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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

JENNIFER L. SAAVEDRA, DR. MELISSA STRAFFORD, CAROL JACQUEZ, and DAVID MATTHEWS, JR., on behalf of themselves and all other persons similarly situated,

Plaintiffs,

vs.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendant.

No. 2:12-CV-09366-SVW(MANX)

Corrected **FIRST AMENDED COMPLAINT**

CLASS ACTION

DEMAND FOR JURY TRIAL

BY FAX

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Plaintiffs Jennifer L. Saavedra, Dr. Melissa Strafford, Carol Jacquez, and David Matthews ("Plaintiffs"), upon information and belief, allege as follows:

I. NATURE OF ACTION

1. This matter arises out of Defendant Eli Lilly and Company's ("Lilly") unfair and unlawful marketing of the "blockbuster" antidepressant Cymbalta (generically known as duloxetine). Lilly sells the same Cymbalta—with the same label and the same marketing—throughout the United States of America. Since Cymbalta first entered the antidepressant market in 2004, Lilly has failed to disclose material facts to consumers and healthcare professionals about the frequency, severity, and/or duration of symptoms associated with stopping Cymbalta, a condition known as Cymbalta withdrawal.

2. Since Cymbalta's release in 2004, with minor variations, the Cymbalta label has listed Cymbalta's withdrawal symptoms to include dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo ("Cymbalta Withdrawal Symptoms"). Also since 2004, with minor variations, the label has misleadingly stated that the Cymbalta Withdrawal Symptoms occur at a rate greater than or equal to 1% or 2%. In truth, studies funded, designed, and conducted by Lilly indicate that up to fifty-one (51) percent of Cymbalta users experience withdrawal symptoms. Of those withdrawal symptoms, approximately 46.3% were moderate and 17.2% were severe. Cymbalta's

label therefore misleads consumers into believing that Cymbalta withdrawal is rare or mild. This Complaint is about those misleading statistics, which were made by Lilly throughout the United States and the Class Period.

3. These facts are material to consumers because, as the studies indicate, Cymbalta withdrawal is a frequent and, at times, painful condition. Users stopping Cymbalta experience a multiplicity of symptoms that can range from mild to severe—the latter consisting of debilitating and painful symptoms that last several months.

4. In response to Lilly's unfair and unlawful marketing practices, a community of former and current Cymbalta users has emerged to provide mutual support and guidance in dealing with Cymbalta withdrawal. Since Lilly has not provided adequate guidance on how to properly deal with Cymbalta withdrawal, programs have been developed to provide guidance regarding how to slowly wean off Cymbalta over months. Regardless of the approach, however, users attempting to stop Cymbalta, even gradually, experience substantial withdrawal symptoms. Users' Cymbalta Withdrawal Symptoms can last for months after they have fully stopped taking the drug.

5. Disclosing the true risks of Cymbalta withdrawal in its marketing and risk disclosure materials would have been harmful to Lilly's sales. Instead of honestly disclosing the risks associated with Cymbalta withdrawal and letting consumers and

prescribing healthcare professionals decide if Cymbalta was worth the risk, Lilly engaged in unfair and unlawful marketing practices.

6. As a result of Lilly's unfair and unlawful marketing practices, it is estimated that Lilly has sold approximately $18 billion in Cymbalta between 2004 and 2011.

7. Plaintiffs bring this Complaint in several capacities. First, Plaintiffs bring this Complaint on behalf of themselves and all those similarly situated in the United States, seeking to enjoin Lilly from marketing Cymbalta with a misleading label, and to improve the truth of the representations on the label, particularly as it applies to withdrawal risks. Second, Plaintiffs bring this Complaint on behalf of themselves and all those similarly situated in the United States seeking a declaration that Cymbalta's warning label, as it has existed from 2004 until now, is misleading with regard to the frequency, duration, and/or severity of Cymbalta withdrawal. Third, Plaintiffs bring suit on behalf of themselves and all those similarly situated in the States of California, Massachusetts, Missouri, and New York, seeking to recover monetary damages and other relief pursuant to those states' consumer protection statutes. Finally, Plaintiff Saavedra individually brings several personal injury claims against Lilly.

II. PARTIES

8. Plaintiff Dr. Melissa Strafford ("Dr. Strafford") is a medical doctor who is a citizen, resident, and domicile of the State of New York. When she first began taking Cymbalta in or about May 2010, Dr. Strafford was a citizen, resident, and domicile of

the State of Massachusetts. Dr. Strafford purchased and/or paid for Cymbalta in Massachusetts from May 2010 to September 2010, and in New York from October 2010 to November 2011. As a medical resident, based on Lilly's extensive representations discussed below, Dr. Strafford believed that Cymbalta would help her manage the symptoms related to her medical condition and chose Cymbalta because of Lilly's representations about the minimal risk of discontinuation symptoms. On information and belief, when Dr. Strafford first purchased Cymbalta the prescription label read as follows:

> Discontinuation of Treatment with Cymbalta - 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 a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.

After taking Cymbalta for a period of time, Dr. Strafford decided to stop Cymbalta. But, despite her best efforts, she could not. She began to experience one or more of the Cymbalta Withdrawal Symptoms. Dr. Strafford was forced to continue Cymbalta just to mitigate the withdrawal. She was, in other words, "hooked." Although it took her

approximately six months, Dr. Strafford was able to slowly wean herself off Cymbalta. However, even after she had finally stopped Cymbalta, she continued to experience withdrawal symptoms for several months. Dr. Strafford would have never started Cymbalta if she had known the truth.

9. Plaintiff Jennifer L. Saavedra is, and was at all times material herein, a citizen, resident, and domicile of the State of California. Plaintiff Saavedra first purchased and/or paid for Cymbalta in or about June 2008. On information and belief, Plaintiff Saavedra read or observed on the Cymbalta prescription label the following language:

> Discontinuation of Treatment with Cymbalta - 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 a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.

Plaintiff Saavedra believed, based on Lilly's extensive marketing and promotion discussed below, that Cymbalta would help her manage the symptoms related to her medical condition. After taking Cymbalta for a period of time, Plaintiff Saavedra

decided to stop Cymbalta. But, despite her best efforts, she could not. She began to experience Cymbalta Withdrawal Symptoms, including, but not limited to, severe nausea, electrical "brain zaps," and even full-body shaking, and debilitating tunnel vision. Plaintiff Saavedra was forced to continue Cymbalta just to mitigate the withdrawal. She was, in other words, "hooked."

10. Although it took her almost an entire year, Plaintiff Saavedra was able to slowly wean herself off Cymbalta. However, even after she had finally stopped Cymbalta, she continued to experience withdrawal symptoms for several months. Plaintiff Saavedra would have never started Cymbalta if she had known the truth.

11. Plaintiff Saavedra brings this lawsuit against Lilly in two capacities. First, Plaintiff Saavedra brings a consumer protection class action, on behalf of herself and those similarly situated, seeking relief for Lilly's unfair and unlawful marketing of Cymbalta in the United States. Second, Plaintiff Saavedra brings suit on behalf of herself for the personal injuries and pain she sustained during her Cymbalta withdrawal.

12. Plaintiff Carol Jacquez ("Plaintiff Jacquez") is, and was at all times material herein, a citizen, resident, and domicile of the State of California, County of Alameda. Plaintiff Jacquez purchased and/or paid for Cymbalta starting in early 2011. On information and belief, Plaintiff Jacquez read or observed on the Cymbalta prescription label the following language:

> Discontinuation of Treatment with Cymbalta - 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.

Plaintiff Jacquez believed, based on Lilly's extensive marketing and promotion discussed below, that Cymbalta would help her manage the symptoms related to her medical condition. After taking Cymbalta for a period of time, Plaintiff Jacquez decided to stop Cymbalta. But, despite her best efforts, she could not. She began to experience one or more of the Cymbalta Withdrawal Symptoms. Plaintiff Jacquez was forced to continue Cymbalta just to mitigate the withdrawal. She was, in other words, "hooked." Although it took her almost six months, Plaintiff Jacquez was able to slowly wean herself off Cymbalta. Plaintiff Jacquez would never have started Cymbalta if she had known the truth.

13. Plaintiff David Matthews, Jr. ("Plaintiff Matthews") is, and was at all times material herein, a citizen, resident, and domicile of the State of Missouri. Plaintiff Matthews purchased and/or paid for Cymbalta starting in 2009. On information and

belief, when Plaintiff Matthews first purchased Cymbalta, the prescription label read as follows:

> Discontinuation of Treatment with Cymbalta - 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 a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.

Plaintiff Matthews believed, based on Lilly's extensive marketing and promotion discussed below, that Cymbalta would help him manage the symptoms related to his medical condition. After taking Cymbalta for a period of time, Plaintiff Matthews decided to stop Cymbalta. As he tried to wean himself off Cymbalta, he began to experience one or more of the Cymbalta Withdrawal Symptoms. Even after he had stopped taking Cymbalta, he continued to experience the withdrawal symptoms. Plaintiff Matthews would have never started Cymbalta if he had known the truth.

14. Defendant Eli Lilly and Company is, and was at all times material herein, an Indiana corporation with its headquarters and principal place of business in Indianapolis, Indiana. Lilly is, and was at all material times herein, a pharmaceutical

company involved in the research, development, testing, manufacture, production, distribution, marketing, and sale of numerous pharmaceutical products, including Cymbalta (generically known as duloxetine). Lilly regularly conducts business nationally, including the sale and marketing of Cymbalta. Cymbalta is distributed and marketed throughout the United States. Cymbalta is therefore the same drug—with the same label and the same marketing—throughout the United States of America.

III. JURISDICTION AND VENUE

15. With regard to the class action claims, this Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(d). Plaintiffs and putative class members are citizens of different States than Lilly. Furthermore, the aggregate amount in controversy exceeds $5,000,000.

16. With regard to the individual claims against Lilly, this Court has subject-matter jurisdiction pursuant to 18 U.S.C. § 1332(a). There is complete diversity of citizenship between Plaintiffs and Lilly and the amount in controversy exceeds $75,000.

17. This Court has personal jurisdiction over Lilly because Lilly has purposefully directed its marketing and sales of numerous pharmaceutical products to the State of California. Lilly has had substantial contacts with the State of California such that maintenance of the action is consistent with traditional notions of fair play and substantial justice.

18. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(b). A substantial portion of the events giving rise to the claims alleged in this Complaint took place within the Central District for the District of California.

IV. FACTUAL BACKGROUND

19. The market for antidepressants is robust and competitive. Since the emergence of "blockbuster" antidepressants in the 1980s, a multi-billion dollar industry has taken hold in the United States and Europe. The antidepressant industry generates revenue in excess of $11 billion each year and the market continues to grow annually. There are dozens of brand name and generic drugs approved by the Food and Drug Administration ("FDA") for the treatment of depression and anxiety. Due to the availability of so many different antidepressants consumers typically "shop around" when trying to find the right drug. Thus, in order to remain competitive in the crowded antidepressant market, pharmaceutical companies spend hundreds of millions of dollars each year promoting directly to consumers and the medical community. The sheer number of drug commercials on television today speaks to the competitive nature of the industry.

20. Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. Lilly is a leader in the antidepressant industry and has enjoyed considerable financial success from the manufacture and sale of psychotropic drugs designed to treat mental illness. In fact, Lilly was the creator of the

first "blockbuster" drug in the antidepressant industry: Prozac (generically known as fluoxetine).

21. When Lilly launched Prozac in 1988, it was touted as the first "Selective Serotonin Reuptake Inhibitor" ("SSRI") antidepressant, a class of drugs that supposedly increases the neurotransmitter serotonin in the brain. It was theorized that reduced levels of serotonin in the brain was the primary physiological cause of depression and through use of an SSRI, such as Prozac, one could "balance the brain's chemistry" and increase otherwise deficient serotonin levels. Although recent research has undermined the "balancing brain chemistry" theory, Prozac was extremely popular in the 1990s and was the top-selling antidepressant of its kind.

22. In August 2001, Lilly's patent on Prozac expired, leading to a proliferation of generic versions of the drug. Needing to fill the void left by the decreased sales of Prozac, Lilly developed a new (and patented) antidepressant: Cymbalta. Unlike Prozac, Cymbalta is a "Serotonin Norepinephrine Reuptake Inhibitor ("SNRI"), which in addition to supposedly increasing the amount of serotonin in the brain, also increases the amount of norepinephrine (a neurotransmitter and hormone associated with cardiovascular regulation). Lilly and other SNRI manufactures admit that "the exact way that Cymbalta works in people is unknown," however, they promote the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

23. Cymbalta was approved by the FDA in 2004 for Major Depressive Disorder ("MDD") after it was initially rejected in 2003 due to Lilly's significant violations of good manufacturing practices and Cymbalta's potential for liver toxicity. The FDA approved Cymbalta after the manufacturing issues were resolved and a liver toxicity warning was included with the prescribing information. Thereafter, Lilly obtained approval of Cymbalta for various other indications including Generalized Anxiety Disorder (2007), fibromyalgia (2008), and musculoskeletal pain (2010). Currently, Lilly is undergoing clinical trials with Cymbalta to gain approval for the treatment of Chronic Fatigue Syndrome.

24. Since gaining approval from the FDA in 2004 for MDD, Lilly has aggressively marketed Cymbalta to the public and the medical community nationwide, spending millions each year on advertising and promotion. Lilly promotes Cymbalta directly to consumers and healthcare professionals nationwide through all major media outlets, including television, radio, internet, print, and a large force of pharmaceutical representatives. After Cymbalta's launch in 2004, Lilly initiated one of the largest (and most expensive) nationwide direct-to-consumer marketing campaigns. Cymbalta's slogan: "Depression Hurts. Cymbalta can help." and its accompanying advertisements flooded all major media markets. The campaign was a huge success and propelled Cymbalta to be one of the top selling "blockbuster" antidepressants from 2004 until the

present. It also made Lilly one of the largest direct-to-consumer advertisers in the pharmaceutical industry.

25. A substantial portion of Lilly's revenue and profits derive from the sale of Cymbalta. Since Cymbalta's approval in 2004, Cymbalta sales have generated billions each year, including approximately $3.1 billion in 2009,[1] $3.5 billion in 2010,[2] and $4.16 billion in 2011.[3]

A. Lilly Misled Consumers Throughout the United States About the Frequency, Severity, and/or Duration of Cymbalta Withdrawal

26. Cymbalta can create a physical dependence. Users who take Cymbalta are faced with severe physiological and psychological symptoms when they attempt to stop, including, *inter alia*, dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis, and vertigo. Accordingly, once Cymbalta users try to stop, the symptoms can be severe enough to force them to start taking Cymbalta again simply to combat the withdrawal symptoms. In other words, users develop a physical dependence on Cymbalta. To beat the physical dependence, users are forced to endure a protracted period of withdrawal—slowly reducing the ingestion of Cymbalta over several months until it is fully out of the body.

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[1] Eli Lilly & Co., Annual Report (Form 10-K), at 12 (Feb. 22, 2010), available at http://investor.lilly.com/sec.cfm?DocType=Annual&Year=&FormatFilter).

[2] Eli Lilly & Co., Annual Report (Form 10-K), at 12 (Feb. 22, 2011), available at http://investor.lilly.com/sec.cfm?DocType=Annual&Year=&FormatFilter).

[3] Eli Lilly & Co., Annual Report (Form 10-K), at 12 (Feb. 24, 2012), available at http://investor.lilly.com/sec.cfm?DocType=Annual&Year=&FormatFilter).

During this period, users still experience substantial withdrawal symptoms, which can even continue for months after fully stopping the drug.

27. Consumers and healthcare professionals nationwide have not been fully and accurately informed of the frequency, severity, and/or duration of Cymbalta withdrawal since Cymbalta first entered the market in 2004. Lilly, through its nationwide marketing strategy, led consumers and healthcare professionals to believe that Cymbalta withdrawal is rare or uncommon. In truth, a significant percentage of Cymbalta users experience withdrawal.

28. Cymbalta's label and prescription information, which is uniform nationwide, mischaracterizes the frequency, severity, and/or duration of Cymbalta withdrawal. The Cymbalta label, as of 2012, states:

> 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 a rate greater than or equal to 1%** and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue.

> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

(emphasis added). Although Lilly has amended Cymbalta's label several times since 2004, such as the inclusion and exclusion of certain withdrawal symptoms and minor word changes, the label has not been materially altered since its first publication.

29. Cymbalta's warning label, which is as it existed in 2004 and up until the present, is unfair and unlawful. It suggests that withdrawal symptoms occur in approximately one (1) percent of users. A reasonable consumer or prescribing healthcare professional reading this warning would gain very little meaningful information about the actual frequency, severity, and/or duration of Cymbalta withdrawal and would reasonably conclude that the likelihood of withdrawal symptoms was generally rare or approximately one (1) percent.

30. In truth, Cymbalta withdrawal is frequent and severe. In six (6) double-blind trials of Cymbalta funded, designed, and conducted by Lilly, approximately forty-

four (44) percent of users experienced some withdrawal symptoms. David G. Perahia, et al., *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 JOURNAL OF AFFECTIVE DISORDERS 207, 208 (2005).[4] Of those withdrawal symptoms, 50.6% were moderate and 9.6% were severe. *Id.* at 208-09. Moreover, during a much larger open-label trial (where users were aware they were taking Cymbalta) involving 1,279 subjects, approximately fifty-one (51) percent of users experienced some withdrawal symptoms. Of those withdrawal symptoms, approximately 46.3% were moderate and 17.2% were severe. The results of studies funded, designed, and conducted by Lilly indicate that approximately half of Cymbalta users experience withdrawal symptoms when they stop taking the drug.

31. Nowhere on the Cymbalta label does it indicate that a significant percentage of users who take Cymbalta, *i.e.*, up to fifty-one (51) percent, experience withdrawal symptoms or that the majority of those withdrawal symptoms will be moderate or severe. During the Class Period, Lilly failed to disclose material facts known to it when it omitted this information from the label and instead stated that Cymbalta Withdrawal Symptoms occur at a rate greater than or equal to 1% or 2%.

[4] The study also noted that the withdrawal symptom data compiled during Lilly's clinical trials was gathered from "spontaneous reports" of symptoms (patients volunteering symptoms), and not using the more accurate "symptom checklist." The authors state that use of a symptom checklist would likely produce even higher incidence rates of withdrawal symptoms.

This label misleadingly suggests to consumers and prescribing healthcare professionals that withdrawal symptoms are rare or approximately one (1) percent.

32. Again, nowhere on Cymbalta's label does it indicate the potential duration of withdrawal symptoms.

33. Recently, on October 3, 2012, the Institute for Safe Medication Practices released a report stating that they "observed a signal for serious drug withdrawal symptoms associated with duloxetine (CYMBALTA), a widely used antidepressant that is also approved to treat arthritis and back pain, anxiety, and fibromyalgia." The report "identified a serious breakdown . . . in providing adequate warnings and instructions about how to manage this common adverse effect." Specifically, the Institute for Safe Medication Practices criticized Lilly on the following grounds:

> Good patient information is essential because abrupt withdrawal effects are likely to affect about 50% of duloxetine patients; they will be severe in at least 10% of that total, and persistent in half. Instead of clear warnings and useful instructions, the duloxetine patient Medication Guide says only:
>
> > **"Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms."
>
> This FDA-approved patient guide is materially deficient. It gives no hint of the persistence or severity of the symptoms known to occur. It does not

> address basic questions: What kind of symptoms are most common? Should patients taper off the dose, and if so, how slowly? What should a patient do if depression or other symptoms recur? Is there a way to tell whether these are withdrawal symptoms or the previous illness returning? We could not identify any FDA-approved or company information for patients about how to discontinue duloxetine. We specifically asked Lilly how the company responded if a patient asked for assistance in stopping duloxetine. "If a consumer requests additional information we inform them to consult their physician because they know the patient's complete medical history," the company said. Consumers could also obtain the prescribing information intended for physicians.

Why Reports of Serious Adverse Drug Events Continue to Grow, QuarterWatch (Inst. For Safe Med. Practices), Oct. 3, 2012, at 12-13. Lilly knew or should have known of the existence of antidepressant withdrawal syndrome in SNRIs and SSRIs for many years. Moreover, Lilly knew or should have known of the frequency, severity, and/or duration of Cymbalta withdrawal as it was documented in studies funded, designed, and conducted by Lilly. However, instead of giving consumers and prescribing healthcare professionals sufficient information to decide whether the potential for Cymbalta withdrawal was worth the risk, Lilly omitted the data. The "discontinuation warning" on Cymbalta gave the impression that Cymbalta withdrawal was rare.

34. That a pharmaceutical company might engage in selective and biased publication of its clinical trials would not be unprecedented. A recent study published in the New England Journal of Medicine exposed this practice. *See* Erick H. Turner, et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 256-60 (2008). The study found "a bias toward the publication of positive results" and that a survey of published literature indicates that ninety-four (94) percent of clinical trial studies were positive, whereas only fifty-one (51) percent of the studies actually submitted to the FDA were positive. The study concluded that, as a result of this selective publication, the published literature conveyed a misleading impression that drugs like Cymbalta were thirty-three (33) percent more effective than the clinical trial data supported.

35. Lilly is no stranger to unfair and unlawful advertising tactics. In 2009, Lilly was criminally prosecuted by the United States Department of Justice for improperly advertising and concealing the adverse side effects of Zyprexa, an antipsychotic drug, between 1996 and 2007 (a period of time wherein Lilly was marketing Cymbalta). Lilly ultimately pled guilty to the charges and was forced to pay a $1.415 billion settlement to the United States, including a $515 million criminal fine, which, at that time, was the single largest settlement in healthcare litigation history.

36. Lilly's history of failing to disclose material information to consumers of which it knew or should have known also extends to its advertising and marketing of Cymbalta.

37. On September 9, 2005, the FDA sent a letter to Lilly requesting that it "immediately cease the dissemination of promotional materials for Cymbalta" because Lilly's journal ads failed to reveal, in the main parts of the ads, material facts essential to the safe and effective use of Cymbalta. Letter from Michelle Safarik & Jialynn Wang, Regulatory Review Officers, Division of Drug Marketing, Advertising, and Communications, FDA, to Stacy Holdsworth, Manager of U.S. Regulatory Affairs, Eli Lilly and Company (September 9, 2005) at 2.[5] In particular, the FDA noted that Lilly's journal ads failed to disclose important risks regarding the drug, including contraindications (such as hypersensitivity) and warnings (such as worsening of depression in patients with major depressive disorder). *Id.*

38. On September 21, 2007, the FDA sent another warning letter to Lilly for unlawfully promoting delayed-release Cymbalta products to consumers through various direct mailer advertisements. According to the FDA, Lilly's Cymbalta advertisement was "false or misleading" because it "overstate[d] the efficacy of Cymbalta by

[5] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054792.pdf.

suggesting that patients with [diabetic peripheral neuropathy] who are treated with the drug experience less pain interference with overall functions, ***when this has not been demonstrated by substantial evidence or substantial clinical experience.***" Letter from Michelle Safarick, Regulatory Review Officer, Division of Drug Marketing, FDA, to Michelle Sharp, Manager of U.S. Regulatory Affairs, Eli Lilly and Company (Sept. 21, 2007) at 4 (emphasis added).[6] The FDA further stated that Lilly's advertisements were misleading because they "fail to reveal facts that are material[.]" *Id.* at 5. Those material facts include "the Precautions relating to hepatotoxicity, ***abrupt discontinuation of Cymbalta treatment***, and use of the drug in patients with concomitant illness." *Id.* (emphasis added).

39. On March 26, 2009, Lilly was sent another warning letter for unlawfully marketing Cymbalta and several other drugs for failing to include relevant risk information and inadequately communicating the drug's approved indications in numerous online advertisements. Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, FDA, to Michelle Sharp, Director of U.S. Regulatory Affairs, Eli Lilly and Company (Mar. 26, 2009) at 2-3.[7] The FDA

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[6] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054170.pdf.

[7] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/

demanded that Lilly cease its illegal marketing practices, and "encourage[d] [Lilly] to review [their] promotional materials for the other prescription drug products that Lilly promotes in the United States and to discontinue or revise any materials with the same or similar violations[.]" *Id.* at 3-4.

40. Yet again, in January 2010, the FDA sent a warning letter to Lilly regarding a print ad and a WebMD Little Blue Book message for Cymbalta delayed-release capsules, stating that these advertisements were false or misleading. Letter from Twyla N. Thompson, FDA, to Michele Sharp, Director of U.S. Regulatory Affairs, Eli Lilly And Company (Jan. 7, 2010) at 1.[8] The FDA explained that the print advertisement was false or misleading because it presented "efficacy claims for Cymbalta, but failed to adequately communicate the risks associated with its use." *Id.* Similarly, the Blue Book message was false or misleading because it "overstate[d] the efficacy of Cymbalta and minimize[d] the risks associated with the drug. *Id.*

41. Despite being monitored by the FDA, and being warned and corrected on numerous occasions, Lilly persists in failing to inform consumers and healthcare providers of the frequency, severity, and/or duration of Cymbalta withdrawal. Lilly's

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EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM143536.pdf.

[8] Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM197257.pdf.

marketing of Cymbalta deceives or is likely to deceive consumers about Cymbalta withdrawal so users develop a physical dependence. For example, Lilly's current marketing campaign, "the Cymbalta Promise" exploits Cymbalta's unknown habit-forming characteristics. The Cymbalta Promise provides new users the "opportunity" to take Cymbalta free of charge for sixty (60) days—the time it takes, according to studies funded, designed, and conducted by Lilly to create withdrawal symptoms in approximately half of users. Lilly knows or should know, given the studies it funded, designed, and conducted, that once it gets users "hooked" by offering free Cymbalta for sixty (60) days, users will have a very difficult time getting off the drug.[9]

42. Lilly's unfair and unlawful marketing of Cymbalta caused Plaintiffs to purchase and use Cymbalta. If Lilly had been truthful in its representations regarding Cymbalta, Plaintiffs would have decided not to purchase Cymbalta.

43. Plaintiffs lost money as a result of Lilly's unfair and unlawful claims and practices in that they did not receive what they paid for when purchasing Cymbalta. Additionally, Plaintiffs altered their positions to their detriment and suffered economic damages.

[9] As Joseph Glenmullen, M.D., indicated in his book, *The Antidepressant Solution: A Step-by-Step Guide to Safely Overcoming Antidepressant Withdrawal, Dependence, and "Addiction"*, a tapering program is advisable to discontinue use of Cymbalta gradually in order to reduce withdrawal symptoms and dangers.

B. Specific Misrepresentations / Material Omissions

44. As discussed throughout this Complaint, Cymbalta's label contains several misleading statements and material omissions. A summary of those misrepresentations and material omissions are as follows:

45. The label misleads consumers into believing that Cymbalta is rare or uncommon by stating that withdrawal symptoms occur at a rate greater than or equal to 1% or 2%.

46. The label materially omits the actual percentage of patients who have been observed to suffer from one or more withdrawal symptoms.

47. The label materially omits the length or duration for which withdrawal symptoms have been observed to occur. If Lilly lacked sufficient information to detail how long Cymbalta withdrawal could occur, that information should have been provided.

48. The label materially omits information about the severity of Cymbalta withdrawal. For example, nowhere on Cymbalta's label does it indicate that withdrawal symptoms were so severe in some users that it required hospitalization.

49. The label does not provide any substantive instruction on how to properly or safely wean off Cymbalta should a consumer desire to stop taking the drug.

50. Lilly's failure to properly label Cymbalta has deprived Plaintiffs and all consumers nationwide of the information they needed, and deserved, to make an informed decision about whether to purchase Cymbalta.

C. Plaintiff Saavedra's Personal Injury Claims

51. Lilly's unfair and unlawful marketing tactics also caused Plaintiff Saavedra to suffer substantial personal injury when she went through a lengthy and painful period of Cymbalta withdrawal.

52. On or about June 8, 2009, Plaintiff Saavedra was prescribed a twenty (20) mg daily dose of Cymbalta by her psychiatrist to treat ongoing depression and general anxiety. Over the course of the next four (4) months, her dosage was increased to ninety (90) mg per day.

53. On or about April 2010, Plaintiff Saavedra decided she no longer wanted to take Cymbalta. She began slowly tapering off her intake of Cymbalta and began experiencing severe withdrawal symptoms. Plaintiff Saavedra experienced, *inter alia*, the following symptoms: severe nausea; tunnel vision which would lead to vomiting when she moved her head; electrical shock sensations in her head; feeling like she would "black out" at any moment; body twitches; whole body shaking; severe insomnia; diarrhea; and wildly erratic emotional swings. Plaintiff Saavedra's symptoms were so debilitating that they directly adversely impacted her ability to work.

54. Plaintiff Saavedra went through Cymbalta withdrawal for approximately one year and was able to finally stop Cymbalta completely on or about May, 2011. Plaintiff Saavedra, however, continued to suffer from withdrawal symptoms for a few months thereafter.

55. Before taking Cymbalta, Plaintiff Saavedra read the prescription information and drug label for Cymbalta. Plaintiff Saavedra believed, based on the information on the label, that Cymbalta withdrawal was rare. Plaintiff Saavedra relied on Lilly's representations in making a decision to start taking Cymbalta.

56. In November, 2011, the Plaintiff Saavedra learned that Cymbalta withdrawal was more common than what was stated on Cymbalta's prescription information and drug label. Specifically, Plaintiff Saavedra learned that Lilly's clinical studies showed that up to half of users who cease taking Cymbalta experience symptoms. If Plaintiff Saavedra had known that a significant percentage of Cymbalta users suffer from withdrawal symptoms, she would never have started taking Cymbalta. Plaintiff Saavedra would have sought a safer, non-habit forming treatment alternative.

V. CLASS ACTION ALLEGATIONS

57. This matter is brought by Plaintiffs on behalf of themselves and those similarly situated. Since Lilly's unfair and unlawful marketing practices occurred within all of the states and the District of Columbia, the matter is brought both as a nationwide class action and as four state subclasses.

58. To resolve the common core issue in the litigation, the misleading Cymbalta label, Plaintiffs seek a nationwide, injunctive relief class pursuant to Rule 23(b)(2) ("Injunctive Class" or "Nationwide Injunctive Class"). The target of this relief is to improve the safety and accuracy of Cymbalta's label. Given that the common core issue of the litigation is whether the Cymbalta label is misleading, Plaintiffs also request

certification pursuant to Rule 23(c)(4), which allows "particular issues" to be "brought or maintained as a class action" ("Issue Class" or "Nationwide Issue Class"). Collectively, the Injunctive Class and Issue Class are referred to as "Classes." Plaintiffs then identify the four state subclasses, brought under Rule 23(b)(3) and (c)(5), which pray for relief including but not limited to monetary damages, pursuant to the four states' consumer protection statutes ("Subclasses").

59. Plaintiffs reserve the right to modify or amend the class definitions at or before Plaintiffs brief the issue of class certification.

A. The Nationwide, Injunctive Class

60. Rule 23(b)(2) provides that an injunctive class may be certified where the party opposing the class has acted or refused to act on grounds that apply generally to the class.

61. Pursuant to Rule 23(b)(2), Plaintiffs bring this action for injunctive relief on behalf of themselves and all others similarly situated in the United States, defined as follows:

> All persons within the United States of America who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("Injunctive Class").[10]

[10] All classes are currently defined to begin in August 2004 when Lilly began marketing and selling Cymbalta. Plaintiff reserves the right to revise the class definition start date(s) as the litigation proceeds.

62. Certification under Rule 23(b)(2) is appropriate because Lilly has acted or refused to act on grounds that that apply generally to the Injunctive Class. Specifically, Lilly has marketed the same Cymbalta using the same misleading labels and advertisements to the entire, nationwide Injunctive Class. Any final injunctive or declaratory relief would apply to the entire Injunctive Class as Lilly would be prevented from continuing its unlawful and unfair marketing practices and be required to honestly disclose to consumers the risks associated with Cymbalta withdrawal.

63. The Injunctive Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Individual joinder of the Injunctive Class members would be wholly impracticable. Cymbalta has been purchased by millions of persons in the United States.

a. Commonality: Questions of law and fact are common to the Injunctive Class and predominate over questions affecting only individual members of the Subclass, including, *inter alia*, the following:

i. Whether Lilly's representations regarding the frequency, severity, and/or duration of Cymbalta withdrawal misled reasonable consumers;

ii. What Lilly knew or should have known about the frequency, severity, and/or duration of Cymbalta withdrawal; and

iii. What representations Lilly should have made to consumers on Cymbalta's label.

b. Typicality: Plaintiffs' claims are typical of the claims of the Injunctive Class, because their claims arise from the same course of conduct by Lilly, *i.e.*, unfair and unlawful marketing practices related to Cymbalta. Plaintiffs are typical class representatives because, like all members of the Injunctive Class, they purchased Cymbalta that was being unfairly and unlawfully marketed within the United States.

c. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the Injunctive Class. Their claims are common to all members of the Class and they have strong interests in vindicating their rights. In addition, Plaintiffs and the Injunctive Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

64. The Injunctive Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior.

65. Notice of this and other classes could be provided by publication in national publications and through individual mailings.

B. Rule 23(c)(4) Nationwide Issue Class

66. Having established that a Rule 23(b)(2) class for injunctive relief is appropriate, Plaintiffs also seek certification under Rule 23(c)(4), which provides that an action may be brought or maintained as a class action with respect to particular issues.

67. Pursuant to Federal Rule of Civil Procedure 23(c)(4), Plaintiffs bring this action on behalf of themselves and all other similarly situated, defined as follows:

> All persons within the United States of America who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("Nationwide Class" or "Nationwide Issue Class").

68. A Nationwide Issue Class is appropriate under Rule 23(c)(4) because, as discussed above, at the heart of this Complaint is whether Lilly's warning label was misleading.

69. Lilly sold the same Cymbalta with the same warning labels across the country. Through its common advertising and warning label, Lilly represented to consumers nationwide that the withdrawal symptoms associated with Cymbalta were rare. In truth, Lilly knew or should have known, based on studies it funded, designed, and conducted, that Cymbalta withdrawal was frequent and severe, and misled consumers within the United States.

70. Since Lilly's misconduct was uniform throughout the United States—Lilly put the same misleading label on every package of Cymbalta— this issue is suited for

nationwide resolution. Specifically, the issue applicable to the Nationwide Issue Class is: whether Lilly's warning label on Cymbalta from August, 2004 to the present was misleading.

71. Under Rule 23(c)(4), certification is appropriate when Plaintiffs establish a class under Rule 23(a) and 23(b)(1), (2), or (3), and when a common issue threads through the case.

72. In addition to the common issue at the heart of the litigation, the Nationwide Issue Class satisfies the familiar Rule 23(a) requirements of numerosity, commonality, typicality, and adequacy for the reasons discussed above.

73. The Nationwide Issue Class also satisfies Rule 23(b).

74. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Nationwide Class. The issues at stake here relate exclusively to Lilly's conduct which was uniform across the entire class, *i.e.*, the unfair and unlawful marketing of Cymbalta within the United States. Therefore, individual issues or defenses would be irrelevant for the purposes of the Nationwide Issue Class. The issues at stake for the Nationwide Class fully predominate over any individual issues on a class wide basis. In addition, this Nationwide Issue Class is superior to other methods for fair and efficient adjudication of this controversy because, *inter alia*:

i. Resolution of the Nationwide Issue would materially advance the litigation of the individual subclasses and potential individual litigants;

ii. Individual joinder of the Subclasses and individual members is wholly impracticable;

iii. The economic damages suffered by the individual members may be relatively modest compared to the expense and burden of individual litigation;

iv. The court system would benefit from a class action because individual litigation would overload court dockets and magnify the delay and expense to all parties;

v. The class action device presents far fewer management difficulties and provides the benefit of comprehensive supervision by a single court with economies of scale; and

vi. Individual litigation by members would not be effective in stopping Lilly's unfair and unlawful conduct which will continue unless stopped by a class action lawsuit.

75. Notice of the Nationwide Injunctive and Issue Classes could be provided by publication in national publications and through individual mailings.

C. The State Subclasses

76. In addition to the foregoing nationwide relief, Plaintiffs allege four separate statewide class actions for consumer protection, pursuant to Rule 23(c)(5), on behalf of the consumers of each state, i.e., the Subclasses.[11] The four states are California, Massachusetts, Missouri, and New York.

77. Pursuant to Rule 23(c)(5), Plaintiffs bring this action on behalf of themselves and one or more of the following Subclasses:

1. All persons within the State of California who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("California Subclass");

2. All persons within the Commonwealth of Massachusetts who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("Massachusetts Subclass");

3. All persons within the State of Missouri who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("Missouri Subclass");

4. All persons within the State of New York who purchased and/or paid for Cymbalta manufactured, distributed, and/or marketed by Lilly from the launch of Cymbalta in August 2004 until the present ("New York Subclass").

78. Counts 1-6 are properly brought and should be maintained as class actions under Rule 23(a) and (c)(5), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

a. Numerosity: Joinder of the individual member of each Subclass would be impracticable. Cymbalta has been purchased by millions of persons in the United States divided among the states.

b. Commonality: Questions of law and fact are common within each Subclass and predominate over questions affecting only individual members of the Subclass, including, *inter alia*, the following:

i. Whether Lilly's representations regarding the frequency, severity, and/or duration of Cymbalta withdrawal misled or deceived reasonable consumers;

ii. What Lilly knew or should have known about the frequency, severity, and or duration of Cymbalta withdrawal; and

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[11] If class certification is not granted with respect to the Nationwide Injunctive or Issue Classes, Plaintiffs reserve the right to plead these Subclasses as Classes under Rule 23.

iii. What representations Lilly should have made to consumers on Cymbalta's label.

c. Typicality: Plaintiffs' claims are typical of the claims of each of the respective Subclasses because their claims arise from the same course of conduct by Lilly, *i.e.*, unfair and unlawful marketing practices related to Cymbalta. Plaintiffs are typical class representatives because, like all members of the various Subclasses, they purchased Cymbalta that was being unfairly and unlawfully marketed.

d. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the various Subclasses. Their consumer protection claims are common to all members of each of the respective Subclasses and they have a strong interest in vindicating their rights—the same rights at stake within the various Subclasses. In addition, Plaintiffs, and the Subclasses, are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

79. Counts 1-6 are properly brought and should be maintained as class actions under Rule 23(b) and (c)(5) because a class action in this context is superior.

a. With regard to Rule 23(b)(1)(A), resolution of the issues presented in the various Subclasses on an individual basis would pose a serious risk of requiring Lilly to follow inconsistent courses of continuing conduct. A

court in one state could determine that the Cymbalta warning was in violation of a state consumer protection law and order Lilly to take specific action, such as changing its warning label. Another court in that state could also determine that the Cymbalta warning was defective but order a conflicting course of conduct. If the issues presented in the various Subclasses are not dealt with by a single court for each Subclass, there is a very real possibility that Lilly would be subjected to an inescapable legal quagmire of not being able to comply with one judgment without violating terms of another. This is further compounded when one considers the potential conflicting orders that could manifest in different state and federal tribunals.

b. Certification is also warranted under Rule 23(b)(2) for each State Subclass. Plaintiffs seek injunctive relief on behalf of each State Subclass Member on grounds generally applicable to each State Subclass, including but not limited to amending the Cymbalta label as to the misleading statistic on its label. Certification under Rule 23(b)(2) is appropriate because Lilly has acted or refused to act on grounds that apply generally to each State Subclass, *i.e.*, Lilly has marketed the same Cymbalta using the same unfair and unlawful labels and advertisements. Any final injunctive or declaratory relief would apply to each State Subclass as Lilly would be

prevented from continuing its unlawful marketing practices and be required to honestly disclose to each State Subclass member, and state consumers in general, the risks associated with Cymbalta withdrawal.

c. With regard to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the various Subclasses. Common questions include, but are not limited to, the following: (1) whether Lilly's representations regarding the frequency, severity, and/or duration of Cymbalta withdrawal misled reasonable consumers; (2) what Lilly knew or should have known about the frequency, severity, and/or duration of Cymbalta withdrawal; and (3) what representations Lilly should have made to consumers on Cymbalta's label. Thus, the common issues of law and fact pertaining to each Subclass predominates over any individual issues. In addition, bringing this action as individual Subclasses is a superior mechanism for resolving this controversy because, *inter alia*,:

i. Individual joinder of each consumer within the Subclasses is wholly impracticable;

ii. The economic damages suffered by the individual members may be relatively modest compared to the expense and burden of individual litigation;

iii. The court system would benefit from the class actions because individual litigation would overload court dockets and magnify the delay and expense to all parties;

iv. The class action device presents far fewer management difficulties;

v. The class action device provides the benefit of comprehensive supervision by a single court with economies of scale; and

vi. Individual litigation by members would not be effective in stopping Lilly's unfair and unlawful conduct which will continue unless stopped by these class actions.

80. Notice of each Subclass could be provided by publication in national and local publications, through the creation of public website, and through individual mailings.

81. To the extent notice is required under the states' consumer protection statutes, Plaintiffs will, or have, complied.

VI. VIOLATIONS OF VARIOUS STATES' CONSUMER PROTECTION STATUTES

82. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

83. Plaintiffs, the Nationwide Class, the Injunctive Class, and the State Subclasses bring this action against Lilly for violations of state consumer protection statutes (Counts 1-6).

84. The allegations alleged herein deal exclusively with the harm caused by Lilly through its unfair and unlawful marketing practices to consumers. The personal injury component of Plaintiff Saavedra's claims, however, is separate from Plaintiffs' classwide claims. Plaintiffs' Consumer Protection Claims deal exclusively with consumer protection and the money spent by consumers for a drug which, as labeled, should never have been on the market in any state within the United States. Plaintiff Saavedra's personal injury causes of action are, instead, alleged in Counts 7-11.

VII. COUNT 1 (CALIFORNIA SUBCLASS): VIOLATIONS OF CALIFORNIA'S CONSUMERS LEGAL REMEDY ACT, CAL. CIV. CODE §§ 1750, *ET SEQ.*

85. Plaintiffs Saavedra and Jacquez, who are residents of California, incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

86. California's Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750, et seq. makes it unlawful to engage in unfair methods of competition and unfair or deceptive acts or practices intended to result, or which results, in the sale or lease of goods or services to any consumer.

87. Plaintiffs Saavedra and Jacquez and the California Subclass were, and continue to be, all times material to the Complaint, "consumers" and "persons" as

defined by the Cal. Civ. Code § 1761. Plaintiffs Saavedra and Jacquez, as well as the California Subclass, purchased and/or paid for Cymbalta for personal and/or family and/or household use during the relevant time period.

88. As alleged throughout this Complaint, Lilly engaged in unfair, deceptive, and/or unlawful marketing in violation of Civ. Code § 1770(a) by representing to the California Subclass that Cymbalta withdrawal was rare or infrequent when, in truth, it is common and severe. Lilly sold and marketed Cymbalta while concealing and misrepresenting the frequency, severity, and/or duration of Cymbalta withdrawal.

89. Specifically, Lilly has violated the following proscribed practices pursuant to Cal. Civ. Code § 1770(a) with the purpose of inducing Plaintiffs Saavedra and Jacquez and the Class to purchase and ingest Cymbalta:

a. § 1770(a)(5): Lilly represented to Plaintiffs Saavedra and Jacquez and the California Subclass that Cymbalta had characteristics, ingredients, uses, or benefits that it does not have. Specifically, Lilly represented to Plaintiffs Saavedra and Jacquez and the California Subclass that withdrawal was rare or infrequent when, in truth, it was common and severe.

b. § 1770(a)(7): Lilly represented to Plaintiffs Saavedra and Jacquez and the California Subclass that Cymbalta was of a particular standard, quality, or grade when it was of another. In this regard, Lilly represented that Cymbalta was not likely to create withdrawal symptoms when, in fact,

Cymbalta withdrawal occurs in a substantial percentage of users, as revealed by the studies it funded, designed, and conducted.

90. Lilly's concealment and misrepresentation regarding the frequency, severity, and/or duration of Cymbalta withdrawal was a material omission/misstatement that would cause a consumer to believe, incorrectly, that Cymbalta withdrawal was a rare adverse effect.

91. Plaintiffs Saavedra and Jacquez were exposed to and/or relied upon Lilly's unfair, deceptive, and/or unlawful marketing practices, including, inter alia, the representation that the warnings related to the frequency, severity, and/or duration of Cymbalta withdrawal were accurate. The California Subclass was uniformly exposed to Lilly's material omissions/misstatements regarding the frequency, severity, and/or duration of Cymbalta withdrawal.

92. Plaintiffs Saavedra and Jacquez and the California Subclass lost money as a result of Lilly's unfair, deceptive, and/or unlawful marketing practices pursuant to Cal. Civ. Code § 1770(a), through the purchase of Cymbalta that was illegally advertised and marketed in violation of Cal. Civ. Code § 1770(a).

93. The conduct described herein by Lilly was long-standing, continuing even after Plaintiffs Saavedra and Jacquez demanded the conduct cease in a Consumer Legal Remedies Act letter. The conduct was done for profit as a deliberate corporate policy rather than an isolated incident, and was morally wrong, callous, and/or oppressive.

94. As a result of Lilly's violations of the California's Consumer Legal Remedies Act, Plaintiffs Saavedra and Jacquez seek an order of this Court permanently enjoining Lilly from perpetrating its unfair, deceptive, and/or unlawful marketing practices. Plaintiffs Saavedra and Jacquez sent Lilly a notice letter pursuant to Cal. Civ. Code § 1782 via certified mail on November 14, 2012, which was received on November 19, 2012. If Lilly does not take action to cease its unfair, deceptive, and/or unlawful marketing practices within thirty (30) days of being served with the notice letter, Plaintiffs Saavedra and Jacquez will seek leave to amend this Complaint to request, in addition to an order enjoining Lilly from continuing its unfair, deceptive, and/or unlawful practices, an order awarding, *inter alia*, Plaintiffs Saavedra and Jacquez and the California Subclass actual damages, restitution, attorneys' fees and costs, and for such other relief as set forth below.

95. Plaintiffs Saavedra and Jacquez reserve the right to amend this Complaint to seek punitive damages.

VIII. COUNT 2 (CALIFORNIA SUBCLASS): VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*

96. Plaintiffs Saavedra and Jacquez incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

97. California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq., protects both consumers and competitors by promoting fair competition in commercial markets for goods and services. California's Unfair Competition Law is

interpreted broadly and provides a cause of action for any unlawful, unfair, or fraudulent business act or practice. Any unlawful, unfair, or fraudulent business practice that causes injury to consumers falls within the ambit of California's Unfair Competition Law.

98. Lilly engaged in substantial advertising and marketing of Cymbalta within the State of California.

99. Because of Lilly's unlawful and unfair business practices, Plaintiffs Saavedra and Jacquez and the California Subclass were misled into purchasing and using Cymbalta. Plaintiffs Saavedra and Jacquez relied, to their detriment, on Lilly's false representations that Cymbalta withdrawal was rare. The California Subclass was uniformly exposed to Lilly's unlawful and unfair business practices.

A. Unlawful Business Practices

100. As set forth in the preceding paragraphs, Lilly has engaged in the unlawful business practice of misleading Plaintiffs Saavedra and Jacquez and the California Subclass regarding the frequency, severity, and/or duration of Cymbalta withdrawal. Lilly's unlawful marketing practices have violated numerous California laws, including, *inter alia*: Cal. U. Com. Code §§ 2313-15 (breach of express and implied warranty); Cal. Bus. & Prof. Code §§ 17500, *et seq.* (false advertising and marketing); and Cal. Civ. Code §§ 1750, et seq. (violations of California's Consumer Legal Remedies Act).

101. As a result of Lilly's unlawful business practices, Plaintiffs Saavedra and Jacquez and the California Subclass purchased Cymbalta without sufficient information

regarding a material side-effect of the drug. Specifically, Plaintiffs Saavedra and Jacquez and the California Subclass were misled into believing that Cymbalta withdrawal was rare, when, in fact, it occurred in almost half of users. Plaintiffs Saavedra and Jacquez reasonably relied upon Lilly's misrepresentations and/or omissions regarding Cymbalta withdrawal in deciding whether to purchase and use the drug. The California Subclass was uniformly exposed to Lilly's misrepresentations and/or omissions regarding Cymbalta withdrawal.

102. In addition to engaging in unlawful marketing practices, Lilly also engaged in an unlawful method of competition. Lilly misled Plaintiffs Saavedra and Jacquez and the California Subclass about the frequency, severity, and/or duration of Cymbalta withdrawal and thereby artificially inflated Cymbalta's price on the open market. Because Plaintiffs Saavedra and Jacquez and the California Subclass were unaware of the high incidence of Cymbalta withdrawal, they were more likely to purchase Cymbalta as opposed to a competing antidepressant that was not habit-forming. The market was unable to correctly valuate Cymbalta and, therefore, Lilly gained an unlawful competitive advantage over competing antidepressant drugs. This unlawful method of competition resulted in Plaintiffs Saavedra and Jacquez and the California Subclass paying a substantially higher price for Cymbalta than it was actually worth.

B. Unfair Business Practices

103. As set forth in the preceding paragraphs, Lilly has engaged in an unfair business practice of misleading Plaintiffs Saavedra and Jacquez and the California Subclass regarding the frequency, severity, and/or duration of Cymbalta withdrawal.

104. A business practice is unfair when it offends an established public policy or when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

105. Lilly's unfair and unlawful marketing practices offend public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. Lilly misled consumers about the habit-forming characteristics of Cymbalta and unjustly benefited from consumers' physical dependence on the drug. This conduct offends any notion of public policy.

106. The harm to Plaintiffs Saavedra and Jacquez and the California Subclass caused by Lilly's unfair business practices outweighs any countervailing benefits to consumers or competition, and could not reasonably have been known and avoided by consumers. Furthermore, Lilly's unfair business practices cannot be excused for any business justification, motive, or rationale in light of the severity of Lilly's misconduct and the harm caused to Plaintiffs Saavedra and Jacquez and the California Subclass.

107. As a result of Lilly's violations of the UCL, Plaintiffs Saavedra and Jacquez seek an order of this Court enjoining Lilly from continuing these unlawful and unfair practices and awarding Plaintiffs Saavedra and Jacquez and the California

Subclass, *inter alia*, actual damages, restitution, a disgorgement of Lilly's profits, and for such other relief set forth below.

IX. COUNT 3 (CALIFORNIA SUBCLASS): VIOLATIONS OF CALIFORNIA'S FALSE ADVERTISING LAW CAL. BUS. & PROF. CODE §§ 17500, *ET SEQ.*

108. Plaintiffs Saavedra and Jacquez incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

109. Plaintiffs Saavedra and Jacquez and the California Subclass bring a cause of action against Lilly pursuant to Cal. Bus. & Prof. Code §§ 17500, *et seq.* ("California's False Advertising Law").

110. The purpose of California's False Advertising Law is to protect consumers from false or misleading advertising and promotions. California's False Advertising Law prohibits the false or deceptive advertising of products to consumers in any form of media, when the company placing the advertisement knows, or should have known, that the advertisement would be likely to mislead consumers about a material aspect of a product.

111. Lilly uses advertising on its packaging and through various media outlets to sell and market Cymbalta directly to consumers. The advertisements and labeling are deceptive, untrue, or misleading within the meaning of the California's False Advertising Law because they misstate the frequency, severity, and/or duration of withdrawal symptoms associate with Cymbalta.

112. In making and disseminating the statements alleged herein, Lilly knew or should have known that the statements were untrue or misleading, and that it acted in violation of California's False Advertising Law. Lilly knew or should have known the true frequency, severity, and/or duration of withdrawal symptoms as the data contained in studies Lilly funded, designed, and conducted. Nevertheless, Lilly engaged in false adverting by placing a misleading and deceptive "discontinuation warning" for the purpose of inducing Plaintiffs Saavedra and Jacquez and the California Subclass into purchasing and ingesting Cymbalta.

113. Lilly's misrepresentations of material facts related to Cymbalta, as detailed above, constitute false and misleading advertising in violation of California's False Advertising Law.

114. Through its deceptive and unlawful marketing practices, Lilly has improperly and illegally obtained money from Plaintiffs Saavedra and Jacquez and the California Subclass.

115. Pursuant to California's False Advertising Law, specifically Cal. Bus. & Prof. Code § 17535, Plaintiffs Saavedra and Jacquez and the California Subclass seek an order of this Court requiring Lilly to fully disclose the true nature of its misrepresentations to consumers and healthcare professionals, disgorging Lilly's ill-gotten gains and/or award full restitution of all monies wrongfully acquired by means of its false advertising, enjoining Lilly from continuing to violate California's False

Advertising Law in its sale and marketing of Cymbalta, awarding those damages available under California law, and for such other relief as set forth below.

X. COUNT 4 (MASSACHUSETTS SUBCLASS): VIOLATIONS OF MASSACHUSETTS'S CONSUMER PROTECTION ACT MASS. GEN. LAWS CH. 93A, §§ 1, *ET SEQ.*[12]

116. Dr. Strafford, who was a resident of Massachusetts when she first purchased Cymbalta, incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

117. Massachusetts's Consumer Protection Act, Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, makes it unlawful to engage in any unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Unfair acts or practices include practices that are within at least the penumbra of some common-law, statutory, or other established concept of unfairness; immoral, unethical, oppressive, or unscrupulous acts; or acts that cause substantial injury. Deceptive acts or practices include those that would reasonably cause a person to act differently from the way he or she otherwise would have acted.

118. As alleged throughout this Complaint, Lilly engaged in unfair, deceptive, and/or unlawful marketing in violation of Mass. Gen. Laws ch. 93A, § 2 by representing to the Massachusetts Subclass that Cymbalta withdrawal was rare or infrequent when, in

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[12] A demand has been sent to Lilly giving notice of the claims alleged herein pursuant to Mass. Gen. Laws Ch. 93A, § 9(3). If after thirty days, Lilly offers a reasonable settlement for the Massachusetts Subclass, Count 4 will be dismissed with prejudice.

truth, it is common and severe. Lilly sold and marketed Cymbalta while omitting and/or misrepresenting the frequency, severity, and/or duration of Cymbalta withdrawal. These unfair and/or deceptive acts or practices would cause a consumer to believe, incorrectly, that Cymbalta withdrawal was a rare adverse effect.

119. Lilly's conduct offends public policy and is immoral, unethical, oppressive, unscrupulous, or substantial injurious to consumers. Additionally, Lilly's conduct was deceptive because it caused Dr. Strafford and members of the Massachusetts Subclass to act differently from the way they would have otherwise acted.

120. Lilly's unfair and/or deceptive acts or practices in violation of Mass. Gen. Laws Ch. 93A, § 2, proximately caused Dr. Strafford and the Massachusetts Subclass adverse consequences or losses, including the loss of money from purchasing Cymbalta. The losses and adverse consequences that Dr. Strafford and the Massachusetts Subclass suffered by purchasing Cymbalta were foreseeable results of Lilly's unfair, deceptive, and/or unlawful advertising and marketing.

121. As a result of Lilly's violations of Massachusetts's Consumer Protection Act, the Massachusetts Subclass seeks an order of this Court awarding the Massachusetts Subclass, *inter alia*, actual damages, restitution, an injunction against the use of unlawful trade practice, attorneys' fees and costs, and for such other relief as set forth below. Dr. Strafford reserves the right to amend this Complaint to seek punitive damages.

XI. COUNT 5 (MISSOURI SUBCLASS): VIOLATIONS OF MISSOURI'S MERCHANDISING PRACTICES ACT MO. REV. STAT. §§ 407.010, *ET SEQ.*

122. Plaintiff Matthews is a resident of Missouri and incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

123. Missouri's Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010, *et seq.*, makes it unlawful to use any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.

124. Plaintiff Matthews and members of the Missouri Subclass purchased merchandise, Cymbalta, from Lilly primarily for personal, family, or household purposes. Lilly advertised and/or sold Cymbalta to Plaintiff Matthews and the Missouri Subclass in trade or commerce.

125. As alleged throughout this Complaint, Lilly engaged in unfair, deceptive and/or unlawful marketing of Cymbalta in violation of Mo. Rev. Stat. §§ 407.020(1) by representing to the Missouri Subclass that Cymbalta withdrawal was rare or infrequent when, in truth, it is common and severe. Lilly sold and marketed Cymbalta while omitting and/or misrepresenting the frequency, severity, and/or duration of Cymbalta withdrawal. Lilly failed to disclose material facts that were either known to it, or upon reasonable inquiry would have been known to it.

126. Lilly's advertising and labeling of Cymbalta constituted material omissions/misstatements that would cause a consumer to believe, incorrectly, that Cymbalta withdrawal was a rare adverse effect.

127. Plaintiff Matthews and the Missouri Subclass suffered ascertainable losses of money or property as a result of Lilly's unfair, deceptive, and/or unlawful marketing practices by purchasing Cymbalta that was illegally advertised and marketed in violation of Mo. Rev. Stat. §§ 407.020(1). The losses of Plaintiff Matthews and the Missouri Subclass include the full purchase price of Cymbalta and/or the costs of purchasing a drug that was worth less than the product they thought they had purchased had Lilly's representations been true and had Lilly fully disclosed the withdrawal risks.

128. As a result of Lilly's violations of the Missouri's Merchandising Practices Act, the Missouri Subclass seeks an order of this Court awarding the Missouri Subclass, *inter alia*, actual damages, restitution, an injunction against the use of unlawful trade practice, attorneys' fees and costs, and for such other relief as set forth below. Plaintiff Matthews reserves the right to amend this Complaint to seek punitive damages.

XII. COUNT 6 (NEW YORK SUBCLASS): VIOLATIONS OF NEW YORK'S CONSUMER PROTECTION FROM DECEPTIVE ACTS AND PRACTICES LAW, N.Y. GEN. BUS. LAW §§ 349, *ET SEQ.*

129. Dr. Strafford is a resident of New York and incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

130. New York's Consumer Protection from Deceptive Acts and Practices Law, N.Y. Gen. Bus. Law §§ 349, *et seq.*, makes it unlawful to engage in any deceptive acts, practices, or false advertising in the conduct of any business, trade, or commerce.

131. Lilly's acts and practices in advertising, marketing, and selling Cymbalta were directed at consumers and had a broad impact on consumers at large. As alleged throughout this Complaint, Lilly engaged in deceptive and unlawful marketing in violation of N.Y. Gen. Bus. Law § 349 by representing to the New York Subclass that Cymbalta withdrawal was rare or infrequent when, in truth, it is common and severe. Lilly sold and marketed Cymbalta while concealing and misrepresenting the frequency, severity, and/or duration of Cymbalta withdrawal. These acts and practices were deceptive because they were likely to mislead a reasonable consumer acting reasonably under the circumstances. For example, Lilly's concealment and misrepresentation regarding the frequency, severity, and/or duration of Cymbalta withdrawal was a material omission/misstatement that would cause a consumer to believe, incorrectly, that Cymbalta withdrawal was a rare adverse effect.

132. Such acts and practices caused actual injury to Dr. Strafford and the New York Subclass.

133. In addition, Lilly engaged in false advertising pursuant to N.Y. Gen. Bus. Law § 350-a, on its drug labeling, direct-to-consumer advertisements, and various other forms of promotion by misstating the frequency, severity, and/or duration of a material

side-effect of Cymbalta, to wit, that Cymbalta withdrawal is relatively rare when, in fact, it occurs in approximately half of Cymbalta users. Lilly's false representations regarding the frequency, severity, and/or duration of Cymbalta withdrawal relate to a material aspect of Cymbalta, because Cymbalta withdrawal is a potential adverse effect of the drug.

134. Lilly's false advertising of Cymbalta had an impact on the public at large.

135. Lilly effectively controlled all of the information about the withdrawal effects of Cymbalta and therefore Lilly's misrepresentations give rise to an inference or presumption of reliance by Dr. Strafford and the New York Subclass. Dr. Strafford and the New York Subclass did not have a reasonable opportunity to discover facts about the withdrawal effects of Cymbalta before purchasing Cymbalta.

136. Dr. Strafford and the New York Subclass suffered injury as a result of Lilly's deceptive and unlawful marketing practices, including lost money from purchasing Cymbalta that was unlawfully advertised and marketed in violation of pursuant to N.Y. Gen. Bus. Law §§ 349 and 350.

137. As a result of Lilly's violations of the New York's Consumer Protection from Deceptive Acts and Practices Law, Dr. Strafford and the New York Subclass seek an order of this Court awarding the New York Subclass, *inter alia*, actual damages, full refunds of all moneys spent on Cymbalta, restitution, an injunction against the use of

unlawful trade practice, attorneys' fees and costs, and for such other relief as set forth below. Dr. Strafford reserves the right to seek treble damages.

XIII. COUNTS 7-11: INDIVIDUAL CAUSES OF ACTION FOR PLAINTIFF SAAVEDRA'S PERSONAL INJURIES

138. Counts 7-11 allege causes of action pertaining to the personal injury Plaintiff Saavedra suffered while weaning off of Cymbalta. Counts 7-11 are not premised on consumer protection. They are based on making Plaintiff Saavedra whole for the personal injury she sustained as a result of Lilly putting to market a product that was unreasonably dangerous to consumers and from which Plaintiff Saavedra sustained significant injury. These claims are brought individually by Plaintiff Saavedra against Lilly in this lawsuit so as not to split her causes of action.

XIV. COUNT 7 (INDIVIDUALLY): BREACH OF EXPRESS WARRANTY

139. Plaintiff Saavedra incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

140. Plaintiff Saavedra brings a cause of action against Lilly for breach of express warranty.

141. Lilly made numerous representations, descriptions, and promises to Plaintiff regarding the frequency, severity and/or duration of withdrawal symptoms caused by ceasing to take Cymbalta. Accordingly, Lilly expressly warranted that Cymbalta had a low or rare incidence of withdrawal.

142. Lilly, however, knew that its representations, descriptions, and promises regarding Cymbalta withdrawal were false. Lilly was aware, as demonstrated in studies of Cymbalta that it funded, designed, and conducted, that withdrawal symptoms occurred in almost half of users. Lilly's representations were misleading and false.

143. Plaintiff Saavedra reasonably relied on Lilly's representations in purchasing and ingesting Cymbalta. Cymbalta, however, did not perform as was warranted. Cymbalta withdrawal was substantially more frequent than had been represented. Accordingly, Lilly breached its express warranty by providing a drug that contained side-effects that were never disclosed to the Plaintiff Saavedra.

144. As a direct and proximate result of Lilly's false and misleading representations and warranties, Plaintiff Saavedra suffered significant damages. Accordingly, Plaintiff Saavedra seeks an order of this Court:

a. Awarding Plaintiff Saavedra compensatory damages;

b. Awarding Plaintiff Saavedra all economic and non-economic damages for the personal injury she sustained while withdrawing from Cymbalta;

c. Imposing exemplary/punitive damages against Lilly;

d. Awarding costs and reasonable attorneys' fees; and

e. Providing for such other relief as set forth below.

XV. COUNT 8 (INDIVIDUALLY): BREACH OF IMPLIED WARRANTY

145. Plaintiff Saavedra incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

146. Plaintiff Saavedra brings a cause of action against Lilly for breach of implied warranty.

147. Lilly made numerous representations, descriptions, and promises to Plaintiff Saavedra regarding the frequency, severity, and/or duration of withdrawal symptoms caused by stopping Cymbalta. Specifically, Cymbalta's label suggests that withdrawal symptoms occurred in approximately one (1) percent of users.

148. Plaintiff Saavedra reasonably relied on Lilly's representations in purchasing and ingesting Cymbalta.

149. As set forth throughout this Complaint, Lilly knew that its representations, descriptions and promises regarding Cymbalta withdrawal were false.

150. When Plaintiff Saavedra purchased Cymbalta, it did not conform to the promises or affirmations of fact made on Cymbalta's label. The incidence of Cymbalta withdrawal was substantially more common than Lilly had represented.

151. Accordingly, Cymbalta failed to conform to Lilly's implied warranty regarding the frequency, severity, and/or duration of Cymbalta withdrawal.

152. As a direct and proximate result of Lilly's false and misleading representations and warranties, Plaintiff Saavedra suffered significant personal injury when she underwent Cymbalta withdrawal. Accordingly, Plaintiff Saavedra seeks an order of this Court:

a. Awarding Plaintiff Saavedra compensatory damages;

b. Awarding Plaintiff Saavedra economic and non-economic damages for the personal injury she sustained while withdrawing from Cymbalta;

c. Imposing exemplary/punitive damages against Lilly;

d. Awarding costs and reasonable attorneys' fees; and

e. Providing for such other relief as set forth below.

XVI. COUNT 9 (INDIVIDUALLY): UNJUST ENRICHMENT

153. Plaintiff Saavedra incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

154. Plaintiff Saavedra brings a cause of action against Lilly for the inequitable and unjust enrichment of Lilly through its unfair and unlawful marketing practices.

155. Lilly has received benefits from Plaintiff Saavedra in the form of the money paid by Plaintiff in purchasing Cymbalta.

156. By misleading Plaintiff Saavedra and the public that Cymbalta withdrawal was rare, Lilly reaped millions of dollars in profits that it otherwise would not have obtained and caused Plaintiff Saavedra to spend money on Cymbalta.

157. Lilly is aware of its receipt of those benefits and received those benefits to the detriment of Plaintiff Saavedra.

158. Lilly continues to retain those benefits to the detriment of Plaintiff Saavedra.

159. Under the circumstances, it would be inequitable and against good conscience for Lilly to retain those benefits.

160. As a direct and proximate result of Lilly's unfair and unlawful marketing practices, Plaintiff Saavedra suffered significant damages. Accordingly, Plaintiff Saavedra seeks an order of this Court:

a. Disgorging Lilly's ill-gotten gains acquired as a result of its unfair and unlawful marketing practices;

b. Awarding restitution to the Plaintiff Saavedra;

c. Imposing exemplary/punitive damages against Lilly;

d. Awarding costs and reasonable attorneys' fees; and

e. Providing for such other relief as set forth below.

XVII. COUNT 10 (INDIVIDUALLY): STRICT PRODUCTS LIABILITY

161. Plaintiff Saavedra incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

162. Plaintiff Saavedra brings a cause of action for strict products liability against Lilly.

163. Lilly is, and was at all times relevant herein, engaged in the business of designing, testing, manufacturing, and promoting prescription medications, including Cymbalta, to the general public.

164. At all times relevant herein, Cymbalta posed a significant risk of injury to users. Specifically, Cymbalta poses a significant risk of creating physical dependence.

165. Lilly was fully aware of the risks Cymbalta posed to consumers. Studies of Cymbalta that were funded, designed, and conducted by Lilly showed that a significant percentage of Cymbalta users experienced withdrawal symptoms.

166. The risks associated with Cymbalta withdrawal, however, were neither obvious nor commonly known. Thus, Lilly owed a duty to adequately warn users, including Plaintiff Saavedra, of the risks associated with stopping Cymbalta.

167. The Cymbalta manufactured, prescribed, and sold by Lilly was not accompanied by proper warnings regarding the frequency, severity, and/or duration of Cymbalta withdrawal symptoms. The warnings did not accurately reflect that a significant percentage of Cymbalta users suffered from withdrawal symptoms. Rather, the warnings suggested that Cymbalta withdrawal was rare, or occurred at a rate of approximately one (1) percent.

168. Plaintiff Saavedra, in accordance with its prescribed and reasonably for foreseeable use, began ingesting Cymbalta to treat her medical conditions. When she attempted to stop, as set forth in preceding paragraphs, she experienced severe withdrawal symptoms over the course of several months. During this period, Plaintiff Saavedra suffered significant personal injury and pain.

169. As direct and proximate result of Lilly's defective production and marketing of Cymbalta, Plaintiff Saavedra suffered significant damages. Accordingly, Plaintiff Saavedra seeks an order of this Court:

a. Awarding Plaintiff Saavedra compensatory damages;

b. Awarding Plaintiff Saavedra all economic and non-economic damages for the personal injury she sustained while withdrawing from Cymbalta including, *inter alia*, pain and suffering, emotional distress, anguish, shock, stress, and mental suffering;

c. Imposing exemplary/punitive damages against Lilly;

d. Awarding costs and reasonable attorneys' fees; and

e. Providing for such other relief as set forth below.

XVIII. COUNT 11 (INDIVIDUALLY): NEGLIGENCE

170. Plaintiff Saavedra incorporates by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

171. Plaintiff Saavedra brings a cause of action for negligence Lilly.

172. Lilly has a duty to exercise reasonable care in the design, formulation, manufacture, sale, promotion, supply and/or distribution of the drug Cymbalta, including the duty to assure the product is as effective as it is promoted, that the product carries adequate warnings, and the duty to ensure that the product does not cause users to suffer from unreasonable, dangerous side effects.

173. Lilly was negligent in the design, manufacture, testing, advertising, marketing, promoting, labeling, supply, and sale of Cymbalta in that it:

a. Failed to provide proper warnings regarding the true frequency, severity, and/or duration of Cymbalta withdrawal symptoms;

b. Failed to provide any warnings that Cymbalta would cause users to become physically dependant on the drug;

c. Misled users by suggesting that Cymbalta withdrawal was rare;

d. Failed to provide proper training and instructions to users and healthcare professionals regarding the appropriate methods for stopping Cymbalta;

e. Failed to warn that the risks associated with Cymbalta exceeded the risks or other comparable treatment options;

f. Failed to warn of the potential duration associated with Cymbalta.

g. Misrepresented the difficulty and severity of symptoms associated with withdrawal;

h. Negligently designed Cymbalta in a way that it knew would cause withdrawal and physical dependence;

i. Recklessly, falsely, and/or deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Cymbalta to the Plaintiff, the public, the FDA and the medical community;

j. Failed to comply with its post-manufacturing duty to warn that Cymbalta was being promoted, distributed, and prescribed without warning of the true risk of side effects and without accurate information regarding potential withdrawal symptoms;

k. Was otherwise careless, negligence, grossly negligent, reckless, and acted with willful and wanton disregard for Plaintiff's rights and safety.

174. Despite the fact that Lilly knew that Cymbalta created frequent and severe withdrawal symptoms, Lilly continued to market Cymbalta to consumers, including Plaintiff. Lilly knew that Cymbalta users, including Plaintiff Saavedra, would suffer reasonably foreseeable injuries as a result of its failure to exercise reasonable care.

175. Had Lilly provided an adequate warning regarding the frequency, severity, and/or duration of Cymbalta withdrawal, Plaintiff Saavedra would never have started Cymbalta, would not have suffered its withdrawal symptoms, and would never have become physically dependant on Cymbalta.

176. As a direct and proximate result of Lilly's negligence, misrepresentations, and recklessness, Plaintiff Saavedra has suffered significant damages. Accordingly, Plaintiff Saavedra seeks an order of this Court:

a. Awarding Plaintiff compensatory damages;

b. Awarding Plaintiff Saavedra all appropriate damages for the personal injury she sustained while withdrawing from Cymbalta including, *inter alia*, pain and suffering, emotional distress, anguish, shock, stress, and mental suffering;

c. Imposing exemplary / punitive damages against Lilly;

d. Awarding costs and reasonable attorneys' fees; and

e. Providing for such other relief as set forth below.

XIX. EXEMPLARY/PUNITIVE/TREBLE DAMAGES – RESERVATION OF RIGHTS

177. Plaintiffs incorporate by reference each and every prior and subsequent allegation of this Complaint as if fully restated here.

178. Plaintiffs reserve their rights to seek exemplary/punitive/treble damages insofar as they are allowed by applicable laws.

XX. DEMAND FOR JURY TRIAL

179. Plaintiffs respectfully request a trial by jury on all claims triable as a matter of right.

XXI. PRAYER FOR RELIEF

180. WHEREFORE, Plaintiffs individually and on behalf all those similarly situated, pray for judgment and the following relief:

a. Certifying this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the proposed Classes and Subclasses described herein;

b. Declaring Lilly's label on Cymbalta misleading;

c. Permanently enjoining Lilly from performing further unfair and unlawful acts as alleged herein.

d. Granting Plaintiffs, the Classes, and each Subclass awards of actual and compensatory damages in such amount to be determined at trial and as provided by applicable law;

e. Granting Plaintiffs, the Classes, and each Subclass a refund of all monies acquired by Lilly by means of its unfair and unlawful marketing and/or labeling of Cymbalta;

f. Granting Plaintiffs, the Classes, and each Subclass awards of restitution and/or disgorgement of Lilly's profit from its unfair and unlawful marketing and/or labeling of Cymbalta;

g. Awarding the Plaintiffs, the Classes, and each Subclass costs of appropriate treatment for consumers of Cymbalta to withdraw from the drug;

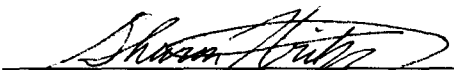
h. Granting Plaintiffs, the Classes, and each Subclass pre-judgment and post-judgment interest;

i. Granting Plaintiffs, the Classes, and each Subclass reasonable attorneys' fees and costs of suit; and

j. Granting Plaintiffs, the Classes and each Subclass such other and further relief as the Court deems just and proper under the circumstances.

DATED this 14th day of December, 2012.

KELLER ROHRBACK L.L.P.



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