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 DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [129]

## I. INTRODUCTION

This products liability action arises from plaintiff Erin Hexum's ("Hexum") alleged "discontinuation" symptoms upon ceasing to take Cymbalta—defendant Eli Lilly and Company's ("Lilly") serotonin norepinephrine reuptake inhibitor ("SNRI"). On April 17, 2013, Hexum sued Lilly in federal court. (Dkt. 1.) 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. Much of this claim hinges on whether the Cymbalta label's statement that "the following symptoms occurred at a rate greater than or equal to 2%" means that the ensuing list of symptoms occurred in the aggregate at a rate greater than or equal

to 2% or that each listed symptom occurred at that rate.

In their Complaint, Plaintiffs assert causes of action for: (1) negligence; (2) strict product liability—design defect; (3) strict product liability—failure to warn; (4) "strict product liability"; (5) negligent misrepresentation; (6) fraud; (7) breach of implied warranty; (8) violation of California's Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200, *et seq.*; and (9) loss of consortium. (Dkt. 1.) However, Plaintiffs have abandoned their claims for strict liability—design defect, breach of implied warranty, violation of the UCL, and for loss of consortium. (Dkt. 191.)

Presently before the Court are Lilly's motion for summary judgment (dkt. 129), Lilly's motion to exclude the expert testimony of Dr. Joseph Glenmullen ("Glenmullen") (dkt. 130), Lilly's supplemental motion to exclude Glenmullen's expert testimony (dkt. 273), and Lilly's motion to exclude expert Dr. Louis Morris's ("Morris") testimony (dkt 129). As discussed in more detail below, much has happened in this case since these motions were filed. After several hearings, the filing of a motion for sanctions, and a round of supplemental briefing, the Court learned of allegedly new evidence not presented in connection with the instant motion for summary judgment. This evidence raises questions regarding, *inter alia*, whether discontinuation symptoms can be avoided by tapering off Cymbalta, Lilly's knowledge regarding whether tapering diminishes the risk of discontinuation symptoms, and whether Lilly deliberately designed Cymbalta's clinical trials in a way calculated to under-report the risk of discontinuation symptoms. Plaintiffs assert that Lilly either improperly asserted privilege over the relevant documents or buried them in a massive "document dump" produced in the last week of discovery.

For the reasons discussed below, the Court DENIES Lilly's motion for summary judgment and DECLINES TO REACH the motions to exclude Glenmullen and Morris.

## II. STATEMENT OF FACTS

### A. Cymbalta's Background

On August 3, 2004, the U.S. Food and Drug Administration ("FDA") approved the use of

Cymbalta[1] (duloxetine) for the treatment of major depressive disorder. (Def.'s SUF ¶ 1.) The FDA simultaneously approved the U.S. Physician Package Insert ("the label") for Cymbalta. *Id.* The Cymbalta label that was FDA approved in September 2011 and in effect in February 2012 cited the risk of discontinuation symptoms in three sections—"Highlights of Prescribing Information," "Dosage and Administration," and "Warnings and Precauations." (Def.'s SUF ¶ 2.) 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)

(Def.'s SUF ¶ 3.) 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)).*

(Def.'s SUF ¶ 4.)

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 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

[1] As noted above, Cymbalta is an SNRI. (Def.'s SUF ¶ 1.)

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)]*.

(Def.'s SUF ¶ 5.)

Though Cymbalta's label recommends tapering, it does not provide specific parameters—such as timeframe or dosage increments— for designing an appropriate taper regime. (Paley Decl., Ex. 1.) The label also states that Cymbal "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." (Paley Decl., Ex. 1, at 5.) Lilly manufactures Cymbalta in 20 milligram, 30 milligram, and 60 milligram delayed release capsules. (*Id.*)

**B. The 2005 Journal of Affective Disorders Article**

In 2005, the Journal of Affective Disorders published an article called "Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder" (the "2005 JAD Article"). (Def.'s SUF ¶ 5.) Three of the 2005 JAD Article's authors—David G. Perahia, Daniel Kajdasz, and Durisala Desaiah—were Lilly employees. (*Id.*) The Article reported data arising from nine clinical trials that Lilly funded, designed and conducted. (Def.'s SUF ¶ 6.) In all of the studies, Cymbalta was abruptly discontinued. (Paley Decl., Ex. 10, at 208.) After discontinuation there was a 1 or 2 week lead-out phase to allow for the collection of discontinuation-emergent adverse events ("DEAEs") at a set time after discontinuation. (*Id.*) DEAEs were elicited by non-probing inquiry and were rated as mild, moderate, or severe. (*Id.*)

The 2005 JAD Article reports that in short-term, placebo-controlled studies, "[s]ignificantly more duloxetine-treated patients (44.3%) reported at least 1 DEAE than placebo-treated patients (22.9%), with dizziness being the most common symptom." (*Id.*; Def.'s SUF ¶ 8.) The Article reports that 39.8% of the reported events were mild, 50.6 % were moderate, and 9.6% were severe. (Def.'s SUF ¶ 9.) Of the DEAEs reported, 53.7% were unresolved as of the

final contact with the patient (either 1 or 2 weeks after discontinuation). (Paley Decl., Ex. 10, at 275.) The Article also includes a table relaying the incidence of specific discontinuation symptoms as follows:

| Event | Placebo (N = 380; *n* (%)) | Duloxetine (Cymbalta) (N = 490; *n* (%)) |
|---|---|---|
| Patients with ≥1 event | 87 (22.9) | 217 (44.3)* |
| Dizziness | 3 (0.8) | 61 (12.4)* |
| Nausea | 1 (0.3) | 29 (5.9)* |
| Headache NOS | 3 (0.8) | 26 (5.3)* |
| Paraesthesia | 1 (0.3) | 14 (2.9)* |
| Diarrhea NOS | 3 (0.8) | 11 (2.2) |
| Vomiting NOS | 2 (0.5) | 12 (2.4)* |
| Irritability | 1 (0.3) | 12 (2.4)* |
| Insomnia | 2 (0.5) | 10 (2.0) |
| Nightmare | 0 (0.0) | 10 (2.0)* |

NOS = not otherwise specified.

* $P < 0.05$ vs. placebo, Fisher's Exact Test.

(Paley Decl., Ex. 10, at 276.)[2]

The Article also reports that in the long-term, placebo-controlled studies, "[s]ignificantly more duloxetine-treated patients reported at least 1 DEAE (9.1%) than did placebo-treated patients (2.0%) with dizziness being the most common symptom[.]" (Paley Decl., Ex. 10, at 210; Def.'s SUF ¶ 10.) The Article reports that of the 34 reported DEAEs in those studies, 70.6% were mild, 26.5% were moderate, and 1 event (2.9%) was severe. (Def.'s SUF ¶ 11.) The Article also includes a table relaying the incidence of specific discontinuation symptoms after long-term treatment occurring in at least two duloxetine-treated patients as follows[3]:

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[2] The Court notes that alongside its 2001 New Drug Approval application Lilly submitted to the FDA nearly identical data to that disclosed in this table. (Paley Decl. in Supp. of Def.'s Summ. J. Reply ("Paley Supp. Reply Decl.") ¶ 6; Paley Supp. Reply Decl., Ex. 19, at 112–20.)

[3] The Court notes that the 2005 JAD Article also includes columns separating out this data by the dose from which the duloxetine-treated patients discontinued.

| Event | Placebo (N = 101; *n* (%)) | Duloxetine (Cymbalta) (N = 242; *n* (%)) |
|---|---|---|
| Patients with ≥1 DEAE | 2 (2.0) | 22 (9.1)* |
| Dizziness | 1 (1.0) | 8 (3.3) |
| Anxiety | 0 (0.0) | 2 (0.8) |
| Headache NOS | 0 (0.0) | 2 (0.8) |
| Irritability | 0 (0.0) | 2 (0.8) |
| Nausea | 0 (0.0) | 2 (0.8) |
| Vomiting NOS | 0 (0.0) | 2 (0.8) |

NOS = not otherwise specified.

* $P < 0.05$ vs. placebo, Fisher's Exact Test.

(Paley Decl., Ex. 10, at 276.)

Finally, the Article reports that in the uncontrolled 52-week open label study, 50.8% of patients reported at least 1 DEAE with dizziness being the most common. (Paley Decl., Ex. 10, at 210; Def.'s SUF ¶ 12.) Of these DEAEs, 36.6% were mild, 46.3% were moderate, and 17.2% were severe. (Paley Decl., Ex. 10, at 210; Def.'s SUF ¶ 13.) The Article also includes a table relaying the incidence of specific discontinuation symptoms for which the incidence was at least 2% as follows:

| Event | Duloxetine (Cymbalta) (N = 553; *n* (%)) |
|---|---|
| Patients with ≥1 DEAE | 281 (50.8) |
| Dizziness (excluding vertigo) | 106 (19.2) |
| Anxiety NEC | 55 (9.9) |
| Nausea | 54 (9.8) |
| Headache NOS | 40 (7.2) |
| Insomnia | 37 (6.7) |
| Irritability | 33 (6.0) |
| Vomiting NOS | 24 (4.3) |
| Nightmare | 16 (2.9) |

| | |
|---|---|
| Paraesthesia | 16 (2.9) |
| Tinnitus | 16 (2.0) |
| Crying | 15 (2.7) |
| Depressed mood | 15 (2.7) |
| Depression NOS | 15 (2.7) |
| Anorexia | 14 (2.5) |
| Diarrhea NOS | 14 (2.5) |
| Myalgia | 13 (2.4) |
| Tremor | 12 (2.2) |
| Nervousness | 11 (2.0) |

NEC = not elsewhere classified; NOS = not otherwise specified.

(Paley Decl., Ex. 10, at 277.)

**C. Hexum's Use and Discontinuation of Cymbalta**

On January 16, 2012, Hexum presented to her physician, Dr. Satinder Bhatia ("Bhatia"), with fibromyalgia. (Pls.' Proposed Findings of Fact ("PFF") ¶ 1.) Bhatia, who was not a specialist on fibromyalgia, recommended that Hexum see a specialist to evaluate her "fibromyalgia/fatigue." (Pls.' PFF ¶ 2.) Bhatia also prescribed to Hexum the antidepressant Lexapro, but Hexum testified that she did not feel comfortable taking an antidepressant before being diagnosed. (Pls.' PFF ¶ 3.)

On February 14, 2012, Hexum first visited Dr. Sean Wollaston ("Wollaston"), a rheumatologist. (Pls.' PFF ¶¶ 4, 6.) During this meeting, Wollston fully evaluated Hexum and discussed her symptoms. (Pls.' PFF ¶ 7.) Wollaston diagnosed Hexum with fibromyalgia and recommended starting her on Cymbalta—first at 30 milligrams per day and then titrating up to 60 milligrams per day. (Pls.' PFF ¶ 9.) According to Hexum, when Wollaston proposed Cymbalta as a possible treatment, she asked him about discontinuation because she knew that she and her husband were going to try to have a child in the future and she wanted to be able to discontinue Cymbalta when they chose to do so. (Pls.' PFF ¶ 10.) According to Hexum, Wollaston told her that "it wasn't a life thing" and that "[a]s long as [she] didn't quit it cold turkey, [she'd] be fine." (Wisner Decl., Ex. 2, at 224:4–18.) Hexum asserts that Wollaston told

her that if she quit cold turkey then she "would not feel good . . . [she would] feel really sick." (*Id.* at 224:23–225:2.) Wollaston testified about his general practices in February 2012 as follows:

> Q: Let me try to maybe go about this discussion from a little bit of a different angle. How did you—back in February of 2012 or any time prior thereto, how did you characterize the possibility of going through withdrawal effects from discontinuing Cymbalta for your patients? What would you have said to a patient about that?
>
> A: I would have informed them that they would need to taper the drug. But probably that would be about it. That we would not advocate the sudden termination of the drug but a tapering of it.
>
> Q: In terms of how rare or common you understood the risks to be, what would you have said to the patient in that regard. Again back—
>
> A: I would have said that the incidents [sic] of adverse side effects would be pretty uncommon.

(Wisner Decl., Ex 1, at 75:19–76:10.) He further testified that:

> Q: And if this data is correct that I am showing you today at 44 to 50 percent, let's pretend that I am your patient and sitting in your office today and you have that data in front of you and you put stock in it and you think it's accurate, how do you characterize the risk to me?
>
> [Objection omitted.]
>
> A: Well, I couldn't write it off as being uncommon if it's 40 to 50 percent and if that data is accurate then it would have to be portrayed as a challenge or difficulty in tapering off of the drug. Different than the risk of something occurring at a rate of one percent or so.

(*Id.* at 76:11–25.)

Hexum conducted some research regarding Cymbalta—looking at "written materials" allegedly accompanying a sample of Cymbalta that was given to her by Wollaston and by viewing material on websites (such as www.Cymbalta.com and WebMD). (Pls.' PFF ¶¶ 13–15.) While Hexum acknowledges that she understood that the discontinuation symptoms described in the materials she read were a possibility, she states that she did not believe her risk of discontinuation symptoms to be significant. (Pl.'s PFF ¶ 17; Paley Reply Decl., Ex. 15, at 251:2–5.) By June 2012, Hexum reported "feeling much better on Cymbalta." (Def.'s SUF ¶ 23.) Nevertheles, Hexum testified that her pain ultimately returned. (Pls.' PFF

Wollaston had prescribed Cymbalta for other fibromyalgia patients prior to prescribing it

to Hexum. (Paley Decl., Ex. 8, at 94:16–19.) Wollaston testified that prior to February 2012, Cymbalta would have been "near the top of the list " of options to which he might have turned for fibromyalgia patients. (*Id.* at 94:22–95:1.) (Def.'s SUF ¶ 24.) Prior to the time when he initially prescribed Cymbalta to Hexum, Wollaston became aware that medicines like Cymbalta and Effexor could cause discontinuations symptoms if they were not tapered. (Paley Decl., Ex. 8, at 105:111–17.) Wollaston first began prescribing antidepressants during his fellowship (from 1999–2001).[4] (Def.'s SUF ¶ 25.) During this time Wollaston also became aware of the need to taper patients off of some of the antidepressants because feeling "queasy, light-headed symptoms would be not uncommon from a sudden discontinuation of antidepressants."[5] (*Id.*; Paley Decl., Ex. 8, 82:1–16.) Prior to prescribing Cymbalta to Hexum, Wollaston had patients who had experienced discontinuation symptoms upon discontinuing Cymbalta. (Paley Decl., Ex. 8, 106:14–19.) Wollaston testified that he'd had patients who experienced, "just feeling generally unwell, being light-headed, dizzy, having an electrical shock sensation, headaches probably" upon discontinuing Cymbalta. (*Id.* at 106:8–13.) Nevertheless, Wollaston described the patients that he treated who experienced discontinuation symptoms upon discontinuing Cymbalta or Effexor (a similar medication not at issue in this case) as "outliers." (*Id.* at 105:22–106:11.) Around the time that he treated Hexum, Wollaston was generally familiar with Cymbalta's label's statement that:

> [f]ollowing abrupt or tapered discontinuation of placebo-controlled clinical trial [sic], the following symptoms occurred at one percent or greater and at a significantly higher rate in Dulexetine treated patients compared to those discontinuing from placebo: Dizziness, nausea, headache, paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis.

(Def.'s SUF ¶ 33.) When asked what the statement that "[f]ollowing abrupt or tapered discontinuation of placebo-controlled clinical trial [sic], the following symptoms occurred at one

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[4] The Court notes Plaintiffs' objection to this statement. Insofar as Plaintiffs object that Wollaston didn't recall using SSRIs during his fellowship, this objection is overruled. The portion of Wollaston's testimony that Plaintiffs' cite contradicts this assertion. Wollaston testified that during his fellowship he would have had occasion to prescribe SSRIs such as Prozac, Paxil, and Zoloft for pain management.

[5] However, Wollaston admitted that he didn't know "that it was discussed entirely what the symptoms would be if you didn't [taper]." (Paley Decl., Ex. 8, 82:6–9.)

percent or greater" meant to him in terms of the frequency of the listed discontinuation side effects, Wollaston testified: "[w]ell, sounds pretty uncommon. Sounds like it [sic] close to one percent, maybe over one percent which is why they used the greater but pretty close to one percent." (Paley Decl., Ex. 8, at 57:25–58:10.)

Hexum's last visit with Wollaston was in October 2012. (Pls.' PFF ¶ 19.) Thereafter she switched to Dr. Ami Ben-Artzi ("Ben-Artzi")—a doctor located closer to Hexum's new house. (Pls.' PFF ¶¶ 20–21.) Ben-Artzi referred Hexum to occupational therapist Jeanne Melvin ("Melvin") and to receive aquatic physical therapy. (Pls.' PFF ¶ 28.) On January 8, 2013, Hexum met with Melvin for an evaluation, during which Hexum expressed her desire to discontinue Cymbalta because she and her husband were considering another child. (Pls.' PFF ¶ 30.) Hexum's desire to quit Cymbalta was conveyed to Ben-Artzi. (Pls.' PFF ¶ 31.) By the time he began treating Hexum, Ben-Artzi knew that patients should taper off Cymbalta rather than discontinuing it abruptly. (Def.'s SUF ¶ 41.) On January 24, 2013, Ben-Artzi directed Hexum to reduce from 60 milligrams to 30 milligrams per day, and thereafter to cease taking Cymbalta. (Def.'s SUF ¶ 42; Pls.' PFF ¶ 31.) Though a note in her medical records states that Hexum should return for a follow-up appointment in 6 to 8 weeks, she did not return to Ben-Artzi after her January 24, 2013 appointment. (Def.'s SUF ¶ 43.) At some point Hexum began "breaking open the capsules and counting out pellets as a way to reduce." (Def.'s SUF ¶ 44.) Ben-Artzi did not advise Hexum to break open the capsules and testified that he would not advise patients to do so because "[m]edications are designed to work in a certain way and the way that they are packaged is to keep their integrity[.]" (Wisner Decl., Ex. 4, at 115:8–116:7.)

While the parties dispute the precise date on which Hexum began tapering, it is undisputed that she was completely off of Cymbalta by February 10 or 11 of 2013. (Pls.' PFF ¶ 32.) Hexum testified that within 24 hours of discontinuing Cymbalta, she began to experience such symptoms as nausea, vomiting, anxiety, dizziness, and feeling like there was electricity running through her body. (Wisner Decl., Ex. 2, at 305:21–306:16.) On February 13, 2013, Hexum emailed Melvin, complaining of mood swings, headaches, anxiety, numbness and tingling, aches, dizziness, weakness, "brain zaps," light sensitivity, hot flashes, cognitive

difficulties, hearing problems, hypersensitivity to touch, and vomiting. (Def.'s SUF ¶ 49.) Hexum also testified that she experienced episodes of shaking in which she lost control of her bladder. (Wisner Decl., Ex. 2, at 307:11–23.) The parties dispute whether these episodes were seizures and whether they were caused by Cymbalta withdrawal.

These symptoms and others also purportedly caused by Hexum discontinuing Cymbalta were completely resolved, at the latest, by June 2013. (Pls.' PFF ¶ 34.) After discontinuing Cymbalta, Hexum became pregnant with her third child. (Def.'s SUF ¶ 53.)

**D. Hexum's Other Medical Conditions**

Hexum has a history of migraine disorder—she suffered from two migraines during adolescence. (Wisner Decl., Ex. 2, at 167:22–169:11.) She also experienced migraines during pregnancy. (*Id.* at 169:12–24.) In 2005, Hexum sought emergency treatment for numbness, tingling, and vomiting—which she claims was caused by a pinched sciatic nerve and food poisoning. (Def.'s SUF ¶ 16.)

At some point between 2008 and 2010 (the timing is disputed) Hexum suffered from syncope episodes that she described as feeling like "earthquakes" accompanied by nausea, blurred vision, and tinnitus. (Wisner Decl., Ex. 2, at 150:21–158:7.) Hexum testified that these episodes only occurred while she was pregnant. (*Id.* at 155:6–156:17.)

In 2011, during one of her pregnancies, Hexum's husband found her passed out on the floor. (Paley Decl., Ex. 4, at 60.) Hexum was subsequently diagnosed with "[i]ntrauterine pregnancy with atypical migraine and visual disturbance." (*Id.* at 61.)

## III. PROCEDURAL HISTORY

On February 27, 2015, Lilly filed the instant motion for summary judgment. (Dkt. 129.) Since then, much has happened in this case.

On April 21, 2015, Plaintiffs moved for sanctions against Lilly. (Dkt. 265.) In their sanctions motion, Plaintiffs asserted that Lilly improperly withheld documents—1,000 of which were allegedly withheld under the guise of attorney-client privilege—and failed to timely provide an accurate privilege log. (Dkt. 265: Mot. 1.) On May 18, 2015, the Court ordered Lilly to produce a revised privilege log by May 26, 2015. (Dkt. 292.) On June 1, 2015, the

Court held a hearing regarding the newly produced privilege log and documents. (Dkt. 295.) On the same day, the Court granted leave for the parties to file supplemental briefing. (*Id.*)

Alongside their supplemental briefing, Plaintiffs submit internal Lilly documents regarding Cymbalta's clinical trials, Cymbalta's approval for the treatment of Generalized Anxiety Disorder ("GAD"), and similar topics. (Dkt. 302.) Plaintiffs assert that these documents were previously either improperly withheld, improperly redacted, or were buried in a "document dump" of thousands of documents that Lilly allegedly produced in the last week of discovery and provided in a non-native electronic format that was difficult to use.

Of particular note: Plaintiffs provide a 2006 email from David Perahia ("Perahia") to Michael Detke ("Detke") and others in which Perahia discusses potential updates to Cymbalta's "Medical Beliefs" documents. In the email, Perahia states:

> [i]n terms of whether the use of a taper reduces the number of reported DEAEs, data from BU & CQ suggest that it doesn't while data from HMDD suggest that it does ! Further, bearing in mind the hazards of comparing across different types of trials, I don't think we're in a position to make a data-driven recommendation with regard to dose tapering, although our 'official' position is obviously to recommend tapering.

(Supp. Wisner Decl., Ex. 4.) Plaintiffs also submit excerpts from the HMBR Study Report, which discusses a study of Cymbalta that included a two-week taper period. (Supp. Wisner Decl., Ex. 5, at 34.) That study found that there was "no statistical significance among the study drug stopping method (taper compared with abrupt) during the drug-tapering phase." (*Id.* at 144.)

Plaintiffs further submit another 2006 email chain regarding possible revisions to the proposed Cymbalta label to be submitted with Lilly's application for FDA approval of Cymbalta to treat GAD. In an email sent by Richard Bump ("Bump") to other Lilly personnel after a meeting regarding the label, Bump says:

> My point was not so much what events should be included, but concern that the implication from the wording is that tapering eliminates the risk of discontinuation symptoms. **None of the individual studies specifically designed to look at this (SUI or GAD) have shown a benefit to tapere [sic] compare with abrupt discontinuation.** I just believe the sentence that concludes the first paragraph is not accurately reflecting the lack of benefit (or lack thereof) of tapering in studies designed to look at this specifically.

(Supp. Wisner Decl., Ex. 6) (emphasis added). In a later email responding in part to Bump's statement, Detke writes:

> My proposal is that we plan to delete the sentence struck through below.[6] Overall it strongly implies that tapering substantially improves tolerability, which does not represent the data accurately. To Rick's [Bump's] point, it (perhaps more weakly) implies that tapering solves all tolerability problems entirely, which would be an even worse misinterpretation of the actual data. To Greg's point today, the last paragraph, second sentence[7] still indicates that tapering is recommended, and is inconsistent, but I would not recommend removing it now because 1) it's from previous class labeling and not worth the fight, and more importantly 2) it may still help patients to taper and almost certainly won't hurt them in the vast majority of clinical situations . . .

(*Id.*) Finally, Plaintiffs submit a 2008 email chain between Detke and Teresa S. Williams ("Willams"). Williams was working on clinical trials for a different drug and requested information about the Cymbalta drug trials. In response to Williams's inquiry about whether Lilly used elicited scales (symptom checklists) during the Cymbalta trials, Detke answers that they did not. (Wisner Decl., Ex. 16.) He then sends a follow-up email one minute later stating that: "[i]f you use an elicited scale, you'll see higher rates. This WILL end up in the label." (*Id.*)

In response to Plaintiffs' latest filing, Lilly asserts that the documents at issue were largely produced before the close of discovery. In particular, Lilly asserts that Plaintiffs' Exhibits 4 and 6 were produced in December 2014 (just before the close of discovery). (Jones Supp. Decl. ¶¶ 5, 7.) Lilly asserts that Plaintiff's Exhibit 5 was produced in July 2013. (*Id.* at ¶ 6.) Finally, Lilly admits that Plaintiff's Exhibit 16 was not produced to Plaintiffs until April 2015. (*Id.* at ¶ 17.)

## IV. MOTION FOR SUMMARY JUDGMENT

### A. Legal Standard

Federal Rule of Civil Procedure 56 requires summary judgment for the moving party when the evidence, viewed in the light most favorable to the nonmoving party, shows that there

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[6] That sentence reads "[w]hen patients were tapered over 2 weeks after acute treatment in 9 or 10 week GAD studies, no adverse events met criteria as described above." (Supp. Wisner Decl., Ex. 6.)

[7] That sentence reads "[a] gradual reduction in the dose rather than abrupt cessation is recommended whenever possible." (*Id.*)

is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Tarin v. County of Los Angeles*, 123 F.3d 1259, 1263 (9th Cir. 1997).

The moving party bears the initial burden of establishing the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). On an issue for which the moving party does not have the burden of proof at trial, the moving party may satisfy this burden by "'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325. Once the moving party has met its initial burden, the nonmoving party must affirmatively present admissible evidence and identify specific facts sufficient to show a genuine issue for trial. *See id.* at 323-24; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A scintilla of evidence or evidence that is not significantly probative does not present a genuine issue of material fact. *Addisu v. Fred Meyer*, 198 F.3d 1130, 1134 (9th Cir. 2000). "When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 1356, 89 L. Ed. 2d 538 (1986)

The Court need not reach issues not raised in a party's opening brief. *See Bowhay v. Colvin*, No. CV 12-2506 AN, 2013 WL 819794, at *9 (C.D. Cal. Mar. 5, 2013) (citing *In re Rains*, 428 F.3d 893, 902 (9th Cir.2005)). The Court may, but need not, consider materials in the record to which the parties do not cite. Fed. R. Civ. P. 56(c)(3); *Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1031 (9th Cir. 2001) ("The district court need not examine the entire file for evidence establishing a genuine issue of fact, where the evidence is not set forth in the opposing papers with adequate references so that it could conveniently be found.").

"To survive summary judgment, a party does not necessarily have to produce evidence in a form that would be admissible at trial, as long as the party satisfies the requirements of Federal Rules of Civil Procedure 56." *Block v. City of Los Angeles*, 253 F.3d 410, 419 (9th Cir. 2001). "At the summary judgment stage, we do not focus on the admissibility of the evidence's form. We instead focus on the admissibility of its contents." *Fraser v. Goodale*, 342 F.3d 1032, 1036

(9th Cir. 2003). Thus, even if evidence is presented upon a motion for summary judgment in a form that does not strictly meet the requirements of the Federal Rules of Evidence, the Court will still consider the evidence if it is apparent that the deficiency can be overcome at trial. *Id.* at 1037; *see also Fonseca v. Sysco Food Servs. of Ariz., Inc.*, 374 F.3d 840, 846 (9th Cir. 2004.) "However, the Court may not consider inadmissible hearsay evidence which could not be presented in an admissible form at trial." *Stonefire Grill, Inc. v. FGF Brands, Inc.*, 987 F. Supp. 2d 1023, 1037 (C.D. Cal. 2013).

**B. Application**

Lilly moves for summary judgment on all of Plaintiffs' claims, asserting *inter alia*, that Plaintiffs' cannot establish that Lilly's purportedly misleading or inadequate warning caused Plaintiffs' injuries. In relevant part, Lilly asserts that Plaintiffs cannot establish causation because: (1) Hexum's physicians had independent knowledge of the relevant risks, and (2) Plaintiffs' requested warning would not have changed Hexum's doctor's decision to prescribe Cymbalta.

**1. The Two Prior Cases Granting Summary Judgment to Lilly on Claims that Lilly Failed to Adequately Warn of Cymbalta's Risks**

Two courts have already granted summary judgment to Lilly on similar claims to those at issue here: *McDowell v. Eli Lilly & Co.*, No. 13 CIV. 3786, 2014 WL 5801604 (S.D.N.Y. Nov. 7, 2014) and *Carnes v. Eli Lilly & Co.*, No. CA 0:13-591-CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013).

In *McDowell*, the plaintiff had a history of depression and anxiety. *McDowell*, 2014 WL 5801604, at *4. Before taking Cymbalta he tried six other antidepressants, both alone and in combination, but to no avail. *Id.* Cymbalta was first prescribed to the plaintiff in 2008 by Nurse Practitioner Joan Caruana ("Caruana"). *Id.* at *5. The plaintiff relied on the data in the 2005 JAD Article and asserted several claims based on the supposed inadequacy of Cymbalta's label's warnings. *Id.* at *1–4.

The court first found that the Cymbalta label discontinuation warning[8] was adequate as a matter of New York law. *Id.* at *10. Under New York, law, a warning is adequate if it provides "specific detailed information on the risks of the drug." *Id.* at *11. More specifically, it is adequate when the prescribing information communicates "information regarding the precise malady incurred." *Id.* (internal quotations and citation omitted.) The Court found that the label portrayed "with sufficient intensity the risk involved in taking the drug." *Id.* at *12. The Court noted that the label included a detailed list of possible discontinuation symptoms, including those that the plaintiff allegedly experienced. *Id.* The court also noted that the label included approximately twelve symptoms occurring "at a rate greater than or equal to 1%" in placebo-controlled clinical trials for Cymbalta. *Id.* The court found this method of communicating information on individual symptoms consisted with accepted practice and in accord with FDA regulations and guidance directing that the label "list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database. *Id.* (quoting 21 C.F.R. § 20157(c)(7)). The court further found adequate the label's statements that "[a]lthough these events [discontinuation symptoms] are generally self-limiting, some have been reported to be severe." *Id.* at *13. *McDowell* noted that other courts had refused to require drug package inserts to include specific adverse event frequencies. *Id.* at *14 (citing *Hurley v. Lederle Labs., Div. of Am. Cyanamid Co.*, 651 F.Supp. 993, 1002 (E.D.Tex.1986)). The court also found probative Caruana's testimony that she did not understand the label's statement that certain discontinuation symptoms occurred at a rate greater than or equal to 1% to refer to the rate at which all of the symptoms (in the aggregate) were observed. *Id.*

The court then found that the plaintiff failed to establish a triable issue regarding whether the Cymbalta discontinuation warning proximately caused his harm. *Id.* at *15–18. First, Caurana testified that she had independent knowledge of the risks of abruptly discontinuing Cymbalta. *Id.* at *16. According to Caruana, she knew from her clinical experience that "at least half" of her patients experience some discontinuation symptom upon abrupt withdrawal and

[8] The Court notes that the label in effect when the *McDowell* plaintiff was first prescribed Cymbalta was materially the same as the label in effect when Hexum was first prescribed the drug.. *See McDowell*, 2014 WL 5801604, at *1–3.

that she knew that "most" patients who stopped taking Cymbalta abruptly would experience discontinuation symptoms. *Id.* at *7, *15. Finally, the court again noted that Caruana testified that she did not understand the Cymbalta label to mean that all of the listed discontinuation symptoms combined (rather than each symptom individually) occurred in only 1% of patients. *Id.* at *15.

In *Carnes v. Eli Lilly & Co.*, the court considered similar claims that Cymbalta's label's warnings regarding the risk of discontinuation symptoms upon discontinuing Cymbalta were inadequate. The plaintiff based his claims on the data disclosed in the 2005 JAD Article. *Carnes*, 2013 WL 6622915, at *2. The plaintiff suffered from chronic pain following a spinal injury sustained in 2004 in a helicopter crash. *Id.* at *1. His physician first prescribed Cymbalta in 2011. The plaintiff later asked a different physician to switch him from Cymbalta to a different medication. *Id.* That physician reduced the plaintiff's dosage to 30 milligrams per day. *Id.* When the plaintiff returned roughly two months later, she told the plaintiff to cease taking Cymbalta. *Id.*

Like the label at issue in *McDowell*, the Cymbalta label then in effect listed roughly twelve discontinuation symptoms observed following "abrupt or tapered" discontinuation. *Id.* at *1–2. It stated that "the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo." *Id.* at *2. The plaintiff argued that he could establish proximate cause by showing that his doctor engaged in a joint decisionmaking process with patients regarding prescriptions, that if the doctor received a stronger warning the doctor would have relayed it to the plaintiff, and that if the plaintiff received the stronger warning then the plaintiff would have refused to take Cymbalta. *Id.* at *5. The court rejected this argument as being without authority and as an attempt to displace the learned intermediary doctrine. *Id.* The court found that there was no triable issue of fact regarding proximate causation as to the first doctor to prescribe Cymbalta because the doctor testified that he would have still prescribed Cymbalta to the plaintiff even if he had received the purportedly required warning**.** *Id.* at *5. The court also found that the initial prescribing doctor had independent knowledge of the risk and frequency of discontinuation

symptoms upon abrupt withdrawal because the doctor estimated that more than half of his patients experienced discontinuation symptoms upon abruptly discontinuing Cymbalta. *Id.* The Court further found that the plaintiff couldn't establish proximate cause as to the doctor who helped him discontinue Cymbalta because the plaintiff was already taking Cymbalta by the time that doctor started treating him. *Id.* at *7. Additionally, the court noted that this second doctor did not testify that her decision to taper the plaintiff's prescription would have been affected by a stronger warning. The court thus granted Lilly's motion for summary judgment. *Id.* at *7.

**2. Plaintiffs' Failure to Warn Claim**

**a. Legal Standard**

Under California law, a prescription drug manufacturer owes to the medical profession a duty to provide adequate warnings if it "knows, or has reason to know, of any dangerous side effects of its drugs." *Thomas v. Abbott Labs.*, No. CV-12-07005-MWF CWX, 2014 WL 4197494, at *5 (C.D. Cal. July 29, 2014) **(**citing *Carlin v. Superior Court*, 13 Cal.4th 1104, 1111–13 (1996)). Under the learned intermediary doctrine, "in the case of prescription drugs, the duty to warn runs to *the physician*, not to the patient." *Id.* (citing *Carlin*, 13 Cal. 4th at 1116) (emphasis in original). Thus, "if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed." *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973) (quoting *Love v. Wolf*, 226 Cal. App. 2d 378, 395 (Cal. Ct. App. 1964)); *see also Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990–91 (C.D. Cal. 2001) (*Motus I*) *aff'd sub nom. Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004) (*Motus II*).

A plaintiff asserting claims based on a failure to warn must prove: (1) that either no warning was provided or that the warning provided was inadequate; and (2) that "the inadequacy or absence of the warning caused the plaintiff's injury." *Id.* at 991 (citing *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358 (2d Cir.1987) (applying California law)). However, no harm can be caused by the "failure to warn of a risk already known" to the physician. *Rosburg v. Minnesota Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (Cal. Ct. App. 1986). To prove causation, Plaintiffs must prove that Lilly's alleged failure to warn was a "substantial factor" in

bringing about their injuries. *See Motus I*, 196 F. Supp. 2d at 991 (citing *Rutherford v. Owens–Illinois, Inc.*, 16 Cal.4th 953, 968 (1997)). "The substantial factor standard is a relatively broad one, requiring only that the contribution of the individual cause be more than negligible or theoretical." *Georges v. Novartis Pharm. Corp.*, 988 F. Supp. 2d 1152, 1157 (C.D. Cal. 2013) (quoting *Bockrath v. Aldrich Chem. Co.*, 21 Cal.4th 71, 79 (1999)).

**b. Application**

The thrust of Plaintiffs' case is that Lilly failed to adequately warn of the likelihood and severity of discontinuation side effects upon discontinuing Cymbalta. This argument hinges in large part on the proper interpretation of Cymbalta's label's statement that after "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 compared to those discontinuing from placebo: dizziness, nausea, headache paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis."

Until the recently filed supplemental briefs, Plaintiffs based their claim that Cymbalta's label is inadequate on the data disclosed in the 2005 JAD Article—which was entitled "Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder." As discussed above, the 2005 JAD Article analyzes data collected from multiple clinical studies—each of which examined discontinuation symptoms following the abrupt discontinuation of Cymbalta. The Article finds that in short-term studies and upon abrupt discontinuation, 44.3% of Cymbalta-treated patients experienced at least 1 discontinuation symptom compared to 22.9% of patients taking the placebo. (Def.'s SUF ¶¶ 6, 9.) It also separately identifies the frequency with which any individual symptom occurred. The discontinuation symptoms listed in the above-quoted section of the Cymbalta label each occurred at a rate between 2% and 12.4%. (Paley Decl., Ex. 2, at 35.)

Plaintiffs assert that the label is properly understood to refer to the side effects in the aggregate, suggests that 1% or only slightly greater than 1% of Cymbalta-treated patients experienced any of the listed discontinuation symptoms, and is therefore misleading because the data shows that 44.3% of Cymbalta-treated patients experienced one or more of the listed

discontinuation symptoms.[9] Lilly asserts that the label is properly understood to refer to the frequency with which *each* of the listed discontinuation symptoms occurred, and that its statement that those discontinuation symptoms each occurred at a rate of 1% or greater accurately represents the data—which shows that each of the listed discontinuation symptoms occurred at a rate of no more than 12.4%.[10]

(1) Insufficient Evidence That Lilly's Alleged Failure to Warn Caused Plaintiffs' Physicians' Conduct in Prescribing Cymbalta

Plaintiffs argue that under *Motus II* they can establish proximate cause by showing that a doctor's prescribing practice involves a joint decision with his patient, that stronger warnings would have led him to alter his warnings to Hexum, and that if Hexum had received the stronger warnings she wouldn't have taken the medication. *See Motus II*, 358 F.3d at 661 (stating that "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"). Lilly argues that Plaintiffs must show that a stronger warning would have caused the doctor not to prescribe Cymbalta. *See Motus I*, 196 F. Supp. 2d at 997. As discussed below, even if Lilly's legal theory is correct, Plaintiffs' evidence suffices to raise a triable issue of fact.

Hexum testified that when discussing her treatment options with Wollaston, she told him that she planned to have another child in the near future and thus didn't want to start a treatment that would be difficult or ill-advised to stop. (Pls.' PFF ¶ 106.) Hexum testified that in response to her concerns, Wollaston told her that if she quit "cold turkey" then she'd "feel really sick . . . it won't be good" but that as long as she tapered off the drug she'd be fine. (Wisner Decl., Ex. 2,

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[9] The Article also finds that in the short term studies, 50.6% of discontinuation symptoms reported were moderate while 9.6% were severe. (Def.'s SUF ¶ 10.) The study also found that in a long-term open-label study, half of patients reported at least one discontinuation symptom, with 17.2% of symptoms reported as severe and 46.3% reported as moderate. (Def.'s SUF ¶¶ 13–14.)

[10] Lilly cites *McDowell*'s holding that the label is adequate as a matter of law and asserts that it believes that the case could be decided on that issue. Nevertheless, Lilly expressly states that the Court need not reach the issue of the label's adequacy because Plaintiffs fail to raise a triable issue as to proximate cause. Absent an invitation from Lilly or Plaintiffs, the Court will not reach the issue of Cymbalta's label's adequacy.

at 224:12–225:13.) Wollaston also testified that if the actual risk of Cymbalta discontinuation symptoms was 44–50%, then that data:

> would have been part of a discussion. One percent or greater signifies a pretty low likelihood; 44 to 50 percent is not a low likelihood so I think that would have changed the discussion about the medication and about discontinuing said medication particularly if part of that discussion was her plan to discontinue it in the relatively near future based on our earlier discussion that she was planning on having another child.

(Paley Decl., Ex. 8, at 73:24–75:3.)

Wollaston's other testimony about how his decision to prescribe Cymbalta would have been impacted by stronger warnings is admittedly somewhat ambiguous. For example, Wollaston testified as follows:

> Q: If Ms. Hexum had come to you with that presentation of symptoms of several year history of chronic pain, having been referred by her primary care doctor and in light of the other possible treatment options, would you have made the same decision to prescribe Cymbalta to Ms. Hexum?
>
> [Objection omitted.]
>
> A: I believe so.
>
> Q: Well, let me ask you a slightly different question. Given your experience and your training and given Ms. Hexum's presentation with her symptoms in February of 2012, and the other possible options for her as a patient with fibromyalgia, if the prescribing information for Cymbalta had said just what it said today that we've looked over except it also said, "In the clinical trials for the medicine, discontinuation symptoms occurred in at least some patients 44.3% of the time while symptoms occurred for patients on placebo 22.9% of the time," would that have impacted your decision to prescribe the medicine to Ms. Hexum?"
>
> [Objection omitted.]
>
> A: I don't know. I think it would as I stated previously be part of a discussion about the medication options for the condition insomuch as if it was really that common to develop adverse effects *despite the tapering of the drug*, then that may be part of a discussion. But I honestly don't know and I haven't seen this data before or know how accurate is it but if it was the case, I think that would be part of my discussion with them about the difficulty of getting off the drug.
>
> Q: But it would not have changed your ultimate decision to prescribe the drug?
>
> [Objection omitted.]
>
> A: Again, I don't know. I think that would be—I think that would be part of the equation but whether or not the conclusion is still to prescribe Cymbalta or not, I think it would be given fair consideration still but I don't know the

> answer to whether it would still be prescribed or not. I think it would be—again, at the very least, it would be a discussion about the risk of this adverse effects *with the tapering* of the drug and then a discussion about that individual patient's concerns or desires about such and probably my experience with other people on the drug.

(Paley Decl., Ex. 8, at 114:18–118:20) (emphasis added). Wollaston's testimony about how the information about the 44–50% risk of discontinuation symptoms would have impacted his description of the risk of discontinuation symptoms *with* tapered discontinuation indicates that he misunderstood the nature of the 2005 JAD Article's findings. Wollaston apparently believed that the 2005 JAD Article described the risk of experiencing discontinuation symptoms upon tapered withdrawal. Thus, he testified that he doesn't know if a warning that there was a 44–50% risk of discontinuation symptoms with tapering would have caused him to choose not to prescribe Cymbalta for Hexum.[11] He further testified that, at the very least, such a warning regarding the risk of discontinuation symptoms with tapering would be given fair consideration.

As discussed above, with their supplemental briefing Plaintiffs submit evidence indicating that tapering may not help diminish the risk of experiencing discontinuation symptoms. Additionally, Wollaston testified that in February 2012, his general practice was to warn patients of the need to taper. This testimony is corroborated by Hexum's testimony that Wollaston told her she'd be fine if she tapered but sick if she quit "cold-turkey." Thus, Wollaston apparently believed that tapering helps diminish the risk of experiencing discontinuation symptoms. Further, Plaintiffs assert that Lilly either improperly withheld this information or buried it under an avalanche of documents produced in the last week of discovery. Thus, according to Plaintiffs, they were unable to ask Wollaston how this information would have affected his decision to prescribe Cymbalta to Hexum.

On this record, where: (1) Hexum told Wollaston that it was important for her to be able to discontinue the medication in the somewhat near future; (2) Wollaston testified that he wasn't sure if he would have changed his decision to prescribe Cymbalta if the risk of discontinuation

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[11] The Court recognizes that because Wollaston apparently believed that the 2005 JAD Article described the risk of experiencing discontinuation symptoms upon tapered withdrawal, it is unlikely that his opinion would change. Nevertheless, on this record the Court finds that granting summary judgment would be inappropriate.

symptoms with tapered discontinuation was 44–50%; (3) the evidence shows that Wollaston believed that tapering would diminish the risk of discontinuation symptoms; and (4) the evidence indicates that this belief might be false, Plaintiffs raise a triable issue of fact regarding proximate cause.[12]

For the aforementioned reasons, the Court DENIES Lilly's motion for summary judgment.

(2) Independent Knowledge

Plaintiffs also assert that Wollaston had independent knowledge of the relevant risks. As discussed above, Wollaston prescribed Cymbalta to other fibromyalgia patients before prescribing it to Hexum. (Paley Decl., Ex. 8, at 94:16–19.) Wollaston first began prescribing antidepressants during his fellowship—during which time he became aware of the need to taper patients off of some antidepressants because feeling queasy or light-headed would "be not uncommon" from sudden discontinuation. (*Id.* at 82:1–16; Def.'s SUF ¶ 25.) Before prescribing Cymbalta to Hexum, he had patients who experienced discontinuation symptoms upon discontinuing Cymbalta. (Paley Decl., Ex. 8, at 106:14–19.) These patients, who he described as "outliers," experienced such symptoms as light-headedness, dizziness, electrical shock sensation, headaches, and feeling generally unwell. (*Id.* at 106:8–19.) Wollaston also testified that back in 2012, he generally would have characterized Cymbalta's risk of discontinuation symptoms by simply informing patients that they would need to taper off Cymbalta. (*Id.* at 74:21–75:5.) By the time Wollaston prescribed Cymbalta for Hexum, he knew of the need to taper patients off of a medicine like Cymbalta because of the risk of discontinuation symptoms. (*Id.* at 104:13–105:8.)

On balance, the evidence indicates that Wollaston had independent knowledge of the need to taper off Cymbalta because of a risk of discontinuation symptoms upon abrupt

[12] The Court notes that by the time Ben-Artzi began treating Hexum she had already been taking Cymbalta for roughly eight months. However, at the June 11 hearing, Plaintiffs indicated that they intend to proceed on the theory that Lilly improperly failed to warn doctors of the minimum time to taper. Thus, a stronger warning given to Ben-Artzi might have prevented Hexum's harm from taking Cymbalta—i.e. discontinuation side effects. Plaintiffs thus raise a triable issue of fact as to Ben Artzi.

discontinuation. However, as discussed above, Plaintiffs submit evidence indicating that tapering may not diminish the risk of experiencing discontinuation symptoms upon withdrawing from Cymbalta. Thus, Plaintiffs raise a triable issue of fact regarding Wollaston's knowledge.

Moreover, in light of the newly uncovered evidence, the Court finds this case distinguishable from both *McDowell* and *Carnes*. Both of those courts relied, in relevant part, on the prescribing physicians' knowledge of the risks of *abrupt* withdrawal. *See McDowell*, 2014 WL 5801604, at *15–17; *Carnes*, 2013 WL 6622915, at *5–6. Additionally, neither court considered the possibility that there was no difference in the risk of discontinuation symptoms from discontinuing Cymbalta abruptly or tapering.

(3) Conclusion

On this record, Plaintiffs' evidence is sufficient to raise a triable issue of fact and Lilly fails to show that it is entitled to summary judgment under Rule 56. For the aforementioned reasons, the Court DENIES Lilly's motion for summary judgment on Plaintiffs' failure to warn claim.

**3. Plaintiffs' Other Claims Related to Lilly's Alleged Failure to Warn**

In addition to their strict liability—failure to warn claim, Plaintiffs allege claims for: negligence,"strict product liability," negligent misrepresentation, and fraud. (Dkt. 1.) To the extent that each of these claims is premised on the alleged inaccuracy, inadequacy, or misleading nature of Cymbalta's label, each requires proof that the label's alleged deficiencies caused Plaintiffs' injuries. Thus, for the reasons discussed above, the Court DENIES Lilly's motion for summary judgment on each of these claims. *Cf. Motus I*, 196 F. Supp. 2d at 987, 995–999 (granting summary judgment on claims for wrongful death/negligence, strict liability, "survival action," fraud and breach of warranty where all of these claims were "based to some extent" on the defendant's alleged failure to warn and the plaintiff failed to establish causation).[13]

**4. Plaintiffs' Other Claims Related to an Alleged Design Defect**

In addition to Plaintiffs' abandoned designed defect claim, their negligence claim asserts a design defect. Though the complaint fails to specify a design defect, in their Memorandum of

[13] The Court need not address Lilly's arguments as to Plaintiffs' abandoned claims.

Contentions of Law and Fact Plaintiffs assert that Lilly negligently failed to design a lower dosage Cymbalta pill to allow for "proper" tapering. (Dkt. 191: Mem. at 6.) Plaintiffs also indicated at the June 11, 2015 hearing that they intend to proceed with claims based on this 20 milligram "cliff."

The Court notes that pursuant to Federal Rule of Civil Procedure 56(f), it has the authority to grant summary judgment on grounds not raised by a party. Moreover, the Court believes that the briefing and hearing regarding the current motion for summary judgment gave Plaintiffs sufficient notice and a reasonable opportunity to respond to any arguments. *See* Fed. R. Civ. Prod. 56(f); *Norse v. City of Santa Cruz*, 629 F.3d 966, 971 (9th Cir. 2010) (en banc).

It is undisputed that Ben-Artzi told Hexum to switch from 60 milligrams per day to 30 milligrams per day and then to discontinue Cymbalta entirely. Def.'s SUF ¶ 42; Pls.' PFF ¶ 31.) He did not instruct Hexum to take decrease from 30 milligrams to 20 milligrams before discontinuing entirely. Thus, the failure to design a lower dosage Cymbalta pill than the lowest dose then available—20 milligrams—could not have caused Plaintiffs' harm.

In light of the foregoing, the Court hereby cautions Plaintiffs that the Court is dubious of their ability to show that the 20 milligram "cliff" caused their harm. Thus, absent a sufficient proffer of evidence from Plaintiffs, the Court would be inclined to grant summary judgment to Lilly on a claim based on this theory.

## V. SCHEDULE FOR FUTURE PROCEEDINGS

At the hearing held on June 11, 2015, Plaintiffs explained how the newly uncovered Lilly documents will affect their theory of the case. Lilly argued that it would be prejudiced if Plaintiffs were allowed to proceed on a theory not laid out in their complaint. For the reasons discussed at the June 11 hearing, the Court GRANTS Plaintiffs leave to file an amended complaint. Plaintiffs SHALL file their amended complaint on or before June 29, 2015.

Additionally, the Court GRANTS Plaintiffs leave to augment their expert witnesses's declarations to the extent that there is newly uncovered information. Plaintiffs SHALL file their supplemental expert reports on or before June 29, 2015. In light of the foregoing, the Court DECLINES TO REACH Lilly's motions to exclude Morris and Glenmullen and GRANTS Lilly

leave to file amended *Daubert* motions objecting to Plaintiff's expert witnesses. Lilly SHALL file any such amended *Daubert* motion on or before July 7, 2015. Plaintiffs SHALL file any response to such amended *Daubert* motions on or before July 14, 2015.

Moreover, in light of the foregoing, the Court sets this case for trial on August 11, 2015. A pretrial conference shall be held on August 10, 2015 at 3:00 P.M.

## VI. ORDER

1. For the aforementioned reasons, the Court DENIES Lilly's motion for summary judgment on all of Plaintiffs' claims.

2. In light of the foregoing, the Court GRANTS Plaintiffs LEAVE to file an amended complaint and to supplement their expert declarations to the extent that there is newly discovered evidence. Plaintiffs SHALL file their amended complaint and amended expert declarations on or before June 29, 2015.

3. In light of the foregoing, the Court GRANTS Lilly leave to file amended *Daubert* motions objecting to Plaintiff's expert witnesses. Lilly shall file any such amended motion on or before July 7, 2015. The Court GRANTS Plaintiffs leave to file a response to Lilly's amended *Daubert* motions. Plaintiffs SHALL file any such response on or before July 14, 2015.

4. In light of the foregoing, the Court SETS this case for trial on August 11, 2015. The Parties are ORDERED to appear for a pretrial conference on August, 10, 2015 at 3:00 P.M.[14]

**IT IS SO ORDERED.**

Dated: June 19, 2015

STEPHEN V. WILSON
United States District Judge

[14] In light of the foregoing, the Court finds it unnecessary to reach Lilly's argument that it is entitled to summary judgment on Plaintiffs' request for punitive damages. Additionally, given that the Court directed Lilly to complete production of a more detailed privilege log and certain disputed documents and gave Plaintiffs an opportunity to augment the record, the Court need not reach Plaintiffs' request under Federal Rule of Civil Procedure 56(d).