UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendant.

No. 1:14cv1614 AJT/JFA

COMPLAINT

INTRODUCTION

1. Cymbalta (generically known as duloxetine) is a prescription antidepressant manufactured, marketed and sold by Defendant Eli Lilly and Company ("Lilly"). This civil action alleges personal injuries and damages Plaintiff suffered as a result of Lilly's failure to provide adequate instructions for stopping Cymbalta and an adequate warning that fully and accurately informed Plaintiff about the frequency, severity, and/or duration of symptoms associated with Cymbalta withdrawal. In addition, Plaintiff alleges that Lilly defectively designed Cymbalta pills as delayed-release capsules with beads available only in 20, 30 and 60 mg doses, with a label that instructs users that the drug "should be swallowed whole and should not be chewed or crushed, nor the capsule be opened and its contents be sprinkled on food or mixed with liquids." Lilly's design (delayed-release capsules with beads available only in 20, 30 and 60 mg doses) and accompanying instructions (Cymbalta should be "gradually tapered," but should only be "swallowed whole") prevented Plaintiff from properly tapering off of the drug.

PARTIES

2. Plaintiff Gilda Hagan-Brown is, and at all times relevant to this Complaint was, a citizen of the State of Virginia and resident Prince William County.

3. Defendant Eli Lilly and Company is, and at all times relevant to this Complaint was, an Indiana corporation with its headquarters in Indianapolis, Indiana. Lilly is a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of numerous pharmaceutical products, including Cymbalta.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C.A. § 1332. There is complete diversity of citizenship between Plaintiff and Lilly and the amount in controversy exceeds $75,000.00.

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

6. Furthermore, Lilly has caused tortious injury by acts and omissions in the State of Virginia, as well as caused tortious injury by acts and omissions outside of the State of Virginia, while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in the State of Virginia.

7. Venue is proper before this Court pursuant to 28 U.S.C. § 1391. A substantial portion of the events giving rise to the claims alleged in this Complaint took place within the Eastern District of Virginia.

FACTUAL ALLEGATIONS

8. Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. A substantial portion of Lilly's sales and profits have been derived from Cymbalta, whose 2013 annual sales exceeded $3.9 billion.

9. Lilly has enjoyed considerable financial success from manufacturing and selling antidepressants, including Prozac (generically known as fluoxetine). Lilly launched Prozac in 1988,

touting it as the first "Selective Serotonin Reuptake Inhibitor" ("SSRI"). SSRIs are a class of antidepressant drugs that have been promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001, leading to a proliferation of generic versions of the drug.

10. In 2001, Lilly needed to fill the void left behind by Prozac's patent expiration, and so it sought approval by the Food and Drug Administration ("FDA") for its next patented antidepressant, Cymbalta. Cymbalta belongs to a class of antidepressants known as "Serotonin and Norepinephrine Reuptake Inhibitors" ("SNRIs"). SNRIs are similar to SSRIs, but in addition to blocking the absorption of serotonin, SNRIs are thought to block the absorption of another neurotransmitter, norepinephrine, thereby increasing the levels of both serotonin and norepinephrine in the brain. These drugs are promoted as treatments for pain as well as depression.

11. The FDA initially rejected Lilly's application in 2003 for approval of Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

12. Eventually, in 2004, the FDA approved Cymbalta with a liver toxicity warning included in the prescribing information. The drug was approved for Major Depressive Disorder ("MDD"). In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and in 2008 for treatment of fibromyalgia.

13. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff Gilda Hagan-Brown, through various media platforms, including internet, print and television. In addition, Lilly has promoted Cymbalta to the medical community by utilizing its well-organized army of sales

representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature.

14. Lilly's promotional campaigns have continuously failed to provide adequate instructions to users and health care professionals for stopping Cymbalta and have failed to include adequate warnings that fully and accurately inform users and health care professionals about the frequency, severity, and/or duration of Cymbalta withdrawal.

15. Withdrawal symptoms are not connected to a patient's underlying condition but rather are the body's physical reactions to the drug leaving the system. While many SSRIs and SNRIs can cause withdrawal symptoms, the initiation, frequency, and severity of withdrawal symptoms correlate to a drug's half-life. The half-life of a drug is the time it takes for the concentration of the drug in the body to be reduced by half. This information is one of the basic pharmacokinetic properties of a drug and is known to researchers developing the drug. Cymbalta has one of the shortest half-lives of any of the SSRIs and SNRIs. Since 2004, the Cymbalta label has stated that the half-life of Cymbalta is approximately 12 hours. In contrast, the half-life of Prozac is seven days. The shorter the half-life, the faster the body eliminates the drug from the system, thus creating a higher risk of withdrawal symptoms. Because Cymbalta's half-life is less than one day and Cymbalta is generally administered once daily, it is possible for users of Cymbalta to experience withdrawal symptoms after simply forgetting to take one dose. This also means that users cannot safely taper off of the drug by taking a capsule every other day.

16. Despite Lilly's awareness of Cymbalta's half-life and the correlation between a short half-life and withdrawal risk, Lilly did not include any cross-references between the Pharmacokinetics section of the label and either the Precautions section or the Dosage and Use section. In fact, rather than drawing attention to the potential consequences of Cymbalta's extremely short half-life, Lilly misleadingly referenced all other SSRIs and SNRIs, as if Cymbalta could be expected to pose a similar risk of withdrawal as all other drugs of its class generally:

> 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 liability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

(2004 Cymbalta label.) The extremely short half-life of Cymbalta should have alerted Lilly's researchers to the fact that the risk of Cymbalta withdrawal would be more frequent than that experienced with other SSRIs and SNRIs.

17. Lilly should have been aware of the significance of antidepressant withdrawal, because Lilly had previously researched and publicized the issue in connection with its antidepressant Prozac. Because Prozac has an extremely long half-life relative to other antidepressants, the length of time it takes for a person's body to fully eliminate Prozac from the system provides a built-in gradual tapering of sorts, so that withdrawal symptoms from Prozac are relatively infrequent. Prozac's main competitors in the 1990s, Zoloft and Paxil, had shorter half-lives, and Lilly engineered a campaign to differentiate Prozac from its competitors on this basis, funding clinical studies of antidepressant withdrawal and coining the term "antidepressant discontinuation syndrome."

18. Researchers, including Lilly's own consultants, have postulated that withdrawal reactions result from a sudden decrease in the availability of synaptic serotonin in the face of down-regulated serotonin receptors. *See* Schatzberg et al., Possible mechanisms of the serotonin reuptake inhibitor discontinuation syndrome, J. Clin Psychiatry 58 (suppl7): 23-7 (1997); Blier and Tremblay, Physiological mechanisms underlying the anti-depressant discontinuation syndrome, J Clin Psychiatry 67 (suppl4) (2006): 8-13. They have theorized that, upon chronic dosing, the increased occupancy of pre-synaptic serotonin receptors signals the pre-synaptic neuron to synthesize and release less serotonin. Serotonin levels within the synapse drop, then rise again, ultimately leading to down-regulation of post-

synaptic serotonin receptors. In other words, as SSRIs and SNRIs block the reuptake of serotonin and norepinephrine, structural changes in the brain occur such that production of these neurotransmitters is reduced. These changes in the brain's architecture may contribute to withdrawal symptoms, as a patient is, upon cessation of the drug, left not only with the absence of the drug but also structural changes in the brain that remain for some time even after the drug has fully washed out of the person's system. Because of the short half-life of Cymbalta, the brain has even less time to adjust to the cessation of Cymbalta treatment. Despite Lilly's knowledge of this phenomenon, Lilly did not include in Cymbalta's label or promotional materials any information regarding the increased risk of withdrawal due to structural changes in the brain exacerbated by Cymbalta's short half-life.

19. As Lilly was fully aware of the issue of antidepressant withdrawal and of Cymbalta's elevated withdrawal risk, Lilly should not only have included a strong warning to physicians and patients, but it should have also designed the drug in such a way that would easily allow for a gradual tapering off of the drug. Instead, Cymbalta is manufactured as a delayed-release capsule filled with tiny beads at 20, 30 and 60 mg doses only, and Cymbalta's label and Medication Guide instruct physicians and patients that the capsule "should be swallowed whole and should not be chewed or crushed, nor should the capsule be opened and its contents be sprinkled on food or mixed with liquids." In contrast, other SSRIs and SNRIs are available as scored tablets that can be halved and quartered with relative ease, or are available in liquid form which can be measured and dispensed in small increments.

20. In 2013, Cymbalta's label provided the following precaution regarding stopping 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. . . .

Cymbalta's label also provided the following instructions for stopping Cymbalta:

> A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Id.

21. Thus, in addition to using the euphemistic term "discontinuation" to describe Cymbalta's withdrawal symptoms, the label 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. However, Lilly's own studies, published as a January 2005 article in the Journal of Affective Disorders, showed that, at a minimum, between 44.3% and 50% of Cymbalta patients suffered from "discontinuation" side effects (i.e., withdrawal symptoms). The article 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 acknowledge that use of a symptom checklist would likely produce even higher incidence rates of 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 (2005). Notwithstanding, Lilly omitted this critical information from its label, instead misleadingly stating only that certain symptoms are experienced at a rate of 1% or greater, thus suggesting that Cymbalta withdrawal is rare or infrequent.

22. Moreover, Lilly's clinical trials showed that, overall, between 9.6% and 17.2% of Cymbalta users suffered *severe* withdrawal symptoms, *id.*, yet nowhere in the label does Lilly inform practitioners and patients of that risk.

23. Cymbalta's withdrawal symptoms include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures, and vertigo. When users try to

stop taking Cymbalta, the side effects can be severe enough to force them to start taking Cymbalta again, not to treat their underlying conditions, but simply to stop the withdrawal symptoms. Users thus become prisoners to Cymbalta, and Lilly financially benefits by having a legion of physically dependent, long-term users of Cymbalta.

24. And, as set forth above, the design of Cymbalta pills, as delayed-release capsules filled with tiny beads at 20, 30 and 60 mg doses only, along with the instruction to swallow them whole, prevents users from properly tapering (gradually decreasing their dosage) from Cymbalta in order to avoid or reduce withdrawal symptoms.

25. Despite Lilly's knowledge of the high rate of withdrawal symptoms in users stopping Cymbalta, Lilly neither provided adequate instructions to users and physicians for stopping Cymbalta nor included adequate warnings in its product label, marketing, or advertising to fully and accurately inform users and physicians about the frequency, severity, and/or duration of the withdrawal symptoms.

26. Lilly's misleading direct-to-consumer promotional campaigns and its failure to adequately warn users and physicians about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms have paid off financially for Lilly. Cymbalta became a "blockbuster" drug with over $3.9 billion dollars in annual sales. In the past few years, Cymbalta has either been the most profitable or second most profitable drug in Lilly's product line. Lilly had the knowledge, the means, and the duty to provide adequate instructions for stopping Cymbalta and adequate warnings about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms. Lilly could have relayed these instructions and warnings through the same means it utilized to promote its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements, and sales representatives.

27. Falsely reassured by the misleading manner in which Lilly reported Cymbalta's withdrawal symptoms, physicians, including Plaintiff Gilda Hagan-Brown's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate instructions for stopping Cymbalta and

without adequate warnings that fully and accurately inform them about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms.

28. At all times relevant, Lilly knew or should have known of the significantly increased risk of withdrawal symptoms, including their severity and duration, posed by Cymbalta and yet failed to adequately warn about said risks.

29. At all times relevant, Lilly engaged in willful, wanton, and reckless conduct, including its defective design of Cymbalta and its failure to fully and accurately warn about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms, all of which induced physicians to prescribe Cymbalta and consumers to use it, including Plaintiff Gilda Hagan-Brown and her physicians.

30. Plaintiff Gilda Hagan-Brown's use of the drug and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to its failure to provide adequate instructions for stopping Cymbalta and its failure to include adequate warnings that fully and accurately inform users and physicians of the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms.

31. In or around September 2012, Plaintiff Gilda Hagan-Brown was prescribed Cymbalta by her physician, for treatment of Fibromyalgia and Osteoarthritis of the cervical spine.

32. In or around March 2013, Plaintiff Gilda Hagan-Brown elected to wean off of Cymbalta because she did not like the feeling of intoxication that the medication produced. As a result, Plaintiff Gilda Hagan-Brown elected to wean off of Cymbalta under the care and supervision of her Physician.

33. Plaintiff Gilda Hagan-Brown experienced severe and dangerous withdrawal symptoms upon attempting to discontinue Cymbalta. By way of example, Plaintiff Gilda Hagan-Brown experienced suicidal thoughts, severe depression, migraines, buzzing in her head, anxiety, mood swings, dizziness, glazed eyes, Irritable Bowel Syndrome, dry mouth, and sweating.

34. At all times relevant, Lilly knew or should have known that Cymbalta was in a defective condition and was and is inherently dangerous and unsafe when used in the manner instructed and provided for by Lilly.

35. If Lilly had adequately, accurately and properly warned about the withdrawal symptoms associated with stopping Cymbalta, including accurately reporting their frequency, severity, and/or duration, Plaintiff Gilda Hagan-Brown's physician would not have prescribed the drug to Plaintiff Gilda Hagan-Brown; Plaintiff Gilda Hagan-Brown would have refused the drug; and/or Plaintiff Gilda Hagan-Brown's physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid Plaintiff Gilda Hagan-Brown's injuries and damages.

36. As a direct and proximate result of taking Cymbalta, Plaintiff suffered compensable injuries, including but not limited to the following:

a. physical, emotional, and psychological injuries;

b. past and future pain and suffering;

c. past and future mental anguish;

d. loss of enjoyment of life; and

e. past and future medical and related expenses.

FIRST CAUSE OF ACTION
NEGLIGENCE

37. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

38. Lilly owed to Plaintiff Gilda Hagan-Brown, and to other consumers and patients, a duty to exercise reasonable care in the design, formulation, manufacture, sale, promotion, supply and/or distribution of Cymbalta, including the duty to ensure that the product carries adequate instructions and warnings and that the product does not cause users to suffer from unreasonable, dangerous side effects.

39. 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 that fully and accurately inform users and health care professionals about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms;

b. Failed to provide warnings that Cymbalta could cause users to become physically dependent on the drug;

c. Failed to provide adequate training and instructions to users and health care professionals regarding appropriate methods for stopping Cymbalta;

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

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

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

g. Misrepresented the severity of symptoms associated with withdrawal;

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

i. Negligently marketed Cymbalta despite the fact that the risk of withdrawal symptoms was so high and the benefits of the drug were so questionable that no reasonable pharmaceutical company, exercising due care, would have placed it on the market;

j. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed, material facts regarding the safety of Cymbalta to Plaintiff Gilda Hagan-Brown, the public, and the medical community;

k. Failed to comply with its post-manufacturing duty to warn that Cymbalta was being promoted, distributed, and prescribed without adequate warnings that fully and accurately inform users and physicians of the true frequency, severity, and/or duration of potential withdrawal symptoms; and

l. Was otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for Plaintiff Gilda Hagan-Brown's rights and safety.

40. Despite the fact that Lilly knew, or should have known, that Cymbalta caused frequent and severe withdrawal symptoms, Lilly continued to market Cymbalta to consumers, including Plaintiff Gilda Hagan-Brown, without adequate instructions for stopping Cymbalta and without adequate warnings about the frequency, severity, and/or duration of the withdrawal symptoms. Lilly knew, or should have known, that Cymbalta users would suffer foreseeable injuries as a result of its failure to

exercise ordinary care, as described above. Lilly knew or should have known that Cymbalta was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

41. Had Lilly provided adequate instructions for the proper method for stopping Cymbalta and/or adequate warnings regarding the frequency, severity, and/or duration of its withdrawal symptoms, Plaintiff Gilda Hagan-Brown's injuries would have been avoided.

42. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff Gilda Hagan-Brown suffered significant injuries as set forth herein. Plaintiff Gilda Hagan-Brown has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff Gilda Hagan-Brown has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff Gilda Hagan-Brown has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

43. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION
STRICT PRODUCT LIABILITY – DESIGN DEFECT

44. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

45. Lilly is, and was at all times relevant herein, engaged in the business of designing, testing, manufacturing, and promoting prescription medications, including Cymbalta, to citizens of the State of Virginia, including Plaintiff Gilda Hagan-Brown.

46. Lilly manufactured, marketed, promoted, and sold a product that was merchantable and/or reasonably suited to the use intended. Cymbalta was expected to, and did, reach Plaintiff Gilda Hagan-Brown without substantial change in the condition in which it was sold. Its condition when sold was the proximate cause of the injuries sustained by Plaintiff Gilda Hagan-Brown.

47. Lilly introduced a product into the stream of commerce that is defective in design, in that the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by Lilly, and Lilly's omission of the alternative design renders the product not reasonably safe. The harm of Cymbalta's design outweighs any benefit derived therefrom. The unreasonably dangerous nature of Cymbalta caused serious harm to Plaintiff Gilda Hagan-Brown. Lilly placed Cymbalta into the stream of commerce with wanton and reckless disregard for public safety.

48. Lilly knew or should have known that physicians and other health care providers began commonly prescribing Cymbalta as a safe product despite the fact that the design of Cymbalta pills, as delayed-release capsules of beads at 20, 30 and 60 mg doses only, along with the instruction to swallow them whole, prevents users from being able to properly taper (gradual decrease in dosage) from Cymbalta in order to avoid or reduce withdrawal symptoms. Cymbalta users such as Plaintiff are thus unable to avoid the danger of Lilly's design upon cessation of treatment. Moreover, Lilly knew that the likelihood of experiencing withdrawal symptoms (such that gradual tapering would be required) is significant.

49. Lilly could have redesigned Cymbalta at a reasonable cost in order to allow users to taper gradually and thus with less risk of injury. The risk of harm inherent in Lilly's design of Cymbalta capsules outweighs the utility of its design. There are other antidepressant medications and similar drugs on the market with safer alternative designs with respect to patients' and physicians' ability to gradually decrease the dosage.

50. As a direct and proximate result of Lilly's widespread promotional activities, physicians commonly prescribe Cymbalta as safe.

51. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff Gilda Hagan-Brown suffered significant injuries as set forth herein. Plaintiff Gilda Hagan-Brown has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff Gilda Hagan-Brown has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff Gilda Hagan-Brown has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

52. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION
FAILURE TO WARN

53. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

54. Lilly researched, tested, developed, designed, licensed, manufactured, packaged, inspected, labeled, distributed, sold, marketed, promoted and/or introduced Cymbalta into the stream of commerce and in the course of same, directly advertised and/or marketed Cymbalta to consumers or persons responsible for consumers, and therefore, had a duty to warn Plaintiff Gilda Hagan-Brown and Plaintiff Gilda Hagan-Brown's physicians of the risks associated with stopping Cymbalta, which Lilly knew or should have known are inherent in the use of Cymbalta.

55. Lilly had a duty to warn users and physicians fully and accurately of the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms which it knew or should have known, can

be caused by the discontinuation of Cymbalta and/or are associated with Cymbalta discontinuation, experienced suicidal thoughts, severe depression, migraines, buzzing in her head, anxiety, mood swings, dizziness, glazed eyes, Irritable Bowel Syndrome, dry mouth, and sweating.

56. Furthermore, Lilly had a duty to provide users and physicians with adequate instructions for stopping Cymbalta.

57. Cymbalta was under the exclusive control of Lilly and was neither accompanied by adequate instructions for stopping Cymbalta nor accompanied by adequate warnings regarding the frequency, severity, and/or duration of symptoms associated with the discontinuation of Cymbalta. The information given to consumers and physicians did not properly instruct users and physicians on how to stop Cymbalta and did not accurately reflect the risk, incidence, symptoms, scope, or severity of the withdrawal symptoms as compared to other similar products available in the market, which possessed lower risk of such symptoms. The promotional activities of Lilly further diluted and/or minimized any warnings that were provided with the product.

58. Lilly misled users and health care professionals as to the severity, frequency, and/or duration of Cymbalta withdrawal symptoms in order to foster and heighten sales of the product.

59. Cymbalta was defective and unreasonably dangerous when it left the possession of Lilly in that it contained instructions insufficient to fully inform users and physicians on how to stop Cymbalta and that it contained warnings insufficient to alert Plaintiff Gilda Hagan-Brown to the dangerous risks and reactions associated with it, including but not limited to severe, debilitating withdrawal symptoms. Even though Lilly knew or should have known the risks associated with Cymbalta, it failed to provide adequate instructions and warnings.

60. The foreseeable risks of withdrawal-related harm posed by Cymbalta could have been reduced or avoided by the provision of reasonable instructions or warnings by Lilly. Lilly's omission of reasonable instructions or warnings rendered Cymbalta not reasonably safe.

61. Plaintiff Gilda Hagan-Brown used Cymbalta as intended or in a reasonably foreseeable manner.

62. Plaintiff Gilda Hagan-Brown could not have discovered any defect in the drug through the exercise of reasonable care.

63. Lilly, as manufacturer of Cymbalta and other pharmaceutical prescription drugs, is held to the level of knowledge of an expert in the field, and further, Lilly had knowledge of the dangerous risks associated with the discontinuation of Cymbalta.

64. Plaintiff Gilda Hagan-Brown did not have the same knowledge as Lilly and no adequate warning was communicated to her physicians.

65. Lilly had a continuing duty to warn users, including Plaintiff Gilda Hagan-Brown and her physicians, and the medical community of the dangers associated with Cymbalta discontinuation. By negligently and wantonly failing to provide adequate instructions and failing to adequately warn of the withdrawal symptoms associated with Cymbalta discontinuation, Lilly breached its duty.

66. Although Lilly knew or should have known of Cymbalta's withdrawal symptoms, it continued to design, manufacture, market, and sell the drug without providing adequate warnings or instructions concerning the use of the drug in order to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harms posed by the drug.

67. In addition, Lilly's conduct in the packaging, warning, marketing, advertising, promoting, distribution, and sale of the drug was committed with knowing, conscious, willful, wanton, and deliberate disregard for the value of human life, and the rights and safety of consumers, including Plaintiff Gilda Hagan-Brown.

68. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff Gilda Hagan-Brown suffered severe injuries as set forth herein. Plaintiff Gilda Hagan-Brown has incurred and will continue to incur physical and psychological pain and suffering, emotional

distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff Gilda Hagan-Brown has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff Gilda Hagan-Brown has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

69. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION
CONSTRUCTIVE FRAUD

70. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

71. Lilly owed a duty to Plaintiff Gilda Hagan-Brown and her physicians to convey and communicate truthful and accurate information about Cymbalta.

72. Lilly represented to Plaintiff Gilda Hagan-Brown, her physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal symptoms were no different, no worse, and no more frequent, than those of other similar products on the market. These representations were, in fact, false. Lilly's representations on the Cymbalta label suggested that withdrawal was rare, or that withdrawal symptoms occurred at a rate of approximately 1% or 2%, without mentioning the overall percentage of users who will experience withdrawal symptoms, which Lilly's own studies showed to be, at minimum, 44%.

73. Lilly was negligent in failing to exercise due care in making the aforesaid representations.

74. Lilly had a pecuniary interest in making said representations, which were made in order to expand sales and increase revenue from Cymbalta.

75. At the time said representations were made by Lilly, at the time Plaintiff Gilda Hagan-Brown and her physicians took the actions herein alleged, Plaintiff Gilda Hagan-Brown and her physicians were ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff Gilda Hagan-Brown and her physicians were induced to, and did, use Cymbalta and attempt to discontinue Cymbalta. If Plaintiff Gilda Hagan-Brown and her physicians had known the actual facts, Plaintiff Gilda Hagan-Brown's injuries would have been avoided because Plaintiff Gilda Hagan-Brown's physician would not have prescribed the drug, Plaintiff Gilda Hagan-Brown would not have taken the drug, and/or the risk would have been conveyed to Plaintiff Gilda Hagan-Brown in a way so as to alter the prescription and avoid Plaintiff Gilda Hagan-Brown's injuries.

76. The reliance of Plaintiff Gilda Hagan-Brown and her physicians upon Lilly's representations was justified because the representations were made by individuals and entities who appeared to be in a position to know the true facts relating to risks associated with Cymbalta.

77. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff Gilda Hagan-Brown suffered pecuniary losses including but not limited to past and future medical and related expenses.

78. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION
ACTUAL FRAUD

79. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

80. As the United States Supreme Court stated in *Wyeth v. Levine*, "...it has remained a central premise of federal drug regulation that the manufacturer [of a prescription drug, such as Cymbalta] bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." 555 U.S. 555, 571 (2009).

81. Lilly committed fraud by actively concealing material adverse information that was in its possession from its labeling and marketing of Cymbalta, including but not limited to, concealing the true frequency, severity and duration of Cymbalta's withdrawal side effects and falsely represented the withdrawal risk associated with Cymbalta.

82. Lilly, through its clinical trial data, knew that, when it made the misrepresentations and/or omissions set forth herein, they were false, that patients and medical professionals would rely upon its misrepresentations and omissions, and that the misrepresentations were intended to cause patients like Plaintiff to purchase and ingest Cymbalta.

83. The specific acts of Lilly include the following:

a. Fraudulently suggesting that the withdrawal risk is rare, or occurred at a rate of approximately one (1) percent, when the overall rate of patients experiencing withdrawal, according to Lilly's own clinical trials, is high (at least 44.3% to 50%). Furthermore, an analysis of the data from Lilly's clinical trials reveals, with statistically significant results, that in comparison to stopping a placebo, stopping Cymbalta elevated the risk of specific withdrawal symptoms as much as 23-fold (i.e., nausea 23-fold, dizziness 17-fold, paresthesia 11-fold, irritability 9-fold, nightmares 8-fold, headaches 7-fold, and vomiting 4-fold);

b. Fraudulently omitting material information in its labeling and marketing concerning the severity of Cymbalta withdrawal including the fact that, in Lilly's clinical trials, between 9.6% and 17.2% suffered severe withdrawal (approximately 50% suffered moderate withdrawal);

c. Fraudulently omitting material information in its labeling and marketing concerning the duration of Cymbalta withdrawal. In fact, more than 50% of patients in the Cymbalta clinical trials continued to suffer from withdrawal symptoms two weeks after coming off the drug. Lilly did not monitor withdrawal beyond two weeks. Lilly was well aware that withdrawal symptoms could be protracted. For instance, the Cymbalta Summary of Product Characteristics" (SmPC) in Europe stated that, "in some individuals [withdrawal symptoms] may be prolonged (2-3 months or more)." The Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition, published in 2010 (in which at least three Lilly consultants were on the working group and review panel) states under "Discontinuation syndrome" that "some patients do experience **more protracted** discontinuation syndromes, particularly those treated with paroxetine [Paxil]" and "as with SSRIs, abrupt discontinuation of SNRIs should be avoided whenever possible. Discontinuation symptoms, **which are sometimes protracted**, are more likely to occur with venlafaxine [Effexor] (and, by implication devenlafaxine [Pristiq]) than duloxetine [Cymbalta] (100) and may necessitate a slower downward titration regimen or change to fluoxetine." Given that Cymbalta's half-life falls between Effexor's and Paxil's – Effexor having the shortest, Cymbalta the second and Paxil the third – the Guideline is artfully worded;

d. Purposefully failing to use systematic monitoring with a withdrawal symptom checklist in the Cymbalta studies underlying Perahia's analysis, whereas in earlier Lilly-sponsored studies comparing Prozac to Paxil, Zoloft, and Effexor, Lilly systematically monitored withdrawal using a symptom checklist. Lilly was well aware of the withdrawal risk because it had orchestrated a marketing campaign differentiating Prozac from competitor antidepressants based on Prozac's comparatively long half-life. In fact, based on Cymbalta's half-life (the second shortest half-life between Effexor and Paxil), one would expect the true risk of withdrawal to be in a range between 66% and 78%. *See* Glenmullen, The Antidepressant Solution – A Step-by-Step Guide to Safely Overcoming Antidepressant Withdrawal, Dependence, and "Addiction" (2005);

e. Because Cymbalta's half-life is the second shortest and the closest to Effexor's, Lilly must have recognized that the risk of Cymbalta withdrawal was substantial, as confirmed by its own clinical trial data, and likely much worse as explained above. However, rather than being forthcoming about this important risk, Lilly instead chose to obscure the risk by using misleading language in its labeling and marketing;

f. Lilly obscured Cymbalta's true withdrawal risks by deflecting attention away from the Cymbalta-specific clinical trial data showing a clear and significant risk and focusing instead on other SSRIs and SNRIs. For instance, Lilly's label stated "During marketing of other SSRIs and SNRIs ... there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt ..." Lilly's use of "spontaneous" reports from "other SSRIs or SNRIs" is misleading given that approximately 40% to 50% of patients in Lilly's own clinical trials of Cymbalta reported adverse events. In using this language, Lilly misleadingly suggests that the withdrawal risks associated with other SSRIs and SNRIs are worse than Cymbalta's risks, which is the opposite of the truth – Cymbalta is one of the worst;

g. In addition to failing to warn about these known risks, Lilly utilized paid Key Opinion Leaders ("KOLs") to endorse the safety and efficacy of Cymbalta and assure prescribing doctors that Cymbalta's withdrawal risks were not as frequent, severe or protracted as they

really are. Lilly did this through medical journal articles, treatment guidelines and medical seminars. For instance, Alan F. Schatzberg, a Lilly consultant and KOL who researched the phenomenon of antidepressant withdrawal as part of Lilly's campaign to promote Prozac in the 1990s, *see* paragraph 18 *supra*, wrote an article titled "Antidepressant Discontinuation Syndrome: Consensus Panel Recommendations for Clinical Management and Additional Research," J. Clin Psychiatry, 2006; 67 (suppl 4), two years after Cymbalta came on the market. However, the article makes no mention of Cymbalta withdrawal or the fact that Lilly's own trials established withdrawal risks that were greater than those Lilly chose to include in the Cymbalta label;

h. Similarly, the American Psychiatric Publishing Textbook of Psychiatry, Fifth Edition with a Foreword written by the same Lilly consultant and KOL, Dr. Schatzberg, published in 2008, makes no mention of Cymbalta nor the frequency, severity or duration of Cymbalta withdrawal. Indeed, the text states:

> Discontinuation symptoms appear to occur most commonly after discontinuation of short-half-life serotonergic drugs (Coupland et al. 1996), such as fluvoxamine [Luvox], paroxetine [Paxil], and venlafaxine [Effexor].

There is no mention of Cymbalta although it had been on the market for four years and has a shorter-half than either Luvox or Paxil. Indeed, it had the second shortest half-life next to Effexor;

i. Lilly also appears to have engaged in selective and biased publication of its clinical trials of Cymbalta. In a recent study published in the New England Journal of Medicine, researchers obtained clinical trials for antidepressants (including Cymbalta) that had been submitted to the FDA and compared them with studies that had been published. The authors found that there was a "bias towards the publication of positive results" and that, "according to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis shows that 51% were positive." The authors found that, as a result of such selective publication, the published literature conveyed a misleading impression of Cymbalta's efficacy resulting in an apparent effect-size that was 33% larger than the effect size derived from the full clinical trial data. *See* Erick H. Turner et al., Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy, 358 NEW ENG. J. MED. 252 (2008).

84. When the above representations and/or omissions were made by Lilly, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Lilly with the intent of defrauding and deceiving the public and the prescribing medical community and with the intent of inducing the public to take Cymbalta and the medical community (including Plaintiff's doctor) to recommend, prescribe, and dispense Cymbalta to their patients without adequate warning.

85. At the time the aforementioned representations or omissions were made by Lilly, and at the time Plaintiff purchased and began to ingest Cymbalta, Plaintiff was unaware of the falsity of Lilly's representations and/or omissions and reasonably relied upon Lilly's representations and omissions.

86. In reliance upon Lilly's representations and/or omissions, Plaintiff was induced to take Cymbalta and suffered significant withdrawal side effects.

87. Lilly's motive in failing to advise physicians and the public of Cymbalta's withdrawal risks was financial gain along with its fear that, if accompanied by proper and adequate information, Cymbalta would lose its share of the antidepressant market.

88. At all times herein mentioned, the actions of Lilly, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiff in particular and to the general public in that Lilly did willfully and knowingly place the dangerous and defective drug Cymbalta on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

89. Punitive damages would be particularly appropriate for Lilly in this case given that fraud and concealment appear to be a part of its modus operandi. Since the 1980s, Lilly has had an ongoing history of concealing serious side effects associated with its drugs and illegally promoting its drugs. For example, in 1985, Lilly and one of its officers pled guilty to multiple criminal counts of violating the Food Drug and Cosmetic Act ("FDCA") arising out of Lilly's concealment of serious liver and kidney dysfunctions associated with its arthritis drug Oraflex. In 2009, Lilly agreed to plead guilty and pay $1.415 billion to the federal government for illegally promoting Zyprexa. This resolution included a criminal fine of $515 million, which, at the time, was the largest settlement ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.

90. At *all times* relevant herein, Lilly's conduct was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and Lilly conducted itself in a willful, wanton, and reckless manner. Despite Lilly's specific knowledge regarding Cymbalta's withdrawal risks as set forth above, Lilly deliberately recommended, manufactured, produced, marketed, sold, distributed, merchandised, labeled, promoted, and advertised Cymbalta as being safe, with minimal withdrawal risks.

91. All of the foregoing constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public. Thus, Lilly is guilty of reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of Plaintiff and others which proximately caused the injuries described herein. Therefore, Plaintiff requests punitive and exemplary damages in an amount to be determined at trial to deter Lilly from continuing its conscious disregard of the rights and safety of the public at large and to set an example so Lilly – as well as other similarly situated drug manufacturers – will refrain from acting in a manner that is wanton, malicious, and in utter, conscious disregard of the rights of a large segment of the public.

92. As a direct and proximate result of Lilly's false representations and/or omissions, Plaintiff has suffered serious injury, incurred and will in the future incur expenses, lost income and sustained other damages, including but not limited to pain and suffering, emotional distress, sorrow, anguish, stress, shock and mental suffering.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

93. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

94. Lilly made numerous representations, descriptions, and promises to Plaintiff Gilda Hagan-Brown 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 symptoms.

95. As described herein, Plaintiff Gilda Hagan-Brown suffered injuries as a direct and proximate result of her discontinuation of Cymbalta.

96. At the time of Plaintiff Gilda Hagan-Brown's use of Cymbalta and resulting injuries, the Cymbalta she was taking was in essentially the same condition as when it left the control and possession of Lilly.

97. At all times relevant, the Cymbalta received and used by Plaintiff Gilda Hagan-Brown was not fit for the ordinary purposes for which it is intended to be used in that, *inter alia*, it posed a higher risk of withdrawal symptoms – of greater duration and severity – than other similar products available in the market.

98. Plaintiff Gilda Hagan-Brown's injuries were due to the fact that Cymbalta was in a defective condition, as described herein, rendering it unreasonably dangerous to her.

99. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff Gilda Hagan-Brown suffered significant injuries as set forth herein. Plaintiff Gilda Hagan-Brown has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff Gilda Hagan-Brown has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff Gilda Hagan-Brown has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment against Lilly as follows:

a. Judgment in favor of Plaintiff and against Lilly, for all damages in such amounts as may be proven at trial;

b. Compensation for economic and non-economic losses, including but not limited to, past and future medical expenses, medical monitoring, out-of-pocket expenses, past and future physical pain and mental anguish, past and future physical impairment, in such amounts as my be proven at trial;

c. Past and future general damages, according to proof;

d. Any future damages resulting from permanent injuries;

e. Psychological trauma, including but not limited to mental anguish, mental distress, apprehension, anxiety, emotional injury, psychological injury, depression, and aggravation of any pre-existing and/or underlying emotional or mental diseases or conditions;

f. Pain and suffering;

g. Loss of enjoyment of life;

h. Punitive and exemplary damages in an amount to be determined by trial;

i. Attorneys' fees and costs;

j. Treble damages;

k. Prejudgment and post-judgment interest;

l. Costs to bring this action; and

m. Any such other and further relief as the Court may deem just and proper in law or in equity.

DEMANDS FOR JURY TRIAL

Plaintiff respectfully requests a jury trial of all issues presented in this Complaint.

Respectfully submitted,

DATED: November 25, 2014

MILLER LEGAL LLC

By: _____

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