IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
HARRISON DIVISION

CHRISTOL HUTCHISON **PLAINTIFF**

CASE NO. 14-3025-PKH

ELI LILLY AND COMPANY, an Indiana Corporation **DEFENDANT**

COMPLAINT

Plaintiff Christol Hutchison ("Hutchison"), by and through counsel, Deacon Law Firm, P.A., for her Complaint against Defendant Eli Lilly and Company ("Eli Lilly"), states and alleges as follows:

I. PARTIES

1. Hutchison is a citizen and resident of Carroll County, Arkansas.

2. Eli Lilly is an Indiana corporation with its headquarters and principal place of business in Indianapolis, Indiana. Eli Lilly's registered agent for service of process in Arkansas is National Registered Agents, Inc. of Arkansas, 124 W. Capitol Ave., Suite 1900, Little Rock, Arkansas 72201.

3. At all times relevant hereto, Eli Lilly was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling, and distributing Cymbalta in the stream of commerce for use by the public, including Hutchison.

II. JURISDICTION AND VENUE

4. Jurisdiction is proper pursuant to 28 U.S.C. § 1332 in that there is complete diversity between all parties and the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of interest and costs.

5. Personal jurisdiction is appropriate in the Western District of Arkansas as Eli Lilly has conducted substantial business in this state and district, markets and distributes its products, including Cymbalta, in this district, and profits from the sale of its drugs in this district. Eli Lilly conducts business in Arkansas and in the Western District of Arkansas and otherwise has a presence in this district sufficient to constitute minimum contacts in order to meet due process requirements for personal jurisdiction.

6. Venue is proper in the Western District of Arkansas pursuant to 28 U.S.C. § 1391. Eli Lilly marketed, promoted, and sold Cymbalta in this district and Hutchison was prescribed, purchased, and consumed Cymbalta in this district; thus, a substantial part of the events or omissions giving rise to the claim occurred in this district.

III. FACTS

7. This lawsuit involves injuries and damages sustained by Hutchison as a result of her use of the Eli Lilly product, Cymbalta.

8. At all times relevant hereto, Eli Lilly was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, advertising, and/or selling Cymbalta in the State of Arkansas and in interstate commerce.

9. In October 2011, Hutchison was prescribed Cymbalta by her physician, Dr. Rene Duffourc, for the treatment of depression and anxiety. This prescription was filled at Poyner Drug in Berryville, Arkansas. The product ingested by Hutchison is identified as Cymbalta 60 mg, NDC code number 0002-3270-30.

10. In December 2011, Hutchison's prescribing physician increased her Cymbalta dosage to 120 mg daily because she reported an increase in chronic back pain.

11. Upon information and belief, in prescribing Cymbalta to Hutchison, her prescribing physician relied upon information published in the package inserts and/or the Physicians' Desk Reference or otherwise disseminated by Eli Lilly; however, as explained in further detail below, the information disseminated by Eli Lilly to Hutchison's prescribing physician at the time he prescribed Cymbalta to her was materially incomplete, inaccurate, misleading, and otherwise inadequate to warn of the potential effects of exposure to and ingestion of Cymbalta.

12. Hutchison ingested Cymbalta as prescribed.

13. In late December 2011, Hutchison began to experience various adverse skin reactions, including, but not limited to, rashes, sores, and peeling skin. She developed sores on her mouth and tongue and experienced blistering on her right foot.

14. Hutchison contacted her prescribing physician, who advised her to seek treatment and immediately discontinue use of Cymbalta.

15. Hutchison sought treatment of her rash-like symptoms at Mercy Clinic Family Medicine in Berryville, Arkansas.

16. Her treating physicians diagnosed Hutchison with Stevens-Johnson syndrome caused by an adverse reaction to Cymbalta.

17. Hutchison began receiving treatment for Stevens-Johnson syndrome; however, Hutchison further developed severe, throbbing pain, primarily in her lower right leg, right foot, and fingertips. These areas became extremely hypersensitive and swollen.

18. The pain Hutchison experienced in her lower right leg and foot continued to worsen; approximately one month after receiving the diagnosis of Stevens-Johnson syndrome,

the pain in Hutchison's right lower leg and foot was so unbearable that she was forced to use a wheelchair or walker in order to avoid bearing weight on this extremity.

19. Hutchison continued treatment for the persistent pain, underwent numerous tests and was referred to a number of specialists to identify the pain's etiology.

20. Hutchison was eventually diagnosed with complex regional pain syndrome type one of the right lower extremity, which resulted from the blistering rash on her right foot caused by her adverse reaction to Cymbalta.

21. Hutchison's use of Cymbalta, as prescribed, caused her to suffer serious, permanent, and disabling injuries, including, but not limited to, injuries of or associated with the central and peripheral nervous systems, specifically, complex regional pain syndrome, resulting in a permanent chronic pain condition.

22. Hutchison's use of Cymbalta, as prescribed, resulted in overexposure to the drug, which has caused her to suffer the serious, permanent, and disabling injuries referenced throughout this Complaint.

23. Hutchison's serious and permanent injuries came about as a foreseeable and proximate result of Eli Lilly's dissemination of materially incomplete, inaccurate, misleading, and otherwise inadequate information and warnings concerning the potential effects of exposure to and ingestion of Cymbalta to Hutchison, her prescribing physician, the medical community, and other foreseeable users of the drug.

24. If Eli Lilly had provided an adequate warning of the adverse side effects of Cymbalta, including that Cymbalta caused or could cause severe skin reactions, including Stevens-Johnson syndrome, Hutchison's prescribing physician would not have prescribed

Cymbalta to Hutchison. Hutchison's prescribing physician would not have prescribed Cymbalta to Hutchison if he knew of its actual risks.

25. Moreover, if Eli Lilly had provided an adequate warning of the adverse side effects of Cymbalta stated in this Complaint to Hutchison, Hutchison would not have ingested Cymbalta.

26. Hutchison has experienced, and will continue to experience, medical injury and related expenses, loss of earning capacity, disability, pain, suffering, mental anguish, and other injuries and damages due to Eli Lilly's tortious conduct stated herein, which resulted in the prescription and ingestion of Cymbalta.

27. Cymbalta is a selective serotonin and norepinephrine reuptake inhibitor that was initially approved for the treatment of major depressive disorder and pain associated with diabetic peripheral neuropathy in 2004.

28. Cymbalta is marketed pursuant to four New Drug Applications (NDA Nos. 021427, 021733, 022148, and 022516), but these applications all concern the same molecular entity and are marketed as the same drug.

29. Beginning no later than May 2007, the FDA communicated with Eli Lilly on the issue of labeling information regarding the association between Cymbalta and serious skin reactions. As early as 2007, the FDA requested revisions to the Cymbalta labeling pertaining to serious skin reactions. In 2008, the FDA requested that the risk of serious skin reactions be added to the Warnings and Precautions section of the Cymbalta labeling. Eli Lilly ignored these and other numerous requests from the FDA to revise the product label to include a warning for serious skin disorders.

30. For years, Eli Lilly pushed to expand the indication for Cymbalta and encouraged doctors to use the drug to treat conditions for which it was not approved. On September 21, 2007, and again on January 7, 2010, the FDA issued warnings to Eli Lilly for misrepresenting the efficacy and capabilities of Cymbalta without adequately communicating the risks associated with its use.

31. On July 19, 2010, the FDA's Center for Drug Evaluation and Research Office of Surveillance and Epidemiology drafted an Updated Safety Report for Cymbalta, which stated in pertinent part:

> [Division of Phamacovigilance] completed a full safety review on 6 August 2008, which evaluated postmarketing reports of serious skin disorders [Stevens-Johnson Syndrome] among the SSRIs and SNRIs and compared the reporting rates across products. [Office of Surveillance and Epidemiology] recommended elevating the current serious skin labeling to the "Warnings and Precautions" section and adding language about the fatality potential with [Stevens-Johnson Syndrome] to the "Postmarketing" section of the duloxetine [Cymbalta] label. Prior to this review, the labeling for serious skin reactions for duloxetine [Cymbalta] stated "serious skin reactions including Stevens-Johnson Syndrome that have required drug discontinuation and/or hospitalization have been reported with duloxetine", and to date, no current labeling changes have been made as a result of this review.

32. An FDA Medication Guide is a direct means of conveying information to consumers about the uses, risks, and benefits of a drug, separate and apart from information the patient may or may not be provided by her prescribing physician. The Medication Guide is the foundation for a distinct duty to warn owed by drug manufacturers to consumers. During the August 19, 2010 Anesthetic and Life Support Drugs Advisory Committee ("ALSDAC") meeting to discuss Eli Lilly's application to extend the indication for use of Cymbalta, the then-current Medication Guide for the product was referenced. A representative of Eli Lilly advised ALSDAC that the company intended to update the Cymbalta Medication Guide to include all major risks described in the U.S. label for the purpose of adequately communicating risks

directly to patients. Although the risk of severe skin reactions, including Stevens-Johnson syndrome and the increased risk of adverse reactions associated with use of the drug in a dose of 120 mg per day were known by Eli Lilly at that time, the Medication Guide was not timely updated to include adequate warnings related to these risks.

33. On or about July 12, 2011, the FDA sent a warning letter to Eli Lilly notifying it, under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act, of additional safety information that needed to be included in the labeling for Cymbalta. The information pertained to the risk of severe skin reactions. Specifically, the FDA's letter stated:

> Since Cymbalta (duloxetine) was approved on August 3, 2004, we have become aware of numerous post marketing cases of severe skin reactions through routine monitoring of FDA's Adverse Event Reporting System (AERS). A recent review of these cases has shown good clinical descriptions of either erythema multiforme or Stevens-Johnson Syndrome for which Cymbalta (duloxetine) exposure is the best or sole plausible explanation. The frequency of reports of severe skin reactions with Cymbalta (duloxetine) relative to the number of prescriptions has been five to ten times the rates observed with other commonly prescribed antidepressant drugs.

34. Eli Lilly responded to this letter by submitting a supplemental new drug application agreeing to change and supplement the warnings in its label. On September 2, 2011, the FDA approved the following language to be added to the Cymbalta label:

> 5.6 Severe Skin Reactions
>
> Severe skin reactions, including erythema multiforme and Stevens-Johnson Syndrome (SJS), can occur with Cymbalta. The reporting rate of SJS associated with Cymbalta use exceeds the general population background incidence rate for this serious skin reaction (1 to 2 cases per million person years). The reporting rate is generally accepted to be an underestimate due to underreporting. Cymbalta should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified.

35. In addition to implementing changes to the label, the FDA required Eli Lilly to update the Cymbalta Medication Guide with the following warning:

> CYMBALTA may cause a serious skin reaction that may affect other parts of your body. This may need to be treated in a hospital and may be life-threatening. Stop taking CYMBALTA and call your doctor right away or get emergency help if you have a severe skin rash, hives, sores in your mouth, or your skin blisters or peels.

36. Eli Lilly failed to timely incorporate the new warnings regarding severe skin reactions into Cymbalta's printed package inserts, patient package inserts, and Medication Guides, and as such, failed to warn Hutchison and her prescribing physician when she was originally prescribed Cymbalta in October 2011. As such, this contributed to her contracting Stevens-Johnson syndrome and was a proximate cause of her injuries and damages.

37. At all relevant times, the prescribing information for Cymbalta in its label advised that it should be administered for major depressive disorder (MDD) at a total dose of 40 mg per day to 60 mg per day during initial treatment. For maintenance, continuation or extended treatment of major depressive disorder, the prescribing information advised that "Cymbalta should be administered at a total dose of 60 mg once daily."

38. In 2003 when the FDA was evaluating Cymbalta for approval action in the treatment of major depressive disorder, the Director, Office of Drug Evaluation for the FDA, warned in an October 16, 2003 memorandum that:

> "[G]iven that most safety data reflects the lower doses, I see no reason to even hint in labeling that higher doses be tried, specifically, by noting that higher doses are effective . . ."

39. However, contrary to the above recommendation from the Director, Office of Drug Evaluation for the FDA, at all relevant times, the Cymbalta label contained the following conflicting and confusing language under Section 2, Dosage and Administration:

> "While a 120 mg/day dose was shown to be effective, there is no evidence that doses greater than 60 mg/day confer any additional benefits."

40. Even though the recommended "total" dosage for treatment of major depressive disorder is 60 mg/day, the Dosage and Administration instruction in the Highlights of Prescribing Information indicates a maximum dose of 120 mg/day is approved to be administered. However, Eli Lilly admits that "there is no evidence that doses greater than 60 mg/day confer additional benefit, while some adverse reactions were observed to be dose-dependent."

41. For years, Eli Lilly lobbied for the approval of Cymbalta for use in the management of chronic pain. On August 31, 2010, the Division of Anesthesia and Analgesia Products, Food and Drug Administration Center for Drug Evaluation and Research held a hearing on Eli Lilly's application for approval of Cymbalta for chronic pain. The committee ultimately approved a more limited indication than requested by Eli Lilly – "for the management of chronic musculoskeletal pain." A significant number of members of the ALSDAC expressed concerns that a broad indication for management of chronic low back pain may end up hurting more patients than actually helping them. In addition, even though Eli Lilly sought approval for a maximum dose of 120 mg/day for treatment of chronic pain, the ALSDAC felt that there was inadequate evidence that a 120 mg daily dose of Cymbalta would provide additional efficacy over that provided by a 60 mg dose for the management of chronic low back pain. ALSDAC refused to recommend an indication for use of Cymbalta in a dose of 120 mg for the treatment of chronic musculoskeletal pain, including chronic low back pain.

42. After the approval of Cymbalta for treatment of chronic musculoskeletal pain in November 2010, the prescribing information of the package insert was changed to reflect that the

recommended dose is 60 mg once daily for chronic musculoskeletal pain. It also noted that "There is no evidence that higher doses confer additional benefit, even in patients who do not respond to a 60 mg dose, and higher doses are associated with a higher rate of adverse reactions."

43. In contrast to the maximum dosage indication for major depressive disorder, both the "recommended dose" and the "maximum dose" for chronic musculoskeletal pain is listed as 60 mg/day in the Eli Lilly prescribing information.

44. In clinical trials where Cymbalta was administered in doses of 60 mg per day or 120 mg per day and compared to a placebo group, patients who received the 120 mg daily dose had the highest rate of discontinuation due to adverse effects.

45. Hutchison's Cymbalta dosage was increased to 120 mg/day in early December 2011, after complaining that her chronic back pain was much worse, in addition to her major depressive disorder continuing. After being on the increased dosage for a few weeks, Hutchison began having symptoms of adverse skin reactions that were ultimately diagnosed as Stevens-Johnson syndrome. The increased dosage contributed to her contracting Stevens-Johnson syndrome and was a proximate cause of her injuries and damages.

46. The Cymbalta package insert, Medication Guide, and instructions for use were confusing and misleading as to the proper dosage for patients, especially for patients being treated for both major depressive disorder and chronic low back pain. Even though Eli Lilly marketed a maximum dose of 120 mg/day for major depressive disorder, it knew that there was no evidence that the additional dosage conferred any additional benefit. Eli Lilly also knew that an increased dosage to 120 mg/day significantly increased the chance of an adverse reaction, such as Stevens-Johnson syndrome.

IV. CLAIMS FOR RELIEF

Count I – Negligence

47. Hutchison incorporates by reference paragraphs 1-46 above.

48. At all relevant times, Eli Lilly had a duty to exercise ordinary care to properly prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell Cymbalta, including a duty to ensure Cymbalta did not cause users (including Hutchison) to suffer from unreasonable, dangerous, or untoward adverse side effects.

49. At all relevant times, Eli Lilly had a duty to give a reasonable and adequate warning to consumers (including Hutchison) of the risks, dangers, and adverse side effects of Cymbalta. At the time Hutchison was prescribed Cymbalta, Eli Lilly had assumed a duty to provide reasonable and adequate warnings directly to patients of all major risks described in the Cymbalta label.

50. At all relevant times, Eli Lilly had a duty to give a reasonable and adequate warning to healthcare providers—including Hutchison's prescribing physician—of the risks, dangers, and adverse side effects of Cymbalta.

51. At all relevant times, Eli Lilly had a duty to revise the Cymbalta labeling to make safety-related changes based on all information known to it and in light all new safety information as it became available after the approval of Cymbalta.

52. Eli Lilly breached its duty by failing to exercise ordinary care in preparing, designing, researching, developing, manufacturing, inspecting, labeling, marketing, promoting, and selling Cymbalta because Eli Lilly knew or should have known that Cymbalta created the risk of unreasonable, dangerous, or untoward adverse side effects.

53. Eli Lilly breached its duty by failing to make timely revisions to the Cymbalta labeling to adequately convey the known risk of serious skin reactions generally and Stevens-Johnson syndrome specifically, after receiving numerous requests from the FDA to do so.

54. Eli Lilly breached its duty by delaying safety-related labeling changes that were necessary to warn of the risk of Stevens-Johnson syndrome, until it was required by the FDA to make the necessary changes, and even then did not timely and adequately disseminate the safety-related labeling changes to Hutchison or her prescribing physician.

55. Eli Lilly negligently prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold Cymbalta in that it:

(a) Failed to use due care in developing, testing, designing, and manufacturing Cymbalta so as to avoid the aforementioned risks to individuals when Cymbalta was being used for treatment of patients;

(b) Failed to accompany its product with truthful, accurate, proper, and/or adequate information regarding adverse side effects and health risks associated with the use of Cymbalta;

(c) Failed to timely revise its warnings to include the risk of severe skin reactions as soon as it had evidence indicating a causal association or relationship between Cymbalta and the aforementioned risks and known adverse effects;

(d) Failed to accompany its product with proper warnings regarding the risk of skin reactions associated with the use of Cymbalta and the treatment and severity of such reactions;

(e) Failed to use due care in the labeling of Cymbalta to warn of the risk of severe skin reactions and other adverse effects to individuals when Cymbalta was being used for the treatment of patients;

(f) Failed to use due care in the promotion of Cymbalta ignoring the risk of severe skin reactions and other adverse effects to individuals when Cymbalta was being used for the treatment of patients;

(g) Failed to provide adequate training and information to healthcare providers, including Hutchison's prescribing physician, for the appropriate

use of Cymbalta, particularly for the treatment of chronic musculoskeletal pain and depressive disorders;

(h) Failed to timely and properly notify physicians and consumers of the September 2011, FDA-mandated changes to the labeling of Cymbalta, failed to insure that physicians and patients received this information, and failed to insure that physicians and patients understood the warnings in the label regarding safe use;

(i) Failed to warn Christol Hutchison, her prescribing physician, and her healthcare providers, prior to actively encouraging and promoting the sale of Cymbalta, either directly or indirectly, orally or in writing, about the adverse side effects and reactions associated with the use of the drug, including, but not limited to, Stevens-Johnson syndrome;

(j) Failed to warn Christol Hutchison, her prescribing physician, and her healthcare providers about the increased risks associated with use of the drug in doses higher than 60 mg per day;

(k) Promoted, marketed, and advertised for the use of Cymbalta in doses higher than 60 mg per day even though Eli Lilly knew or had reason to know that use of the drug in such doses was more likely to cause harmful side effects, including Stevens-Johnson syndrome;

(l) Failed to comply with legal and regulatory obligations under the Federal Food, Drug and Cosmetic Act and applicable regulations.

56. As a direct and proximate result of Eli Lilly's breach of its duties, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count II – Strict Products Liability

57. Hutchison incorporates by reference paragraphs 1-56 above.

58. Eli Lilly is the "manufacturer" and "supplier" as those terms are defined in Ark. Code Ann. § 16-116-102, of a product (i.e., Cymbalta), which was unreasonably and dangerously defective.

59. At all relevant times, Eli Lilly has engaged in the business of selling, distributing, supplying, designing, manufacturing, marketing, and promoting a drug that is defective and unreasonably dangerous to consumers, including Hutchison.

60. At all relevant times, Cymbalta was sold, distributed, supplied, designed, manufactured, and/or promoted by Eli Lilly and was expected to reach, and did reach, prescribing physicians and consumers, including Hutchison, without substantial change in the condition in which it was sold.

61. Cymbalta was and is a defective product, unreasonably dangerous for its reasonably foreseeable and intended uses.

62. Cymbalta was a defective product in the sense that it was not reasonably safe for its intended uses, based on an objective analysis weighing its risks and benefits against those of alternative drugs and therapies.

63. Cymbalta was a defective product in that its use in incremental doses subjects individuals to increased and unreasonable risks that are dose-dependent.

64. At all relevant times, Eli Lilly supplied Cymbalta in a defective condition which rendered it unreasonably dangerous in that Eli Lilly promoted and marketed Cymbalta to be used in doses that were known to cause harmful side effects which outweighed any potential utility.

65. The defective condition of Cymbalta was a proximate cause of Hutchison's injuries and damages.

66. Cymbalta was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Cymbalta was likely to cause injuries such as those suffered by Hutchison. This fact was known to Eli Lilly at the time Cymbalta was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including Hutchison.

67. Nonetheless, Eli Lilly failed to warn physicians and consumers that Cymbalta, as designed and marketed, was capable of causing serious personal injuries such as those suffered by Hutchison. Eli Lilly failed to implement changes in the label of the drug that would have discouraged use of the Cymbalta in doses greater than 60 mg per day for the treatment of certain conditions.

68. The defective and unreasonably dangerous design and marketing of Cymbalta was a proximate cause of Hutchison's injuries and damages.

69. As a direct and proximate result of the above-described acts and omissions of Eli Lilly, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count III – Failure to Warn

70. Hutchison incorporates by reference paragraphs 1-69 above.

71. Eli Lilly has vigorously promoted Cymbalta to physicians, as well as to consumers directly. At all relevant times, Eli Lilly had a duty to communicate an adequate warning to both Hutchison and her prescribing physician.

72. Pursuant to FDA rules and regulations, the two primary vehicles by which official product information is disseminated to the public are the package insert (i.e. the FDA-approved product label), and patient product information, which is commonly known as the Medication Guide.

73. Eli Lilly has an ongoing duty to maintain its label so that it is adequate at all times; this includes the duty to not only create an adequate label but also ensure that its warnings remain adequate as long as the drug is on the market.

74. Federal and state laws both mandate that prescription drugs be accompanied by a product label that contains appropriate information regarding the uses, risks, and benefits of the drug.

75. The product labeling must be revised and supplemented to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug. Eli Lilly failed to timely supplement its product labeling to warn of serious skin disorders, including Stevens-Johnson syndrome.

76. In addition to its state-mandated duty to communicate pertinent safety information and associated risks to prescribing physicians, Eli Lilly assumed a duty to communicate pertinent safety information and risks directly to patients. Specifically, Eli Lilly agreed to update its

Medical Guide to cover all major risks described in the drug label in order to communicate the risks adequately and directly to patients.

77. The Cymbalta Medication Guide that was in use at the time of ingestion of this drug by Hutchison did not adequately disclose a risk of severe skin reactions associated with the use of Cymbalta.

78. The printed package insert, patient package insert, Physicians' Desk Reference, advertisements, and other printed materials did not adequately disclose a risk of severe skin reactions associated with the use of Cymbalta at the time of ingestion of this drug by Hutchison.

79. The Cymbalta label and Cymbalta Medication Guide that were in use at the time of ingestion of Cymbalta by Hutchison did not adequately warn of the increased risks associated with use of this drug in doses higher than 60 mg per day.

80. The printed package insert, patient package insert, Physician's Desk Reference, advertisements, web site, and other materials released by Eli Lilly at the time of ingestion of Cymbalta by Hutchison did not adequately warn of the increased risks associated with use of this drug in doses higher than 60 mg per day.

81. Hutchison relied on Eli Lilly's warnings, or absence of warnings. Hutchison would not have consented to the use of Cymbalta if Eli Lilly had included adequate warnings and instructions. More specifically, Hutchison would not have consented to the use of Cymbalta in the manner and dose prescribed if Eli Lilly had included adequate warnings and instructions regarding the increased risks associated with use of the drug in doses higher than 60 mg per day.

82. Hutchison's prescribing physician relied on Eli Lilly's warnings, or absence of warnings; upon information and belief, her prescribing physician would not have prescribed Cymbalta to Hutchinson at all, nor in the manner and dose prescribed, if Eli Lilly had included

adequate warnings, specifically for use of the drug in treating chronic low back pain and depressive disorders.

83. Cymbalta's inadequate warnings were a proximate cause of Hutchison's injuries and damages.

84. As a direct and proximate result of the above-described acts and omissions of Eli Lilly, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count IV – Failure to Instruct

85. Hutchison incorporates by reference paragraphs 1-84 above.

86. At all relevant times, Eli Lilly had a duty as the manufacturer of Cymbalta to communicate reasonable and adequate instructions with respect to the methods of Cymbalta's safe use to both Hutchison and her prescribing physician.

87. As set forth above, Eli Lilly knew and had reason to believe that danger was reasonably foreseeable in the use of Cymbalta.

88. In complete disregard of the known dangers, Eli Lilly marketed, labeled, promoted, advertised, and sold Cymbalta for use in doses greater than 60 mg per day without evidence that use in such doses conferred any additional benefits.

89. Eli Lilly failed to convey proper and adequate instructions to Hutchison and her prescribing physician regarding use of Cymbalta in increased doses for the treatment of chronic musculoskeletal pain and depressive disorders. At all relevant times, the warnings and instructions that were given by Eli Lilly to the prescribing physician were not adequate, accurate or clear, and were ambiguous.

90. The Cymbalta label and Cymbalta Medication Guide that were in use at the time of ingestion of Cymbalta by Hutchison did not give adequate or reasonable instructions regarding the use of this drug in doses higher than 60 mg per day.

91. For the foregoing reasons, the dangers known to Eli Lilly related to the use of Cymbalta were not known to or reasonably discoverable by Hutchison or her prescribing physician at the time Hutchison was prescribed Cymbalta.

92. Hutchison's prescribing physician relied on Eli Lilly's incomplete and inadequate instructions; upon information and belief, her physician would not have recommended or prescribed Cymbalta at all, nor in the manner and dose prescribed, if Eli Lilly had included adequate instructions, specifically for use of the drug in treating chronic low back pain and depressive disorders.

93. Cymbalta's inadequate and ambiguous instructions on use and dosage were a proximate cause of Hutchison's injuries and damages.

94. As a direct and proximate result of the above-described acts and omissions of Eli Lilly, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past

and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count V – Breach of Implied Warranty of Merchantability

95. Hutchison incorporates by reference paragraphs 1-94 above.

96. Eli Lilly breached its implied warranty of merchantability with respect to Cymbalta.

97. At the time Eli Lilly marketed, promoted, and sold Cymbalta to Hutchison, Eli Lilly impliedly warranted to the public generally and to Hutchison specifically that Cymbalta was merchantable and fit for safe use, including in doses greater than 60 mg per day for treatment of depressive disorder and chronic musculoskeletal pain.

98. At the time Eli Lilly marketed, promoted, and sold Cymbalta to Hutchison for use in the treatment of chronic musculoskeletal pain and depressive disorder, it was not fit for the ordinary purposes for which anti-depressant and pain medications are used in that it was capable of causing serious personal injuries such as those suffered by Hutchison during foreseeable use. The unfit condition of Cymbalta described herein was a proximate cause of Hutchison's damages.

99. Further, Cymbalta was not fit for treatment of chronic low back pain and depressive disorder when used in doses greater than 60 mg daily because no additional benefits are conferred by such use, only an increased risk of adverse side effects.

100. At the time Eli Lilly sold Cymbalta to Hutchison, the drug was not adequately packaged and labeled and did not conform to affirmations made on the label that Cymbalta could

be increasingly effective in treating depressive disorder and chronic low back pain when used in doses greater than 60 mg daily.

101. Hutchison was a person whom Eli Lilly might reasonably expect to use Cymbalta for the treatment of depressive disorder and chronic musculoskeletal pain.

102. Hutchison gave notice to Eli Lilly after she discovered Eli Lilly's breach of the implied warranty of merchantability.

103. As a direct and proximate result of Eli Lilly's breach of the warranty of merchantability, Hutchison sustained injuries and damages.

104. As a direct and proximate result of Eli Lilly's breach of warranty of merchantability, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count VI – Breach of Implied Warranty of Fitness for Particular Purpose

105. Hutchison incorporates by reference paragraphs 1-104 above.

106. Eli Lilly has breached the implied warranty of fitness for a particular purpose with respect to Cymbalta.

107. Eli Lilly knew, or had reason to know, that consumers such as Hutchison would require medication for the safe treatment of depressive disorder and chronic low back pain, and

that consumers would rely on Eli Lilly's skill or judgment to select or furnish suitable medications.

108. Eli Lilly knew, or had reason to know, that Hutchison's prescribing physician would prescribe Cymbalta for the treatment of depressive disorder and chronic low back pain, and that Hutchison's prescribing physician would rely on Eli Lilly's skill or judgment to select or furnish suitable medication.

109. Hutchison and her prescribing physician relied on Eli Lilly's skill and judgment, including, but not limited to, its knowledge of results of various research, studies, and tests related to Cymbalta, when selecting, prescribing, and purchasing Cymbalta. Furthermore, Hutchison and her prescribing physician relied on Eli Lilly's skill and judgment when prescribing and purchasing Cymbalta for use in a dosage of 120 mg/day to treat Hutchison's depressive disorder and chronic low back pain.

110. Cymbalta was not fit for the particular purpose for which it was required because it was capable of causing serious personal injuries such as those suffered by Hutchison during foreseeable use.

111. Further, Cymbalta was not fit for treatment of chronic low back pain and depressive disorder when used in doses greater than 60 mg daily because no additional benefits were conferred by such use, only an increased risk of adverse side effects.

112. The unfit condition of Cymbalta described herein was a proximate cause of Hutchison's damages.

113. Hutchison was a person whom Eli Lilly would reasonably expect to use Cymbalta for the treatment of depressive disorder and chronic low back pain. As a direct and proximate result of this unfitness of Cymbalta, Hutchison sustained injuries and damages.

114. Hutchison notified Eli Lilly after she discovered that Cymbalta was not fit for the particular purpose for which it was required.

115. As a direct and proximate result of Eli Lilly's breach of warranty of fitness for a particular purpose, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count VII – Arkansas Deceptive Trade Practices

116. Hutchison incorporates by reference paragraphs 1-115 above.

117. Eli Lilly willfully engaged in conduct that constitutes a deceptive trade practice in violation of the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-107.

118. As set forth in this Complaint, Eli Lilly engaged in numerous unconscionable, false, or deceptive acts and practices in business, commerce and trade. Eli Lilly also knowingly made false representations as to the uses and benefits of Cymbalta.

119. Eli Lilly had known for years that Cymbalta caused or could cause severe skin reactions, including Stevens-Johnson syndrome. Yet, despite this knowledge, Eli Lilly made representations that its product was safe and concealed information that Cymbalta caused severe skin reactions and Stevens-Johnson syndrome. Even after the FDA had numerous communications and recommendations to Eli Lilly about the inadequacy of their warnings

regarding severe skin reactions, including Stevens-Johnson syndrome, Eli Lilly failed to timely incorporate adequate warnings regarding severe skin reactions into Cymbalta's printed package inserts, patient package inserts, and Medication Guides, and as such, failed to warn Hutchison and her prescribing physician when she was originally prescribed Cymbalta in October 2011.

120. Further, Eli Lilly knowingly ignored repeated recommendations by the FDA's committees, advisors, and representatives, that the maximum recommended human dose of Cymbalta should not exceed 60 mg daily.

121. Eli Lilly knowingly recommended, advertised, marketed, and indicated that Cymbalta could be safely used in doses of 120 mg daily when it knew that use of the higher dose significantly increased the risk of adverse reactions without conferring additional benefits. Eli Lilly knew or should have known that its statements were deceptive, false, incomplete, misleading, and untrue at the time of making such statements. And Eli Lilly knew or should have known that Hutchison and her prescribing physician would rely on its statements and, in fact, intended them to do so. Eli Lilly had an economic interest in making such statements, representations, and advertisements.

122. Eli Lilly fraudulently misled Hutchison and her prescribing physician, with regard to the use and benefits of Cymbalta, all for the purpose of increasing Eli Lilly's profits from the sale of Cymbalta.

123. As a direct and proximate result of Eli Lilly's unconscionable and deceptive actions and its false, incomplete, misleading, and untrue statements, representations, and advertisements, Hutchison sustained injuries and damages.

124. As a direct and proximate result of the above-described acts and omissions of Eli Lilly, Hutchison suffered injuries and damages as specified herein. Hutchison has incurred

actual damages in excess of $75,000.00, including, but not limited to: reasonable and necessary medical expenses incurred in the past; reasonable and necessary medical expenses reasonably likely to be incurred in the future; conscious physical pain and suffering experienced in the past and reasonably likely to be experienced in the future; mental anguish in the past and likely to be experienced in the future; physical injury to her person; physical impairment in the past and likely to be experienced in the future; and loss of earnings in the past and loss of future earning capacity.

Count VIII– Punitive Damages

125. Hutchison incorporates by reference paragraphs 1-124 above.

126. Eli Lilly knew, or should have known, of the defects in design, manufacture, labeling, warning, and marketing that proximately caused the damages suffered by Hutchison. Rather than cure said defects, Eli Lilly consciously, knowingly, and willfully allowed said defects to remain while it continued to vigorously market and promote Cymbalta for its own financial gain. Such conduct was continued by Eli Lilly with malice, or in reckless disregard of the consequences from which malice may be inferred.

127. Specifically, Eli Lilly received numerous communications and recommendations from the FDA pertaining to the Cymbalta labeling and the causal association between serious skin reactions and use of the drug. Eli Lilly knew, or should have known, that failing to change the Cymbalta labeling to adequately warn of these known risks would naturally and probably result in injury, but it continued such conduct with malice or in reckless disregard of the consequences from which malice may be inferred.

128. Eli Lilly consciously, knowingly, and willfully indicated a maximum dosage of 120 mg per day for Cymbalta when it had no evidence showing that use of the drug in doses

higher than 60 mg per day would provide additional efficacy. Eli Lilly promoted, marketed, labeled, and indicated that Cymbalta could be used in doses greater than 60 mg per day when it knew, or should have known, that use in such doses presented a substantially higher risk of harmful side effects and adverse reactions without conferring any additional benefits. Such conduct was continued by Eli Lilly with malice, or in reckless disregard of the consequences from which malice may be inferred. As such, Hutchison is entitled to an award of punitive damages against Eli Lilly.

129. Hutchison demands a trial by jury.

WHEREFORE, Plaintiff Christol Hutchison requests that this Court enter judgment against Defendant Eli Lilly and Company for compensatory and punitive damages in a sum to be determined by the trier of fact, for her costs, pre-judgment and post-judgment interest, attorneys' fees, and all other just and proper relief.

Respectfully submitted,

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