UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01614-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson **APPENDIX A** **PLAINTIFFS' PROPOSED FACTS**
JANINE ALI, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01615-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson **APPENDIX A** **PLAINTIFFS' PROPOSED FACTS**

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PLAINTIFFS' PROPOSED FACTS

In addition to those facts proposed by Defendant Eli Lilly and Company ("Lilly"), there are additional facts relevant to the issues raised in Lilly's Motions for Summary Judgment. Due to the volume of facts at issue, Plaintiffs submit this Appendix outlining those additional facts for the Court to consider in rendering its opinion. Plaintiffs' Proposed Facts ("PPF") are supported by a Declaration of R. Brent Wisner in Support of Plaintiffs' Opposition to Defendant's Motions for Summary Judgment, which authenticates the various documents cited throughout this Appendix and in Plaintiffs' Opposition to Defendant's Motion for Summary Judgment filed

concurrently.

PPF # 1. In 1996, Lilly began a marketing campaign to distinguish Prozac from other antidepressants, such as Zoloft and Paxil, because of Prozac's favorable withdrawal profile. Exh. 1, Detke Depo. at 181:17-184:16; Exh. 2, Email (Nov. 11, 2002) ("Discontinuation symptoms are a big deal in MDD (thanks to ourselves with Prozac promotion)."). Specifically, Prozac has a long half-life (6 days) and Paxil (21 hours) and Zoloft (24 hours) have shorter half-lives. *See* Exh. 5, Lilly's Responses to Requests for Admissions, Nos. 19-25, pgs.11-12. This effort included funding a closed symposium on December 17, 1996, called "SSRI Discontinuation Events" and resulted in the publication of a supplement in the Journal of Clinical Psychiatry. Exh. 3, Excerpts, 58 J. Clin. Psych. Suppl. 7, at *2 (1997). Many of the researchers in this symposium would later be involved with Cymbalta's global advisory boards. Exh. 1, Detke Depo. at 47:18-51:18. Lilly also funded another study during this time period headed by one of individuals, Jerold Rosenbaum and several Lilly employees, which compared withdrawal reactions in patients taking Prozac, Paxil and Zoloft. Exh. 4, J. Rosenbaum et al, *Selective serotonin reuptake inhibitor discontinuation syndrome: a randomized clinical trial*, 44 Biological Psychiatry 2, 77-87, 85 (1998); Exh. 5 at No. 42, pg.19. In the study, withdrawal side effects were systematically monitored using a symptom checklist rating scale called a DESS Checklist, and concluded that Prozac was safer with regard to discontinuation due to its extended half-life. Exh. 4 at *79; Exh. 5 at No. 43, pg. 19; Exh. 26, DESS Checklist at FAVA-003-004. Lilly used this research in its marketing to promote "the idea that Prozac's half-life prevents discontinuation syndrome, making direct comparisons to Paxil and Zoloft." Exh. 6, Prozac Pyramid Positioning / Message Development Research, at 6 (2000).

PPF # 2. Lilly commissioned a "U.S. Strategic Pricing Study for Cymbalta" which

was finalized on August 2, 2002—two years before Cymbalta's launch. Exh. 7. The study explored what attributes influenced third-party payors, physicians, and patients' view of an antidepressant and price. *Id.* at 3-5. For prescribers, one of the primary "factors" that "could justify or warrant consideration of premium pricing relative to Effexor" was if Cymbalta possessed "a significant decrease in rate and severity of withdrawal / discontinuation syndrome." *Id.* at 91. And, under the slide "Product Attributes That Justify A Premium Price Over Other Antidepressants" it states that, "[m]inimization of withdrawal syndrome is seen as important." *Id.* at 96.

PPF # 3. In July 2003, a year before Cymbalta was approved, Dr. David Perahia, a lead research physician for Lilly, expressed concerns over whether Lilly was being sufficiently proactive with regard to Cymbalta's potential withdrawal risks. Exh. 8, Emails (July 2, 2003) at CYM-R-01873414-415. Dr. Perahia sent an email to Dr. Michael Detke, the Cymbalta & Prozac Global Medical Director at the time:

> I must confess to being a little unconfortable [sic] about the whole discontinuation thing. Maybe it's more of a UK specific issue, but paroxetine [Paxil] is taking a fearsome battering in the media over here at the moment, and a significant part of that is discontinuation-related stuff. It's clear that duloxetine has a significant DESS [discontinuation-emergent signs and symptoms] liability (on abrupt discontinuation, admittedly, but how much taper data do we have yet ?), and the perception will be further reinforced by our short t1/2 [half-life] which is seen by many as being directly linked (partly due to the work Lilly did around Prozac's long t1/2……).
>
> … If we're not careful, the environment is set for this to blow up in our faces unless we're proactive about it.

Id. at CYM-R-01873415. In response, Dr. Detke explained that he did not believe the withdrawal issue was as important in the United States based on Lilly's efforts in promoting the half-life issue with Prozac. *Id.* He asked for comment from Dr. Madelaine Wohlreich, a research physician with the U.S. Affiliate. Dr. Wohlreich stated:

> The feeling here has been that since it will be in our FDA label that tapering is recommended, that there is not a lot more that needs to be done proactively.
>
> When we have said at consulting conferences that discontinuation type side effects could be seen on abrupt taper, clinicians have not appeared to be terribly concerned.

Id. Dr. Perahia, however, was not satisfied with simply recommending tapering. He responded:

> It's not that the discontinuation issue will necessarily be something we can proactively use to sell duloxetine (I believe not, at least from a historical perspective), more that it's something that the media and regulatory authorities might well latch on to unless we are proactive about it. I sense we are being a bit complacent around this, and it could hurt us (e.g. no diffs from parox on abrupt discontinuation in our trials, short t1/2 etc. etc.)
>
> As an opening gambit, I would define proactive as:
>
> (1) Write up our data and get it published as a priority rather than dragging our heels
>
> (2) Consider running a trial which might add to the evidence base on how best to manage stopping the drug, e.g. over how long should drug be tapered? (open label treatment, then perhaps 3 arms looking at abrupt discontinuation vs. 2 week taper vs. 4 week taper in a double blind fashion, with frequent visits). Good PR due to being open and pushing the science, with an evidence-based recommendation at the end to boot. I'm sure Matt would blanch at this suggestion, but we can't just stick our head into the sand.
>
> Paroxetine is being torn to pieces by the media (and in fact regulators too) over in Europe, and much of the criticism is stemming from the perception that GSK have been, to put it politely, less than transparent about discontinuation with paroxetine and how best to manage it. I would rather we didn't fall into the same trap.

Id. Notwithstanding Dr. Perahia's suggestion, Lilly never conducted any clinical trials where withdrawal was measured beyond two weeks and conducted one study for a Cymbalta indication where abrupt versus taper was measured. Exh. 9, Wohlreich Depo. at 426:22 – 427:24.

PPF # 4. On August 17, 2004, two weeks after Cymbalta was approved, Boehringer Ingelheim presented a "Patient Segmentation Study" designed to isolate what motivates physicians to prescribe antidepressants. Exh. 10. Under the section "Factors Influencing

Doctor's Selection of an Antidepressant" it states that the most important factor is "avoid dependence / withdrawal issues." *Id.* at 48, CYM-02784163. The document explains that "[t]he results show that when promoting Cymbalta to doctors . . . 'Avoid dependence / withdrawal issues' . . . must be addressed in order for a productive communication." *Id.* at 50, CYM-02784164. Later in the study, the researchers try to unpack the "avoid dependence / withdrawal issues" and explain that it "is one of the important factors in selecting an antidepressant" and thus "can be used as an opportunity for Cymbalta." *Id.* at 69, CYM-02784183. Following a comprehensive analysis of physician preferences, the researchers conclude that, in marketing Cymbalta to physicians, "avoid dependence / withdrawal issues" is one of the four primary factors influencing physician prescribing practices. *Id.* at 156-57, CYM-02784270-*271. For general practitioners, "less side effect profile and 'it does not cause dependence' have to be stressed[.]" *Id.*

PPF # 5. In November 2005, Dr. Perahia published a journal article entitled "Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder" in the Journal of Affective Disorders ("Perahia article"). Exh. 12. This publication contained a re-analysis of Lilly's discontinuation data and made specific recommendations about how to safely taper off Cymbalta based on that analysis. *E.g., id.* at 208 ("It is recommended that, whenever possible, clinicians gradually reduce the dose no less than 2 weeks before discontinuation[.]"). The pooled reanalysis showed that between 44.3% and 50% of Cymbalta patients suffered from "discontinuation" side effects, and that between 9.6% and 17.2% of Cymbalta users suffered *severe* withdrawal. *Id.* at 208-211. Most withdrawal symptoms, moreover, lasted longer than two weeks (the period withdrawal was studied). *Id.* The article also noted that the "main limitation of this review" is that withdrawal data "were assessed

by means of spontaneous reports rather than a symptom checklist" and that the "latter might be expected to produce higher incident rates." *Id.* at 211. Although Lilly had a practice of distributing reprints of articles published by Lilly scientists, *see* Exh. 9, Wolhreich Depo. at 163:8-165:25, the Perahia article was never distributed as a reprint to physicians. Specifically, neither Dr. Bahadori or Dr. Ahmed, the two physicians who prescribed Cymbalta to Plaintiffs Hagan-Brown and Ali, were ever given the Perahia article or told about the data contained therein. Exh. 19, Bahadori Depo. at 131:4-132:13; Exh. 20, Ahmed Depo. at 118:20-119:4.

PPF # 6. Shortly after Cymbalta was approved, Lilly created a medical information letter about discontinuation symptoms that Lilly would send to physicians who specifically requested information about discontinuation. Exh. 9, Wolhreich Depo. at 83:4-87:7; Exh. 11, Decl. Sarah L. Helgeson, 2004 at 7-10 (Oct. 12, 2004). The original letter, which was approved by the FDA, did not include the Perahia analysis. Exh. 11 at 7-10. However, in early 2006, a few months after the Perahia article was published, Lilly updated and received FDA approval of the medical information letter, which included the Perahia analysis. *Id.* Lilly never sent this letter to all U.S. physicians and did not send this letter to either Plaintiff Hagan-Brown's or Ali's prescribers. Exh. 13, Lilly's Responses to Ali's Requests for Production, Nos. 88-95, at 33-38; Exh. 14, Lilly's Responses to Hagan-Brown's Requests for Production, Nos. 88-95, at 33-37; Exh. 15, Letter from Jennifer Holmes at 3 (Mar. 19, 2015).

PPF # 7. The Cymbalta label in Europe, starting in 2006, reads as follows:

> Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt (see section 4.8). In clinical trials adverse events seen on abrupt treatment discontinuation occurred in approximately 45% of patients treated with Cymbalta and 23% of patients taking placebo. The risk of withdrawal symptoms seen with SSRI's and SNRI's may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction. The most commonly reported reactions are listed in section 4.8. Generally these symptoms are mild to moderate, however, in some patients they may be severe in

> intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of no less than 2 weeks, according to the patient's needs (see section 4.2).

Exh. 16, Summary of Product Characteristics (Cymbalta), at 6. It is "conclusively established" that the "information contained in" the European label "is accurate and true" since Lilly admitted it. Fed. R. Civ. P. 36(b); Exh. 5, No. 44, at pg. 20. There are considerable differences between the information contained on the European label and the U.S. label. *See* Exh. 17, Side by Side Comparison of U.S. and European Labels for Cymbalta, at 1-3; Exh. 18, Hoog Depo. at 181:25-184:23; Exh. 21, Kuntz Depo. at 100:4-107:17, 108:15-117:23 (discussing, at length, the differences between the labels with key regulatory officer for Lilly). Nothing prevented Lilly from seeking to include the information contained on the European label on the U.S. Label. Exh. 18, Hoog Depo. at 183:14-184:23. The prescribers for Plaintiffs Hagan-Brown and Ali both testified that (1) the information contained on the European label is not contained in the U.S. Label, (2) the missing information is something they would have wanted to know as prescribers, and (3) had Lilly included this information within the U.S. Label, it would have changed the way they discussed withdrawal risks with both Plaintiffs. Exh. 19, Bahadori Depo. at 112:15-121:8, 149:8-151:14; Exh. 20, Ahmed Depo. at 127:15-135:1, 144:7-146:20.

PPF # 8. In the Cymbalta clinical trials where withdrawal was measured, Lilly deliberately avoided using a symptom checklist or elicited scale to measure withdrawal reactions to avoid seeing higher incident rates. *See* Exh. 22, Email exchange at 1, CYM-02806828 (May 5, 2008). In May 2008, a Lilly researcher working on a different Lilly product emailed Dr. Detke about which "withdrawal scale" Lilly used to "verify that there were no discontinuation

symptoms" associated with Cymbalta. *Id.* Dr. Detke responded that "[w]e didn't use any elicited scales[.]" *Id.* And then, a minute later, Dr. Detke followed up, explaining why Lilly did not use a scale: "If you use an elicited scale, you'll see higher rates. This WILL end up in the label." *Id.*

PPF # 9. Lilly did, however, measure withdrawal reactions using a symptom checklist in two studies comparing Cymbalta against Effexor. The studies, HMBU & HMCQ, had a two-week taper period, wherein patients were stepped off of Cymbalta 30 mg each week. *See* Exh. 23, Excerpts of HMBU Study Protocol at *23, CYM-00804175; Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 124:1-128:10. According to Dr. Perahia, who specifically designed the taper period for HMBU: "I see a number of reasons for having a [taper period] . . . Individuals both inside and outside Lilly have suggested that DESS might provide a significant area of difference between the drugs favouring Cymbalta, so an appropriately-designed taper period may yield valuable data." Exh. 29, Email exchange at 3, CYM-01780903. During the taper period, patients were assessed for withdrawal reactions using the Association for Methodology and Documentation in Psychiatry scale ("AMDP-5"), a checklist that has many of the same symptoms as the checklist used by Lilly during its Prozac study, i.e., DESS checklist. *Compare* Exh. 25 at CYM-01932484-*485 (AMDP-5 Checklist) *with* Exh. 26 at FAVA-003-004 (Prozac study checklist) and Exh. 4 at *79. For Study HMBU, the results showed that, using the AMDP-5 checklist, 78.1% of patients who tapered off Cymbalta experienced at least one withdrawal reaction. Exh. 27 at CYM-00145306; *see* Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 141:5-142:18. For Study HMCQ, using the AMDP-5 checklist, 74.1% of patients who tapered off Cymbalta experienced at least one withdrawal reaction. Exh. 28 at CYM-00149293; *see* Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 144:19-145:9. The data also showed no statistically

significant difference in overall withdrawal reactions between Cymbalta and Effexor. Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 151:19-152:4. Thus, in the two studies where Lilly used a symptom checklist to measure withdrawal reactions for patients tapering off Cymbalta, the data showed that approximately 74%-78% of patients experienced withdrawal. This is almost double the rate observed in the Perahia article, i.e., 44.3%, where only abrupt symptoms were measured without a symptom checklist. When these trials were published in 2008, they did not disclose the data obtained on withdrawal using the AMDP-5 checklist and falsely represented that withdrawal on Effexor was worse. *See* Exh. 45, Perahia et al, A *randomized, double-blind comparison of duloxetine and venlafaxine in the treatment of patients with major depressive disorder*, 42 J. Psych. Res., 22-34 (2008).

PPF # 10. After Cymbalta was approved by the FDA, Lilly conducted a clinical trial wherein Lilly specifically measured whether tapered versus abrupt discontinuation affected the likelihood of withdrawal. Exh. 1, Detke Depo. 197:12-197:20. The study, HMBR, which was completed in March 2006, contained a discontinuation phase, wherein patients were either abruptly discontinued off the drug or tapered over a two week period. Exh. 30, HMBR Study Report at CYM-00745295; Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 153:6-154:17. The taper period contemplated a 50% dose reduction each week until 30mg. Exh. 30, HMBR Study Report at CYM-00745295. The results of the study showed that, while there was a difference between Cymbalta and placebo in the emergence of withdrawal symptoms, there was no difference between tapering or abruptly discontinuing within the Cymbalta treatment groups. *Id.* at CYM-00745467; Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 153:16-159:21. Study HMBR was submitted to the FDA as part of its supplemental New Drug Application seeking an indication for Generalized Anxiety Disorder. Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 154:22-155:7.

As part of that application, Lilly proposed changes to the Cymbalta warning regarding withdrawal, indicating that "when patients were tapered over 2 weeks after acute treatment" no discontinuation symptoms were observed. *See* Exh. 31, Email exchanges at 2, CYM-02363883 (Sept. 14, 2006 – Sept. 17, 2006). This proposed change drew criticism from Lilly physician Richard Bump, who expressed 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 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.

Id. at CYM-02363884. In response, Dr. Detke agreed with Dr. Bump, and proposed that the last sentence in the first paragraph be removed. *Id.* at CYM-02363882. Dr. Detke explained that:

> Overall, it strongly implies that tapering substantially improves tolerability, which does not represent the data accurately. To Rick'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.

Id.; *see* Exh.1, Dekte Depo. at 283:6-283:20, 284:14-284:18. Dr. Detke also went on to note that Lilly's data about tapered discontinuation is inconsistent with the label's warning:

> [T]he last paragraph, second sentence 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[.]

Exh. 31 at CYM-02363882. Dr. Detke acknowledged that the data did not support any benefit from tapering and that the class labeling is inconsistent on this point, but did not recommend changing the label because it is "not worth the fight" and "it may still help patients to taper[.]" After Study HMBR, Lilly did not conduct further clinical trials wherein abrupt and tapered discontinuations were directly compared. Exh. 24, Rule 30(b)(6) Depo., Wohlreich, at 159:11-

159:22; Exh. 9, Wohlreich Depo. at 397:16-400:4. According to Dr. Detke, the observed differences between tapering and abrupt discontinuation were too small to warrant further investigation. Exh. 1, Detke Depo. at 198:2-198:13, 213:9-213:16, 266:9-266:23. Both prescribers for Plaintiffs Ali and Hagan-Brown testified that they would have wanted to know about Lilly's abrupt v. taper data and would have considered such information in appreciating the risks and benefits of Cymbalta before prescribing the drug. Exh. 20, Ahmed Depo. at 142:2-145:18; Exh. 19, Bahadori Depo. at 132:14-138:11.

PPF # 11. Lilly's Rule 30(b)(6) representative on regulatory matters testified that nothing under federal law prevented Lilly from strengthening the discontinuation warnings on the Cymbalta label. Exh. 32, Rule 30(b)(6) Depo., Phillips, at 202:7-204:21.

PPF # 12. In 2007, the Division of Medication Errors and Technical Support ("DMETS") within the FDA issued a Memorandum. Exh. 33, Memorandum, Division of Medication Errors and Technical Support, FDA, at 1-18, CYM-02053036-*53 (Mar. 8, 2007). The Memorandum "identified a signal involving the opening of Cymbalta capsules prior to administration to achieve a lower dose of the drug" during "routine post-marketing surveillance[.]" *Id.* at 1, CYM-02053036. The Memorandum also specifically identified cases wherein patients were "opening the capsules to create a dose of Cymbalta less than 20 mg in an attempt to reduce the adverse events associated with the discontinuation of Cymbalta." *Id.* at 7, CYM-02053042. Lilly did not take any action to warn patients about this issue through changing the Cymbalta label, notwithstanding the fact that it was possible. Exh. 21, Kuntz Depo. at 199:8-205:10.

PPF # 13. Plaintiffs tender the expert opinion of Joseph Glenmullen, M.D. *See* Exh. 34, Glenmullen Expert Report (Sept. 22, 2014); Exh. 35, Glenmullen Addendum (May 11,

2015). Dr. Glenmullen is a Harvard-trained psychiatrist who is a Clinical Instructor in Psychiatry at Harvard Medical School. Exh. 34, Glenmullen Expert Report at 2-3. Dr. Glenmullen is the author of *The Antidepressant Solution: A Step-by-Step Guide to Overcoming Antidepressant Withdrawal, Dependence, and "Addiction"* which specifically focuses on the risks and treatments associated with antidepressant withdrawal. *Id.* As part of Dr. Glenmullen's original report, he reviewed Lilly's clinical data, *id.* at 5-12, adverse event report data, *id.* at 13-16, general literature on antidepressant withdrawal, *id.* at 17-25, and drew on this extensive experience with antidepressants. In his initial report, Dr. Glenmullen concluded that "in every version of the drug's label, Lilly has misrepresented or failed to adequately inform doctors and patients about the frequency, severity, and duration of Cymbalta withdrawal reactions. Lilly's misleading information make it impossible for any patient or physician to make an informed decision about the appropriateness of taking or prescribing Cymbalta." *Id.* at 2; *see id.* at 33-38. As part of his analysis, Dr. Glenmullen also conducted a Bradford Hill Causality Assessment. *Id.* at 28-32. Following his initial report, Dr. Glenmullen reviewed additional documents. Exh. 35, Glenmullen Addendum at 2-4. Specifically, Dr. Glenmullen examined about thirty additional clinical trial protocols and study results, wherein withdrawal reactions were measured, a host of internal Lilly documents and emails, and further published literature by Lilly and others relating to antidepressant withdrawal. *Id.* The additional documents only lend further support for Dr. Glenmullen's expert conclusions. *Id.* at 1.

PPF # 14. Plaintiffs tender the expert opinion of Louis Morris, Ph.D. Exh. 36, Morris Expert Report (Sept. 18, 2014); Exh. 37, Morris Suppl. Expert Report (May 2015). Dr. Morris has a Ph.D. in Social Psychology and worked in FDA leadership for several decades. Exh. 36, Morris Expert Report at 1-3. Between 1986 and 1991, Dr. Morris was the director of

FDA's Division of Drug Advertising and Labeling, which is currently known as the FDA's Office of Prescription Drug Promotion. Id. at 1. Between 1991 and 1997, Dr. Morris was Chief of the FDA Marketing Practices and Communications Brach. *Id.* During his time with the FDA, Dr. Morris specifically focused on labeling and marketing, and personally reviewed drug labels for accuracy and truthfulness. *Id.* at 1-3. Subsequently, Dr. Morris worked in the private sector aiding pharmaceutical companies launch new drugs and develop accurate and non-misleading labeling. *Id.* at 2. In Dr. Morris's original report, he reviewed the Cymbalta labeling and the published literature relating to Cymbalta withdrawal. *Id.* He also consulted with Dr. Glenmullen and reviewed a declaration prepared by Dr. Glenmullen in related withdrawal litigation. *See* Exh. 46, Decl. J. Glenmullen (Aug. 9, 2013). Dr. Morris concludes "[b]ased upon my experience at FDA and consulting for the pharmaceutical industry, and based upon my review of the materials, my opinion to a reasonable degree of professional certainty is that the information presented to physicians and patients about Cymbalta is misleading and inadequate to inform prescribers and patients about the risks of discontinuation." Exh. 36, Morris Expert Report at 14. After issuing his original report, Dr. Morris subsequently reviewed additional documents, namely, Lilly's experts' reports, internal Lilly communications, Lilly's communications with the FDA, and various Lilly marketing studies. Exh. 37, Morris Suppl. Expert Report at 1, 18-21. After his additional review, Dr. Morris's "ultimate opinion remains" that the "product label information presented to physicians about Cymbalta is misleading and inadequate to inform prescribers and patients about the risks of discontinuation." *Id.* at 1.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brent Wisner, hereby certify that on the 10th day of July, 2015, a true copy of the foregoing APPENDIX A PLAINTIFFS' PROPOSED FACTS was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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