UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CLAUDIA HERRERA AND PETER LOWRY,

Plaintiffs,

v.

ELI LILLY AND COMPANY, an Indiana Corporation,

Defendant.

CASE NO. 2:13-cv-02702-SVW-MAN

ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [120]

I. INTRODUCTION

This products liability action arises from plaintiff Claudia Herrera's ("Herrera") alleged "discontinuation" symptoms upon ceasing to take Cymbalta—defendant Eli Lilly and Company's ("Lilly") serotonin norepinephrine reuptake inhibitor ("SNRI"). On April 17, 2013, Herrera sued Lilly in federal court. (Dkt. 1.) Herrera and her husband, plaintiff Peter Lowry ("Lowry"), 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. 186.)

Presently before the Court are Lilly's motion for summary judgment (dkt. 120), Lilly's motion to exclude the expert testimony of Dr. Joseph Glenmullen ("Glenmullen") (dkt. 138), 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 139). 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 ("label") for Cymbalta. *Id.* The Cymbalta label that was FDA approved and in effect in March 2007 included the following language in the "Precautions" section:

> Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo-controlled clinical trials of up to 10-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in either the MDD [major depressive disorder] or GAD [generalized anxiety disorder] Cymbalta-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.
>
> During marketing of other SSRIs [selective serotonin reuptake inhibitors] and SNRIs . . ., 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 previous prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

(Def.'s SUF ¶ 2.) The 2007 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 (see PRECAUTIONS). Patients should be monitored for these symptoms when discontinuing treatment. 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.

(Def.'s SUF ¶ 3.)

Though Cymbalta's label recommends tapering, it does not provide specific parameters—such as timeframe or dosage increments— for designing an appropriate taper

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

regime. (Paley Decl., Ex. 9.) The label also states that Cymbal "should be swallowed whole and should not be chewed or crushed, nor should the contents be sprinkled on food or mixed with liquids." (Pls.' RFF ¶ 50.) 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]:

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)

[2] The Court notes that in the related action of *Hexum et al. v. Eli Lilly and Co.*, No. 2:13-cv-2701, Lilly submitted evidence showing that alongside its 2001 New Drug Approval application Lilly submitted to the FDA nearly identical data to that disclosed in this table. (2701 Dkt. 153-1: Paley Decl. in Supp. of Def.'s Summ. J. Reply ("Paley Supp. Reply Decl. re Hexum") ¶ 6; Paley Supp. Reply Decl. re Hexum, 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.

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. Herrera's Use and Discontinuation of Cymbalta

Around 2006 or 2007, Herrera[4] began experiencing depression on two or three days per month. (Def.'s SUF ¶ 16.) At the same time she also began experiencing anxiety that hindered her ability to perform at work. (*Id.*) Herrera also has a self-diagnosed history of trichotillomania (compulsively pulling out one's hair), which she asserts began at age 12. (Wisner Decl., Ex. 5, at 162:24–163:19.) Herrera's general practitioner, Dr. Mark Braunstein[5] ("Braunstein"), prescribed Wellbutrin to treat her depression.[6] (Def.'s SUF ¶ 19.) According to Herrera, Wellbutrin was ineffective. (*Id.*) Braunstein prescribed Cymbalta for Herrera around March 2007. (Def.'s SUF ¶ 20.) Herrera does not recall what Braunstein told her about the risks of taking Cymbalta. (Wisner Decl., Ex. 5, at 113:8–15.) When asked whether she recalls what Braunstein told her about discontinuing Cymbalta, Herrera testified that "[w]e never discussed the stopping of the drug—of the drug. I don't remember." (*Id.* at 115:3–6.) She also testified that she did not discuss Cymbalta discontinuation or Cymbalta tapering with Braunstein. (*Id.* at 170:12–18.) The only written material that Braunstein provided to Herrera regarding Cymbalta

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[4] The Court notes that Herrera testified that as of the date of her deposition she suffered from memory loss. (Wisner Decl., Ex. 5, at 39:10–13.) Herrera's deposition indicates that she can't remember some of the events at issue in this case—such as what Braunstein told her about Cymbalta's risks. (Wisner Decl., Ex. 5, at 94:5–20; 113: 8–12.) Plaintiffs thus face substantial hurdles regarding Herrera's credibility. Nevertheless, the Court may not and does not reach those credibility issues upon consideration of the instant motion for summary judgment.

[5] The Court notes that in his deposition, Braunstein had limited recollection of Herrera and his treatment of her depression. *See, e.g.*, (Wisner Decl., Ex. 1, 44:10–45:20) (discussing Braunstein's limited memory of Herrera). The difficulties caused by Braunstein's forgetfulness are compounded by the unavailability of his medical records pertaining to Herrera. While Braunstein's inability to remember Herrera might impact his credibility (which the Court does not here consider), it does not render his testimony inadmissible. Except where otherwise noted, Braunstein's testimony is not overly speculative; in his deposition he testified to the best of his recollection or attested to his general practices.

[6] Herrera's pharmacy records also indicate that a different doctor prescribed Zoloft and Wellbutrin for her in 2001. (Paley Decl., Ex. 7.)

was the package insert, which was included with the Cymbalta samples that he gave her. (*Id.* at 113:16–20; 114:23–115:24.) Herrera asserts that she read this information to the best of her ability. (*Id.* at 113:21–25.)

Although Braunstein is a general practitioner, he asserts that from 2001 to 2010 close to 50% of his practice was comprised of patients who he was following for psychiatric conditions. (Paley Decl., Ex. 2, at 23:9–20.) Braunstein prescribed Cymbalta to "many" patients prior to prescribing Cymbalta to Herrera. (Paley Decl., Ex. 2, at 117:20–118:2.) According to Braunstein, he learned of the need to taper off of antidepressants twenty years ago as part of his basic psychpharmacology training (though the antidepressants he studied then were not SSRIs or SNRIs). (*Id.* at 131:10–21.) Additionally, based on the Cymbalta materials provided to him in 2007, Braunstein then knew that a "significant number of people" had unpleasant withdrawal symptoms from Cymbalta upon abrupt withdrawal.[7] (*Id.* at 73:11–24.) Because of this knowledge, Braunstein always warns people that they can't abruptly stop taking Cymbalta—they need to taper it instead. (*Id.* at 73:19–23.) Thus, while Braunstein doesn't recall his conversation with Herrera, he testified that he believes that he probably warned her that she couldn't abruptly stop taking Cymbalta but would need to taper it. (*Id.* at 74:1–3.) At the time he prescribed Cymbalta to Herrera, Braunstein would have had a "working knowledge" of the information contained in Cymbalta's product label and would have relied (at least in part) on the information therein. (*Id.* at 54:14–55:5.)

When asked to explain the meaning of the Cymbalta label's language that "the following symptoms occurred at a rate greater than or equal to 1 percent,"[8] Braunstein said that it means

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[7] Notwithstanding the foregoing, Braunstein also testified that he did not become aware of the extent of the withdrawal syndrome from Cymbalta that he knew of on the date of his deposition until two years prior (sometime in 2012). (Paley Decl., Ex. 2, at 151:11–25.) He then went on to clarify that the thing he was surprised to learn was that Cymbalta was supposedly "addictive"—which Braunstein uses to mean that some people supposedly can't discontinue Cymbalta at all because of the extreme severity of their discontinuation side effects. (*Id.* at 153:2–154:2.) Braunstein thus uses the word "addictive" to mean something other than causing discontinuation side effects. (*Id.*)

[8] Counsel apparently read to Braunstein the wrong version of the label. Regardless, the only difference between this portion of the labels is the use of 1% or 2%—which is immaterial to the present analysis.

"exactly what it says, that it could be equal to 1 percent rate or much higher[.]" (*Id.* at 137:13–25.) He also testified that he understands the phrase "at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo" to mean that "it's a lot higher rate, but they don't tell you how much higher." (*Id.* at 137:5–12.) Braunstein testified that he did not see or receive the 2005 JAD Article prior to his 2014 deposition. (*Id.* at 158:17–161:3.) He also testified that he doesn't remember if he had seen the data reflected in the 2005 JAD Article in 2007, but that:

> the numbers sound like—the 44% of patients having withdrawal symptoms sounds . . . not like what [he] would have known back then; that so many lasted two weeks or longer . . . [he] had seen it, but [he doesn't] know that [he] knew it was 10 %. [He] might have thought it was lower than that at two weeks and later of actual withdrawal symptoms, not re-emergence of underlying symptoms.

(*Id.* at 74:7–15.) He further testified that this was an important distinction. (*Id.* at 74:17.) He also testified that if Lilly was aware that the risk of discontinuation side effects was between 44 and 50 percent, then he believes Lilly should have disclosed this information. (*Id.* at 22–24.) He also testified that while this was a "high number," he was aware from personal experience "that these symptoms were common." (*Id.* at 163:6–16.)

Herrera asserts that her depression and anxiety improved within one month of commencing Cymbalta. (Def.'s SUF ¶ 21.) She took Cymbalta every day from the time she commenced Cymbalta in 2007 until she discontinued it in 2012. (Wisner Decl., Ex. 5, at 135:12–14.)

Around early 2012, Herrera "realized that [she] wasn't feeling very well for a long time on Cymbalta." (Wisner Decl., Ex. 5, at 84:7–11; Def.'s SUF ¶ 38.) She was experiencing weight gain, lethargy, some anxiety, and was feeling "bluesy" all the time. (Def.'s SUF ¶ 38.) Herrera asserts that "a bulb went off in [her] head and told [her] it's time to get off any drugs." (*Id.*; Wisner Decl., Ex. 5, at 84:17–19.) She therefore spoke to Dr. Mayur Patel ("Patel")—a pulmonologist who was treating Herrera's mother. (Wisner Decl., Ex. 5, at 79: 9–23, 84:13–22.) Though the precise parameters are disputed, it is undisputed that Patel prescribed a tapering regimen for Herrera. (Def.'s SUF ¶ 40.) According to Herrera, Patel told her to drop from 60 milligram to 30 milligram doses of Cymbalta for 30 days, after which she should cease taking

any Cymbalta. (Wisner Decl., Ex. 5, at 84:23–85:2.) According to Patel, he told Herrera to take 30 milligrams of Cymbalta per day for three weeks, at which point she should return for a follow up visit. (Paley Decl. in Supp. of Def.'s Reply ("Second Paley Decl."), Ex. 14, at 82:13–17.) Herrera did not return to Patel for the March 1, 2012, visit that was scheduled for her. (Def.'s SUF ¶ 41.) While taking 30 milligrams of Cymbalta per day, Herrera felt the same as when she was taking 60 milligrams per day. (Wisner Decl., Ex. 5, at 243:23–244:2.)

Herrera discontinued any Cymbalta use on or about March 1, 2012. (Def.'s SUF ¶ 42.) Herrera asserts that she first felt what she claims were Cymbalta withdrawal symptoms on March 3, 2012. (Wisner Decl., Ex. 5, at 251:19–21.) On March 13, 2012, Herrera returned to Patel's office with complaints of depression, anxiety, difficulty sleeping, nausea, and diarrhea. (Def.'s SUF ¶ 43.) She also complained of having a sensation like she needed to use the restroom. (Wisner Decl., Ex. 5, at 251:3–14.) In addition to these symptoms, Herrera asserts that she experienced brain zaps, suicidal ideation, muscle spasms, the sensation of objects crawling in her skin, hot flashes, body shivers, memory loss, and skin irritation. (Def.'s SUF ¶ 46.)

On March 28, 2012, Herrera asked her husband to call Patel and to ask Patel what to do because her condition wasn't improving. (Wisener Decl., Ex. 5, 263:1–9.) On that date, Patel prescribed 30 milligrams of Cymbalta to Herrera. (Def.'s SUF ¶ 44.) Herrera refused to take the 30 milligram dose of Cymbalta that Patel prescribed. (*Id.*) She did not return to Patel's office until March 2013. (Def.'s SUF ¶ 45.)

D. Herrera's Other Medical Conditions[9]

Sometime in 2007 or 2008, Herrera was diagnosed with hypothyroidism. (Wisner Decl., Ex. 5, at 206:9–16.) In 2010, Herrera was diagnosed as perimenopausal. (Wisner Decl., Ex. 5, at 199:19–200:6.) In her June (or July) 2010 intake questionnaire, Herrera indicated that she was feeling "bluesy", suffered from hot flashes, had "dry/patchy" skin, had a stiff/heavy head/neck, had mild back pain, had tinging or numbness (which she asserts plagued her feet and lower legs),

[9] The Court notes that Plaintiffs dispute the validity of the diagnoses that Herrera received. Thus, in this section the Court merely describes these diagnoses to provide context for the Court's analysis of the legal issues. The Court does not here decide that Herrera in fact suffered from these conditions.

had gained weight, had very low energy, was unable to sleep or wake up, had very poor sexual desire, suffered from lightheadedness or dizzy spells, had headaches, and had changes in her visual acuity. (*Id.* at 172:9–193:6.) Though Herrera asserts that she doesn't remember suffering from memory problems in 2010, she checked the box on the intake form that she completed in 2010 indicating that her memory and concentration were very poor. (*Id.* at 188:13–190:25.)

III. PROCEDURAL HISTORY

On February 5, 2015, Lilly filed the instant motion for summary judgment. (Dkt. 120.) Since then, much has happened in this case.

On April 21, 2015, Plaintiffs moved for sanctions against Lilly. (Dkt. 257.) In their sanctions motion, Plaintiffs asserted that Lilly improperly withheld documents—1,000 of which were allegedly withheld pursuant to attorney-client privilege—and failed to timely provide an accurate privilege log. (Dkt. 257: 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. 300.) 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.[10] 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[11] 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

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[10] 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.)

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

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 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) Herrera's physicians had independent knowledge of the relevant risks, and (2) Plaintiffs' requested warning would not have changed Herrera'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[12] 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 consistent 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

[12] The Court notes that the label in effect when the plaintiff was first prescribed Cymbalta had slight differences from that in effect when Herrera was first prescribed the drug. *See McDowell*, 2014 WL 5801604, at *1–3. The most relevant difference is that the "Warnings and Precautions" section stated that the listed side effects occurred following "abrupt or tapered discontinuation in placebo-controlled clinical trials." *Id.* at *2.

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 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 largely on the proper interpretation of Cymbalta's label's statement that after "abrupt discontinuation in placebo-controlled clinical trials of up to 10-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in either the MDD [major depressive disorder] or GAD [generalized anxiety disorder] Cymbalta-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paraesthesia; vomiting; irritability; and nightmare."

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 one discontinuation symptom compared to 22.9% of patients taking the placebo. (Def.'s SUF ¶ 8.) 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. 10, at 276.)

Plaintiffs assert that the label is properly understood to refer to the side effects in the aggregate, suggests that 2% or only slightly greater than 2% 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.[13] 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 2% 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%.[14]

In the instant motion, Lilly argues that Plaintiffs can't establish proximate cause because Herrera's prescribing physicain had independent knowledge. Lilly's argument that the prescribing physician had independent knowledge of the relevant risks turns on a possible distinction between abrupt and tapered withdrawal: If there is a difference between the risk of discontinuation symptoms upon abrupt withdrawal and the risk of discontinuation symptoms

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[13] 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 ¶ 9.) 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 ¶¶ 12–13.)

[14] 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.

upon tapered withdrawal, then the physicians' independent knowledge of the need to taper could satisfy the relevant warning.

As discussed above, as of 2007 (when Braunstein prescribed Cymbalta to Herrera) he had already prescribed it for "many" other patients. Additionally, as of 2007, he knew that there were a "significant number of people that did have unpleasant withdrawal symptoms with Effexor and then with Cymbalta upon abrupt withdrawal." (Paley Decl., Ex. 2, at 73:19–22.) In light of this knowledge, he always warns people not to stop Cymbalta suddenly. He further testified that he knew that these symptoms were "common." (*Id.* at 163:10–11.) Additionally, Braunstein had seen some combination of "[d]ysphoric 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" with virtually every anti-depressant with which he's ever had experience. (*Id.* at 139:6–140:15.) He understood this independently of Cymbalta's prescribing information. (*Id.* at 140:16–20.)

While this evidence clearly shows that Braunstein had independent knowledge in 2007 of a significant likelihood of experiencing discontinuation symptoms upon abrupt withdrawal, it says nothing of Braunstein's knowledge regarding the risk of discontinuation symptoms upon tapered withdrawal. Moreover, Braunstein's testimony clearly indicates that he believed that tapering would substantially decrease the risk of experiencing discontinuation symptoms. For example, Braunstein testified that if a revised warning had been given he would have "maybe even more emphasized that do not stop this abruptly, that this is something that has to be weaned off of *or there's a high risk of withdrawal reaction*[.]" (Paley Decl., Ex. 2, at 164:15–25.)

Alongside their recent supplemental briefing, Plaintiffs submit evidence indicating that the risk of experiencing discontinuation symptoms upon withdrawing from Cymbalta may be the same regardless of whether the patient tapers off of the medication or discontinues abruptly. Moreover, 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 Braunstein how this information would have affected his decision to prescribe Cymbalta to Herrera.

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.

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).[15]

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 Contentions of Law and Fact Plaintiffs assert that Lilly negligently failed to design a lower dosage Cymbalta pill to allow for "proper" tapering. (Dkt. 186: 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."

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

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. However, before the Court does so Plaintiff is entitled to 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).

Plaintiffs assert that Patel told Herrera to take 30 milligrams for 30 days and then to cease taking Cymbalta. (Wisener Decl., Ex. 5, at 242:4–12.) Herrera also asserts that she followed this plan. (*Id.* at 242:22–243:4.) Herrera does not allege that she took any 20 milligram Cymbalta pills. Thus, based on the evidence currently before the Court, 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 4, 2015. A pretrial conference shall be held on August 3, 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 4, 2015. The Parties are ORDERED to appear for a pretrial conference on August, 3, 2015 at 3:00 P.M.[16]

IT IS SO ORDERED.

Dated: June 19, 2015

STEPHEN V. WILSON
United States District Judge

[16] 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).