IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

JESSE MCDOWELL, Plaintiff, vs. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	)	Civil Action No. **COMPLAINT** **AND JURY DEMAND**

COMPLAINT

Plaintiff Jesse McDowell brings this action for products liability alleging personal injuries and damages, including serious and life-threatening withdrawal symptoms, suffered by Plaintiff as a direct and proximate result of his ingestion and cessation of the prescription drug, Cymbalta (duloxetine), which is manufactured, marketed, and sold by Defendant Eli Lilly and Company (hereinafter, "Defendant" or "Lilly").

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Jesse McDowell (hereinafter, "Plaintiff") is, and at all times relevant to this Complaint was, a citizen of the State of New York and resident of Kings County.

2. 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, a prescription antidepressant drug.

3. This Court has personal jurisdiction over Lilly insofar as Lilly is authorized and licensed to conduct business in New York, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

4. Furthermore, Lilly has caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district 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 this judicial district.

5. This Court has subject matter jurisdiction in the form of diversity jurisdiction, pursuant to 28 U.S.C.A. § 1332, in that there is a complete diversity of citizenship between Plaintiff and Defendant and the amount in controversy exceeds $75,000.00.

6. Venue is proper pursuant to 28 U.S.C. § 1391.

FACTUAL ALLEGATIONS

7. 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 its drug Cymbalta, whose 2009 annual sales exceeded $3 billion, making it the second most profitable drug in Lilly's current product line.

8. Lilly has enjoyed considerable financial success from manufacturing and selling prescription drugs for the treatment of clinical depression, including the popular antidepressant 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 were promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. It has been theorized that reduced levels of serotonin cause depression; however, recent studies have undermined this theory. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001.

9. 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's ("FDA") for its next antidepressant, Cymbalta. Unlike Prozac, Cymbalta is a "Serotonin-Norepinephrine Reuptake Inhibitor" ("SNRI"), which Lilly promoted as increasing the brain chemicals serotonin and norepinephrine in the synaptic clefts between the neurons in the brain. Lilly and other SNRI manufacturers admit that the precise mechanism of action is not clear, however, they have promoted the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

10. In 2003, the FDA initially rejected Lilly's application to approve Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

11. Eventually, in 2004, manufacturing issues were resolved and 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.

12. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending hundreds of millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff, through all major media channels, 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. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

13. Lilly's promotional campaigns have continuously overstated the efficacy of Cymbalta and understated, downplayed, and/or failed altogether to state the true withdrawal side effects associated with Cymbalta.

14. Presently and at all times material herein, the Cymbalta label provided the following precaution regarding discontinuation: "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...."

15. In addition to using the euphemistic term "discontinuation" to describe withdrawal side effects, Lilly also made it appear that such discontinuation symptoms were rare and only affected approximately 1% of Cymbalta users.

16. To the contrary, according to a January 2005 article published in the Journal of Affective Disorders, Lilly's Cymbalta clinical trials showed that a significant percentage (44.3%) of Cymbalta patients suffered from "discontinuation" side effects. David G. Peahia *et al.*, Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder, 89 JOURNAL OF AFFECTIVE DISORDERS 207 (2005). In this published, peer-reviewed paper, the withdrawal side-effect rates for Cymbalta were nearly double that experienced by placebo users, and these findings were statistically significant. Accordingly, the rate of withdrawal or "discontinuation" for Cymbalta (as established by Lilly's clinical trials) was 44.3%, yet in its packaging label, Lilly misleadingly presented this rate as approximately 1%.

17. Moreover, Lilly's clinical trials showed that, overall, 9.6% of Cymbalta users suffered *severe* withdrawal side effects, yet nowhere in the label does Lilly inform practitioners and patients of that risk.

18. Cymbalta's withdrawal side effects 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 patients 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 condition, but simply to stop the withdrawal symptoms. Patients thus become prisoners to Cymbalta, and Lilly financially benefits by having a legion of physically dependent, long-term users of Cymbalta.

19. Notwithstanding Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly failed to adequately, properly, and fully warn patients and physicians about the risk.

20. Instead, in its product labeling, marketing and advertising, and in information made available to consumers and physicians, Lilly reported a far lower risk, downplayed any difference in the withdrawal risk for Cymbalta as compared to other similar antidepressants, and affirmatively misled the consuming patient population and mischaracterized the drug's risk profile.

21. In addition to failing to adequately warn about the actual rate and severity of withdrawal side effect risks, Lilly also overplayed the efficacy of Cymbalta. Seeking to capture a greater segment of the antidepressant market, in 2005, Lilly initiated the direct-to-consumer marketing campaign: "Depression hurts. Cymbalta can help." Cymbalta advertisements bearing this slogan appeared ubiquitously on television, in print and on the internet. Lilly's advertising campaign made it appear that Cymbalta not only treated depression but that it also treated physical pain associated with depression. Scientists reviewing the Cymbalta data have

concluded that Lilly's claims are misleading. For example, in a 2008 article published in Psychotherapy and Psychosomatics, the author concluded that "the marketing of duloxetine as an antidepressant with analgesic properties for people with depression does not appear to be adequately supported."

22. Lilly has also augmented its misleading advertising campaigns by engaging in selective and biased publication of its clinical trials of Cymbalta. By way of example, Lilly has generally published only favorable studies of its Cymbalta clinical trials and refused to publish any of the negative and unfavorable studies. Such selective publication of clinical trial data gives the impression that the drug is safer and more effective than it actually is. 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).

23. Lilly's misleading direct-to-consumer promotional campaigns, its

misleading presentation of Cymbalta's efficacy and its failure to adequately warn regarding Cymbalta's withdrawal and dependency side effects have paid off financially for Lilly. Cymbalta has become a "blockbuster" drug with over $3 billion dollars in annual sales. In the past few years, Cymbalta has been the second most profitable drug in Lilly's product line. Coincidently, the only drug ahead of Cymbalta is Zyprexa, an antipsychotic drug that Lilly promoted illegally. Indeed, 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.

24. Lilly had the knowledge, the means and the duty to provide adequate warnings regarding Cymbalta's common and severe withdrawal and dependency side effects as well as a duty to honestly portray the safety and efficacy of Cymbalta. Lilly could have relayed these warnings through the same means it utilized to advertise its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements and sales representatives.

25. In October 2012, the Institute for Safe Medication Practices (ISMP), a non-profit healthcare consumer safety watchdog, issued findings from its independent investigation of Cymbalta adverse events found in the FDA Adverse Event Reporting System (FAERS). *See* QuarterWatch, *Monitoring FDA MedWatch Reports*, Why Reports of Serious Adverse Drug Events Continue to Grow, Oct. 3, 2012, ISMP.

26. The report announced that the investigation uncovered "a signal for serious drug withdrawal symptoms associated with duloxetine (CYMBALTA)," and detailed for the public what Lilly has long known: "[W]ithdrawal symptoms were reported in 44-50% of patients abruptly discontinuing duloxetine at the end of clinical studies for depression, and more than half of this total did not resolve within a week or two." *Id.* at 11

27. The ISMP report continued: "[W]e identified a serious breakdown at both the FDA and the manufacturer, Eli Lilly and Company, in providing adequate warnings and instructions about how to manage this common adverse effect." *Id.*

28. Explaining the lack of adequate warnings, the ISMP stated:

> 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.
>
> ....
>
> We could not identify any FDA-approved or company information for patients about how to discontinue duloxetine. *Id.* at 12-13.

29. In conclusion, the report minced no words in its indictment of Lilly's product information: "A major lapse has occurred in the FDA-approved information for patients about the risks of stopping duloxetine." *Id.* at 15.

30. Falsely reassured by the misleading and deceptive manner in which Lilly reported Cymbalta's withdrawal risk, physicians, including Plaintiff's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate, accurate and proper warnings relating to discontinuation of the drug.

31. In or around the spring of 2009, Plaintiff was prescribed Cymbalta by his physician, for treatment of depression and anxiety.

32. On or around March 1, 2012, Plaintiff was still experiencing severe anxiety and depression. Plaintiff's prescribing doctor advised him to taper his ingestion of Cymbalta over a seven month period.

33. Upon discontinuing Cymbalta, Plaintiff experienced severe and dangerous withdrawal symptoms. By way of example, Plaintiff experienced extreme brain zaps that left him disoriented and confused. Additionally, Plaintiff suffered from frequent suicidal thoughts, bouts of insomnia, and debilitating headaches.

34. At present, Plaintiff continues to suffer symptoms of withdrawal, including but not limited to brain zaps and severe headaches.

35. 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.

36. 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.

37. At all times relevant, Lilly engaged in a willful, wanton, and reckless

conduct, including its defective design of Cymbalta, its failure to warn about Cymbalta's risks, and its pattern of affirmative misrepresentations and omissions relating to the safety and efficacy of Cymbalta. It overstated the drug's efficacy, downplayed withdrawal side effects, and misstated the actual risk and severity of side effects, all of which induced physicians to prescribe Cymbalta and consumers to use it, including Plaintiff and his physicians.

38. Plaintiff's use of the drug and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to Cymbalta.

39. If Lilly had adequately, accurately and properly warned about the withdrawal risk associated with Cymbalta, including the high risk of experiencing them and their frequency and severity, Plaintiff's physician would not have prescribed the drug to Plaintiff; Plaintiff would have refused the drug; and/or Plaintiff'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's injuries and damages.

40. 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

COUNT I - NEGLIGENCE

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

42. Lilly owed to Plaintiff, and to other consumers and patients, 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 that the product is as effective as it is promoted, that the product carries adequate warnings and that the product does not cause users to suffer from unreasonable, dangerous side effects.

43. 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 and severity of the withdrawal and dependency side effects associated with Cymbalta;

b. Failed to provide warnings that Cymbalta could cause patients to become physically dependent on Cymbalta;

c. Failed to provide adequate training and instructions to patients and/or health care professionals regarding appropriate uses and discontinuation of Cymbalta;

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

e. Negligently misrepresented the efficacy of Cymbalta by portraying

Cymbalta as being more efficacious than it really is;

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

g. Negligently marketed Cymbalta despite the fact that the risk of the drug 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;

h. Recklessly, falsely, and 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;

i. 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 its efficacy; and

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

44. Despite the fact that Lilly knew, or should have known, that Cymbalta caused unreasonable, dangerous side effects, Lilly continued to market Cymbalta to consumers, including Plaintiff, when there were safer and more effective alternative methods and treatments. 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 the Cymbalta designed, formulated, manufactured, and/or supplied by it 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.

45. Had Lilly provided an adequate warning regarding the frequency and severity of the withdrawal and dependency risks, Plaintiff's injuries would have been avoided.

46. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff 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.

47. 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.

COUNT II - STRICT PRODUCTS LIABILITY – DESIGN DEFECT

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

49. At all times relevant, Lilly was engaged in the business of selling Cymbalta in the State of New York.

50. There are other antidepressant medications and similar drugs on the market with safer alternative designs to Cymbalta, in that the drugs provide equal or greater efficacy and far less risk than Cymbalta.

51. Cymbalta was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design and formulation.

52. Cymbalta was defective in design or formulation in that it posed a greater likelihood of injury compared to other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

53. Cymbalta was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with, nor was otherwise accompanied by, warnings adequate to alert consumers, including Plaintiff and his physicians, of the risks described herein, including the significant increased risk of withdrawal symptoms.

54. Although Lilly knew or should have known of the defective nature of Cymbalta, it continued to design, manufacture, market, and sell Cymbalta in order to

maximize sales and profits at the expense of the public health and safety. By so acting, Lilly acted with a conscious and deliberate disregard of the foreseeable harm caused by Cymbalta.

55. Lilly knew or should have known that physicians and other healthcare providers began commonly prescribing Cymbalta as a safe and effective product despite its lack of efficacy and potential for serious side effects.

56. As a direct and proximate result of Lilly's widespread promotional activity, physicians, like Plaintiff's physician, commonly prescribed Cymbalta and believed it to be safe and effective.

57. Lilly introduced a product into the stream of commerce that is dangerous and unsafe in that the harm of Cymbalta outweighs and benefit derived therefrom. The unreasonably dangerous nature of Cymbalta caused serious harm to Plaintiff.

58. Lilly manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the direct and proximate cause of the injuries sustained by Plaintiff.

59. The Cymbalta manufactured, marketed, promoted and sold by Lilly was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

60. Cymbalta failed to perform safely when used by ordinary consumers, including Plaintiff, when used as intended and in a reasonably foreseeable manner.

61. Plaintiff used Cymbalta as prescribed and in a manner normally intended, recommended, promoted, and marketed by Lilly.

62. Lilly's conduct as described herein was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Lilly and deter it from similar conduct in the future.

63. As a direct and proximate result of the design defects alleged herein, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff 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.

64. 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.

COUNT III - STRICT PRODUCTS LIABILITY – FAILURE TO WARN

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

66. Lilly researched, tested, developed, designed, licensed, manufactured,