a taper period, and it would be over." (*Id.* at 110:2–6.) She also said that Wollaston told her that discontinuing off of Cymbalta would not be difficult unless she "quit cold turkey." (*Id.* at 110:7–9.)

Hexum testified that she read Cymbalta's label prior to taking the drug. (*Id.* at 110:18–111:4.) When asked what she remembers about reading the Cymbalta label "at this time" (presumably when Wollaston first prescribed it), Hexum testified that "the one percent sticks out from—I remember not thinking there was any more than a two percent chance that I was going to have a withdrawal, and that seemed very low to me, almost inconsequentially low." (*Id.* at 111:4–7.) When asked if she read the whole label, Hexum testified that she "think[s] so. It was very long." (Day 2 P.M. Tr. 22:8–10.) She further testified that she remembers reading in the label that: (1) there was a "possibility that if [she] discontinued the medicine that [she] might experience intolerable symptoms[,] (*Id.* at 23:2–5); (2) she would need to be monitored when discontinuing Cymbalta; and (3) that if she experienced intolerable symptoms she might need to go back on her dosage and then slowly come back down. (*Id.* at 22:23–23:12.) She also testified that she understood there was "a possibility that [she] might experience any of the symptoms that were described in the label[.]" (*Id.* at 23:13–18.)

Wollaston testified that, as is typical for fibromyalgia, he started Hexum at 30 milligrams per day for a week or two and then increased her to 60 milligrams per day. (Day 2 A.M. Tr. 57:6–10.) Hexum testified that during her visit with Wollaston, she received both a prescription for Cymbalta and a large bag of 30 milligram samples. (*Id.* at 112:8–14.) Wollaston acknowledged that in February 2012 it would have been common for him to initiate a prescription for a drug like Cymbalta by giving the patient samples. (*Id.* at 66:2–5.)

3. Hexum's Use of and Discontinuation from Cymbalta

Hexum took Cymbalta for roughly a year. (*Id.* at 113:23–24.) She testified that her

fibromyalgia symptoms improved while taking Cymbalta. (*Id.* at 113:20–22.) Around the end of 2012, Hexum began seeing a different rheumatologist, Dr. Ben-Artzi ("Ben-Artzi) because she moved further away from Wollaston's office. (*Id.* at 113:25–114:13.) Ben-Artzi also referred Hexum to Ms. Jeanne Melvin ("Melvin"), a sleep therapist. (*Id* at 114:14–115:21.)

Around the middle or end of January 2013, Hexum began to discuss coming off of Cymbalta. (*Id.* at 116:8–117:10; 119:3–5.) Hexum testified that Ben-Artzi told her to decrease from 60 milligrams to 30 milligrams and then to completely cease taking Cymbalta. (*Id.* at 117:14–118:2.) Hexum does not recall with certainty the date on which she began tapering off of Cymbalta. (Day 2 P.M. Tr. 29: 10–12.) While Hexum testified that she was told to taper Cymbalta over two weeks, she admitted that she isn't certain that she was instructed to taper over two weeks rather than another time period. (*Id.* at 29:13–19.) She testified that the transition from 60 milligrams to 30 milligrams was relatively uneventful. (*Id.* at 34:13–18.) However, according to Hexum, when she completely ceased taking Cymbalta around February 10, 2013, she developed a host of symptoms—including anxiety, numbness, tingling, involuntary muscle jerks, small electric jolts, brain zaps, and vomiting**.** (*Id.* at 8:3–11:23.) She also asserted that she had symptoms that she believed were a seizure—which led her husband to bring her to the emergency room. (*Id.* at 12:13–13:16.) Hexum admitted that at some point she started opening Cymbalta capsules and taking out half the pellets to create a smaller dose for herself. (*Id.* at 29:20–30:5; 33:5–34:5.) She testified that she didn't remember if Ben-Artzi or Melvin advised her to open the Cymbalta capsules in this manner. (*Id.* at 34:2–12.)

Hexum eventually successfully discontinued Cymbalta. (*Id.* at 18:11–13.) She asserts that today she no longer takes Cymbalta or any other drugs for fibromyalgia. (*Id.* at 18:11–19:16.) Hexum testified that she hasn't had fibromyalgia symptoms since starting "the alternative treatment and devot[ing] [herself] to that full time." (*Id.* at 18:15–18.) According to Hexum, "it's been the best [she's] ever—[she's] felt since [she's] been diagnosed with fibromyalgia." (*Id.* at 19:7–9.) She also testified that after discontinuing Cymbalta she had the baby that she wanted. (*Id.* at 19:10–14.)

III. PROCEDURAL HISTORY

At the close of Plaintiffs' case in chief, Lilly moved for a directed verdict. Lilly argued that Plaintiffs failed to show causation because: (1) Wollaston didn't read the label, (2) Plaintiffs failed to show that Wollaston wouldn't have prescribed the drug if given a stronger warning, and (3) that if given a stronger warning, Wollaston would have transmitted it to Hexum and that if that warning was transmitted she would not have taken the drug. (*Id.* at 39:11–46:6.) Plaintiffs responded in argument that while the transcript was not yet available, they believed that the record would show that the sales representatives who brought Cymbalta samples kept Wollaston up to date on the product labeling. (*Id.* at 50:19–25.) Plaintiffs also argued that Wollaston testified regarding whether he had a clear recollection of specifically reading the label, and never said he didn't read the label. (*Id.* at 51:1–5.)

In response to the Court's question, Plaintiffs confirmed that they had presented all relevant evidence they though was necessary. (*Id.* at 54:9–11.) The Court then raised the issue that there might be an absence of necessary evidence concerning whether Ben-Artzi read the label. (*Id.* at 54:12–22.) Plaintiffs asserted that Ben-Artzi's testimony was not necessary to their case. (*Id.* at 55:3–9.) According to Plaintiffs, they had established "proper evidence" that if Lilly gave a stronger warning, Hexum wouldn't have taken the drug, and so she would never have needed to taper off of it. (*Id.* at 55:8–12.) Instead, the reason why Lilly intended to call Ben-Artzi was because he might be relevant to mitigation or comparative fault—defenses on which Lilly bears the burden of proof. (*Id.* at 55:13–17.) After further argument, the Court recessed to examine the transcript before reconvening on the following day. (*Id.* at 57:22–58:4.)

When the Court reconvened, the Court gave both sides an opportunity to add to their arguments regarding the motion for directed verdict. (Aug. 13 2015 A.M. Tr. ("Day 3A.M. Tr.") 3:6–13.) Lilly stated that the only thing it would add is "what's in the transcript"; the Court responded that it had considered that. (*Id.* at 3:14–16.) Plaintiffs stated that they had no further arguments. (*Id.* at 3:17.)

IV. LEGAL STANDARD

Federal Rule of Civil Procedure 50(a) provides that:

> If a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary

basis to find for the party on that issue, the court may:

> (A) resolve the issue against the party; and
>
> (B) grant a motion for judgment as a matter of law against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.

Fed. R. Civ. P. 50(a)(1). A party may move for judgment as a matter of law "at any time before the case is submitted to the jury." Fed. R. Civ. P. 50(a)(2).

A court may grant the motion if it finds that no reasonable jury would have a legally sufficient evidentiary basis to find for the party on that issue. Fed. R. Civ. P. 50(a)(1). "In entertaining a motion for judgment as a matter of law, the court may not make credibility determinations or weigh the evidence." *Go Daddy*, 581 F.3d at 961 (internal citations, quotation marks, and alterations omitted). Rather, "the court must draw all reasonable evidentiary inferences in favor of the non-moving party." *Ritchie v. United States*, 451 F.3d 1019, 1022 -1023 (9th Cir. 2006). *See also Go Daddy*, 581 F.3d at 961 (quoting *Josephs v. Pac. Bell*, 443 F.3d. 1050, 1062 (9th Cir. 2006) (stating that on a Rule 50 motion, "[t]he test applied is whether the evidence permits only one reasonable conclusion"); *Graves v. City of Coeur D'Alene*, 339 F.3d 828, 838 (9th Cir. 2003) (same), *abrogated on other grounds by Hiibel v. Sixth Judicial Dist. Court*, 542 U.S. 177 (2004). An inference is reasonable "when it may be drawn from the evidence without resort to speculation[.]" *Lakeside-Scott v. Multnomah Cnty.*, 556 F.3d 797, 802 (9th Cir. 2009) (quoting *Genthe v. Lincoln*, 383 F.3d 713, 716 (8th Cir.2004)). "[A] reasonable inference cannot be supported by only threadbare conclusory statements instead of significant probative evidence." *Id.* (quoting *Barnes v. Arden Mayfair, Inc.*, 759 F.2d 676, 680–81 (9th Cir.1985)) (internal quotation marks omitted).

V. DISCUSSION

Plaintiffs assert claims for negligence, strict liability—failure to warn, fraud, and negligent misrepresentation. For each of these claims, Plaintiffs bear the burden of proving causation—in this context by proving that the alleged inadequacy of Lilly's Cymbalta warning caused Plaintiffs' injury. *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990–91 (C.D. Cal. 2001)

[hereinafter "*Motus I*"], *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004) [hereinafter "*Motus II*"]; *Thomas v. Abbott Labs.*, No. CV-12-07005-MWF CWX, 2014 WL 4197494, at *5 (C.D. Cal. July 29, 2014).[3] Because California follows the learned intermediary doctrine, Lilly's duty to warn "runs to the physician, not to the patient." *Motus I*, 196 F. Supp. 2d at 990 (*Superior Court of Sutter County*, 13 Cal.4th 1104, 1116 (1996)). Thus, Plaintiffs must prove that stronger warnings would have "altered the conduct of the prescribing physician." *Motus II*, 358 F.3d at 661 ("[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.").

Plaintiffs attempt to show causation as follows: (1) if Lilly gave Wollaston stronger warnings then Wollaston would have conveyed that information to Hexum; (2) if Hexum received the stronger warnings, then she would have told Wollaston to prescribe something other than Cymbalta; and (3) because Wollaston doesn't force patients to take drugs he would have prescribed something other than Cymbalta. Thus, Plaintiffs argue that if Lilly gave Wollaston stronger warnings (which were allegedly required) then Hexum would never have taken Cymbalta. Plaintiffs' proof of this causal chain fails at virtually every link.

A. Whether Wollaston Read the Label

Plaintiff asserts that she was harmed because, but for Cymbalta's inadequate warning she would not have taken Cymbalta, and had she never taken Cymbalta she would not have discontinued Cymbalta and thus would not have experienced her alleged discontinuation symptoms. Plaintiff bears the burden of proving that stronger warnings would have altered her prescribing doctor's conduct. *Motus II*, 358 F.3d at 661 (affirming grant of summary judgment to defendant where plaintiff failed to establish proof that stronger warnings would have changed the plaintiff's decedent's medical treatment or averted his suicide). Logically, to satisfy this burden Hexum must first prove that Wollaston read Cymbalta's label before prescribing Cymbalta to Hexum—if Wollaston didn't read Cymbalta's label before prescribing it to her, then

[3] *See also* CACI Nos. 1205, 1222, 1900, 1903.

stronger warnings in Cymbalta's label could not have altered his prescribing conduct.[4]

On this record, Hexum fails to offer sufficient proof that Wollaston read Cymbalta's label before prescribing Cymbalta to Hexum. As discussed above, Wollaston said that when he prescribes a medicine, he does what he feels is appropriate to educate himself about it. Wollaston did not testify that he generally feels it appropriate to educate himself about the drugs he prescribes by reading their label. When asked, "[y]ou don't typically read the package inserts for the drugs that you prescribe, correct[,]" Wollaston replied that "[he doesn't read the package inserts [another name for the label] cover to cover certainly." (Day 2 A.M. Tr. 90:10–12.) Notably, Wollaston did not state that it was incorrect to say that he doesn't typically read the labels for drugs he prescribes. He further testified that he doesn't recall having reviewed Cymbalta's label prior to prescribing Cymbalta to Hexum in 2012, has no specific recollection of ever reviewing Cymbalta's label, and can't say with certainty whether he saw the one percent language prior to being deposed in this case. In fact, the only source that Wollaston testified that he likely reviewed prior to prescribing Cymbalta to Hexum was *Up to Date*—which he acknowledges is neither a copy of the Cymbalta label nor Lilly's warning.

Wollaston further testified that he is aware that all SNRIs and SSRIs carry at least some discontinuation risk and that this knowledge is why he recommends tapering as a general matter. (*Id.* at 76:5–10.) Hexum testified that she doesn't remember the exact conversation she had with Wollaston about discontinuation, just that she would need to taper and not quit cold turkey.

Hexum testified that during the visit when Wollaston initiated her on Cymbalta, she

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[4] The Court notes that the Eighth Circuit, applying Minnesota law, has found that the doctor's failure to read a warning does not necessarily bar recovery. *In re Levaquin Products Liab. Litig.*, 700 F.3d 1161, 1168 (8th Cir. 2012); *see also Winter v. Novartis Pharm. Corp.*, 739 F.3d 405, 409 (8th Cir. 2014) (citing *In re Levaquin Products Liability Litigation* and applying Missouri law). However, these cases are inapt because both Minnesota and Missouri apply a rebuttable heeding presumption—a presumption that an adequate warning, if given will be read and heeded. *See In re Lavaquin*, 700 F.3d at 1168; *Winter*, 739 F.3d at 408 (presumption under Missouri law that an adeqate warning, if given, will be heeded); *Johnson v. Medtronic*, Inc., 365 S.W.3d 226, 232 (Mo. Ct. App. 2012) (presumption under Missouri law that an adequate warning will be read and heeded). Where it applies, the rebuttable heeding presumption shifts the burden to the defendant to show that an adequate warning would *not* have affected the prescribing doctor's conduct in prescribing the drug. *Motus I*, 196 F. Supp. 2d at 991. In contrast, California has not adopted a rebuttable presumption. *Id.* at 992–95. Thus, the Eighth Circuit cases recognizing that a doctor's failure to read a warning does not necessarily bar recovery are inapt to Plaintiffs' California law claims.

received a large bag of samples. Wollaston testified that it was "pretty common" in 2012 for him to meet with drug companies' sales representatives, and that "from time to time" he met with Lilly's sales representatives about Cymbalta. Without tying his testimony to Cymbalta, Wollaston said that when he met with Lilly's sales representatives they brought him samples, and that the sales representatives are required to bring labels with the samples. Wollaston did not testify that sales representatives were his only source of Cymbalta samples. He also testified that if the sales representatives brought something to his attention and said that there was a change in the label, then they would usually give it to him and he would read it. However, Wollaston did not have a practice of keeping track of any revisions or updates to the label by way of the materials that they brought him. Moreover, Wollaston conceded that he doesn't remember any specific discussions with sales representatives before February 2012 about Cymbalta and its discontinuation risk. Wollaston further admitted that he doesn't recall if that ever happened. Finally, when Wollaston testified about educating himself about the drugs that he prescribes, he conceded that he would not rely on sales representatives to "do [his] education for him[.]" (*Id.* at 84:12–21.)

On this record, there is no proof beyond speculation that Wollaston read Cymbalta's label before prescribing it to Hexum. He conceded that he has no recollection of having read it in the relevant time period and, at the very least, he typically doesn't read the a drug's entire label before prescribing it. Wollaston does not remember specifically what he told Hexum about Cymbalta's discontinuation risk when he initiated her on Cymbalta. (*Id.* at 64:3–10.) Additionally, Hexum testified that she doesn't recall the exact conversation she had with Wollaston. The only thing Hexum remembered from her conversation with Wollaston about discontinuing Cymbalta was that he told her not to quit cold turkey—which Wollaston testified was his general practice. Neither Wollaston nor Hexum testified to any aspect of their discussion prior to Hexum beginning Cymbalta which was sufficiently connected to Cymbalta's label (rather than Wollaston's general knowledge of SNRIs) to support an inference that Wollaston saw the label during the relevant time period.

Plaintiffs' evidence that Wollaston had Cymbalta samples in his office at the time that

Hexum initiated Cymbalta, along with Wollaston's testimony that he had received samples from Lilly's sales representatives (which must be given with the drug label), could raise an inference that Wollaston had spoken to Lilly's sales representatives at some point prior to initiating Hexum on Cymbalta. Wollaston also testified generally that the purpose of drug companies' sales representatives coming to his office was to tout the drugs' benefits and to enlighten them about "any changes to the package insert, any adverse affects associated with the drug." (*Id.* at 59:18–24.) Wollaston also testified that *if* the sales representatives brought something to his attention and said there was a change to the label, "they would usually give it to me, and I would read it." (*Id.* at 60:17–19.) Nevertheless, Wollaston doesn't remember having ever spoken to a sales representative about Cymbalta's discontinuation risk prior to February 2012.

To conclude, based on this evidence, that Wollaston saw Cymbalta's label prior to February 2012, a jury would have to assume: (1) because Wollaston had Cymbalta samples when he prescribed Cymbalta to Hexum, he must have obtained those samples from a Lilly sales representative and not some other source; (2) Wollaston must have met with a Lilly sales representative before prescribing Cymbalta to Hexum; (3) when Wollaston received the samples he must have received Cymbalta labels; (4) that when Wollaston met with the Lilly sales representative, the sales representative pointed out a change in Cymbalta's label; (5) that when the Lilly sales representative point out the change in Cymbalta's label, that sales representative followed the "usual" practice and gave Wollaston a copy of it; and (6) that Wollaston then read the Cymbalta label. This long chain of assumptions is presented against Wollaston's conceded inability to remember having any contact with the Cymbalta label or any discussions with Lilly's sales representatives about Cymbalta's discontinuation risk prior to prescribing Cymbalta to Hexum in February 2012. On this record, the only basis for a jury to find that Wollaston read Cymbalta's label prior to prescribing Cymbalta to Hexum is speculation. Thus, on this record, it is unreasonable to infer that Wollaston saw the Cymbalta label prior to prescribing it to Hexum.

Similarly, for the reasons described above and in light of Plaintiffs failure to offer any evidence about what Lilly's sales representatives discussed with Wollaston, it is unreasonable to infer that Lilly's sales representatives discussed Cymbalta's discontinuation risk prior to

February 2012. Moreover, Wollaston himself admitted that he doesn't rely on sales representatives to do his "education" for him.

Though Plaintiffs offer evidence that Hexum herself read the label, they do not argue that this is sufficient to carry their burden of proving causation. Regardless, the Court notes that under the learned intermediary doctrine, the duty to warn runs to the physician and not the patient. *Motus II*, 358 F.3d 659, 661 (citing *Carlin v. Superior Court*, 13 Cal.4th 1104, 1116 (1996)). The reason for this rule is that the choice involved in prescribing a drug is "essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities." *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968). Thus, while courts recognize an exception to this rule for mass immunization programs, this exception is premised on the fact that such mass immunization programs involve dispensing the drug without any individualized balancing by a physician of the associated risks. *Id.* at 131. This is not a case where a drug was dispensed en masse without any individualized assessment by a physician. Thus, there is no reason to deviate from the learned intermediary doctrine, under which it is the physician and not the patient who the manufacturer must warn.

For the aforementioned reasons, the Court FINDS that Plaintiffs failed to carry their burden of proving that stronger warnings would have altered Wollaston's conduct. *Motus II*, 358 F.3d at 661 (finding that summary judgment was properly granted to defendant where the prescribing doctor "testified that he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men before prescribing the drug to" the plaintiff's decedent) Accordingly, the Court GRANTS Lilly's motion and ENTERS JUDGMENT AS A MATTER OF LAW in Lilly's favor on the issue of causation for each of Plaintiffs' claims. *See Lakeside-Scott*, 556 F.3d 797, 808–09 (9th Cir. 2009) (finding defendant entitled to judgment as a matter of law because, *inter alia*, liability was premised on a purely speculative inference supported by "only threadbare conclusory statements").

B. Whether Stronger Warnings by Wollaston Would have Induced Hexum Not to Take Cymbalta

The Court further notes that Plaintiffs fail to offer sufficient proof that if Wollaston

received a stronger warning and conveyed that warning to Hexum, then she would not have taken Cymbalta. Hexum testified as follows:

> Q: Now, Ms. Hexum, if you had known the risks of suffering withdrawal side-effects was more than this one or two percent which was listed on the material that you read, would you have taken this drug at that time?
>
> A: I mean, I can't guess and speculate what I would have done. I can tell you that I definitely would have exhausted other efforts or seen if there were other treatments available before that.

(Day 2 A.M. Tr. 111:25–112:7.) Hexum was later asked "if he [Wollaston] would have told you that those side effects were more than 44 to 78 percent, or 1 out of 2, or 3 out of 4, would you have taken that drug?" (Day 2 P.M. Tr. 5:13–17.) Hexum responded "I imagine not." (*Id.* at 5:18.)

Hexum's response—"I imagine not"—is too ambiguous and speculative to allow a jury to find that if given stronger warnings Hexum would never have taken Cymbalta. Her testimony that she would have exhausted other efforts or seen if there were other treatments before taking Cymbalta is similarly unavailing. Hexum offers proof that Wollaston knew of and "sometimes" had success with nonprescription medication alternative treatments for fibromyalgia. She also offers evidence that Wollaston knew of other prescription drugs used to treat fibromyalgia. Finally, she offers her own evidence that she is currently free from fibromyalgia symptoms and uses only nonprescription medication treatments. However, this evidence only shows that Hexum has successfully managed her fibromyalgia without medication *after* nearly a year of treatment with Cymbalta. Moreover, this evidence is offered against Wollaston's admission that the other medications used to treat fibromyalgia have their own risks of side effects, that all SSRIs and SNRIs carry some discontinuation symptom risk, and his statement that Cymbalta was one of his top choice treatments for fibromyalgia.

The only way for a jury to find that Hexum would never have taken Cymbalta if given stronger warnings is for the jury to assume that if given a stronger warning, Hexum would have told Wollaston that she wanted to try other treatment options before Cymbalta; that Wollaston, pursuant to his joint decisionmaking process, would have prescribed other alternative treatments for Hexum; that one of those treatments would have been successful if tried before Hexum ever

took Cymbalta; and thus that Hexum would not have taken Cymbalta. On this record, there is nothing beyond speculation to support this chain of inferences. Thus, Hexum fails to offer sufficient evidence to support a reasonable inference that if Wollaston conveyed stronger warnings to her then she would not have taken Cymbalta. Therefore, even assuming *arguendo* that Hexum established that if given stronger warnings then Wollaston would have conveyed those warnings to Hexum, she failed to offer sufficient evidence to allow a rational jury to conclude that Hexum would not have taken Cymbalta if Lilly provided stronger warnings. For this additional reason, Plaintiffs failed to satisfy their burden of proving causation.

C. Ben Artzi

While the Court need not reach this issue, the Court notes that Plaintiffs' failure to offer any proof regarding whether Ben Artzi read the Cymbalta label is an additional shortcoming of Plaintiffs case. Before trial, Ben Artzi was designated as Lilly's witness. Plaintiffs did not intend to, nor did they, call Ben Artzi during their case in chief. During oral argument regarding Lilly's motion for directed verdict, Plaintiffs expressly stated that Ben Artzi's testimony was not necessary to their case. They further stated that by resting their case they meant to convey that they had presented all of the evidence they deemed necessary. Finally, when given an additional opportunity to raise any new arguments, Plaintiffs declined to do so.

The Court takes this to mean that Plaintiffs do not claim that Lilly failed to warn Ben Artzi (the tapering physician) that a two-week taper was insufficient or that Lilly failed to adequately instruct Ben Artzi regarding how to design a taper regimen. Regardless, given that there is no evidence in the record that Ben Artzi read Cymbalta's label, Plaintiffs would not be able to claim that the failure to so instruct or warn Ben Artzi caused their harm. Any inference that Ben Artzi read Cymbalta's label would be purely speculative.

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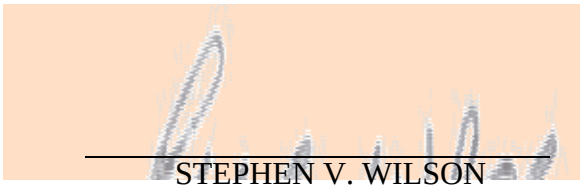
VI. ORDER

For the aforementioned reasons, the Court GRANTS Lilly's motion for directed verdict. The Court thus ENTERS JUDGMENT in Lilly's favor on all of Plaintiffs' claims.

IT IS SO ORDERED.

Dated: August 18, 2015



STEPHEN V. WILSON
United States District Judge