UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

McKIBBINS, SHEJUAN Plaintiff, v. EISAI, INC. and ARENA PHARMACEUTICALS, INC. Defendants.	::	Case No.: **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, by and through undersigned counsel, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

NATURE OF THE CASE

2. This action is brought by Plaintiff, SHEJUAN McKIBBINS, who was injured as a result of her use of Belviq, also known as lorcaserin hydrochloride, as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management.

3. Defendants, EISAI, INC. and ARENA PHARMACEUTICALS, INC. (hereinafter referred to as "EISAI", "ARENA" and collectively referred to as "Defendants") designed, manufactured, sold, distributed and supplied Belviq.

4. At all relevant times, Defendants knew or should have known that Belviq could cause cancer or that cancer, including Adenocarcinoma Colon Cancer, or more specifically, Colorectal Cancer, was a foreseeable risk of Belviq.

5. Defendants failed to provide adequately warnings concerning Belviq's cancer risk to Plaintiff, SHEJUAN McKIBBINS, and her prescribing physician.

6. As a result of her use of Belviq, Plaintiff, SHEJUAN McKIBBINS, was diagnosed in October 2018 with Adenocarcinoma Colon Cancer, or more specifically, Colorectal Cancer.

7. Consequently, as a result of the foregoing acts and omissions, Plaintiff seeks compensatory damages as a result of her use of Belviq, which has caused her to develop Colorectal Cancer, Hematochezia (rectal bleeding), a change in bowle habitsh, and small grade hemmorhoids, which required invasive Colonoscopies, as well as other severe and personal injuries which are permanent and lasting in nature, and physical pain and mental anguish, including diminished enjoyment of life.

PARTY PLAINTIFF

8. Plaintiff, SHEJUAN McKIBBINS, is a citizen of the United States of America and is a citizen of Montgomery County in the State of Texas.

9. Plaintiff, SHEJUAN McKIBBINS, was born on January 14, 1980.

10. Plaintiff, SHEJUAN McKIBBINS, first began using Belviq on or about September 16, 2016, and used Belviq through approximately December 1, 2017.

11. As result of using Defendants' Belviq, Plaintiff, SHEJUAN McKIBBINS, was caused to suffer from transmural inflammation with abscess, fistula formations, and occasional non-necrotizing granulomas, and more specifically, Adenocarcinoma Colon Cancer, which was diagnosed on or about December 22, 2018 and which resulted in an association of inflammatory bowle disease and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

12. The injuries and damages sustained by Plaintiff, SHEJUAN McKIBBINS, were caused by Defendants' Belviq.

13. Plaintiff, SHEJUAN McKIBBINS, at all relevant times purchased Belviq in the State of Texas, ingested Belviq in the State of Texas, and was injured by Belviq within the State of Texas.

PARTY DEFENDANTS

14. Defendant EISAI, INC. is a Delaware corporation, having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

15. As part of its business, EISAI, INC. is involved in the research,

development, sales, and marketing of pharmaceutical products, including Belviq and lorcaserin hydrochloride.

16. Upon information and belief, Defendant, EISAI, INC., has transacted and conducted business in the State of Texas.

17. Upon information and belief, Defendant, EISAI, INC., has derived substantial revenue from goods and products used in the State of Texas.

18. Upon information and belief, Defendant, EISAI, INC., expected or should have expected its acts to have consequences within Texas and derived substantial revenue from interstate commerce within the United States and the State of Texas, more particularly.

19. Upon information and belief, and at all relevant times, Defendant, EISAI, INC., was in the business of and did manufacture, test, advertise, promote, market, sell, and distribute the drug Belviq to be used for the primary purpose of chronic weight management.

20. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., is a Delaware corporation with its principal place of business located at 6154 Nancy Ridge Drive, San Diego, California 92121.

21. As part of its business, ARENA PHARMACEUTICALS, INC. is involved in the research, development, sales, and marketing of pharmaceutical products, including Belviq and lorcaserin hydrochloride.

22. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., has transacted and conducted business in the State

of Texas.

23. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., expected or should have expected its acts to have consequence within Texas, and derived substantial revenue from interstate commerce within the United States, and Texas, more particularly.

24. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC., was in the business of and did research, manufacture, test, advertise, promote, market, sell, and distribute the drug Belviq, the primary use and purpose of which is chronic weight management.

FACTUAL BACKGROUND

25. At all relevant times, Defendants were in the business of and did design, manufacture, sell, distribute, and supply Belviq for chronic weight management.

26. ARENA received FDA approval for Belviq, also known as lorcaserin hydrochloride, on June 27, 2012 as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a body mass index (hereinafter referred to as "BMI") greater than or equal to 30 kg/m^2 or adult patients with a BMI greater than or equal to 27 kg/m^2 and at least one weight-related comorbid condition.

27. ARENA and EISAI jointly launched Belviq in the United States in 2012, with ARENA manufacturing Belviq and EISAI as the exclusive distributor.

28. Four years later, on July 15, 2016, ARENA received additional FDA

approval for Belviq XR, an extended-release tablet of lorcaserin hydrochloride, for the same indication as Belviq (hereinafter Belviq and Belviq XR will be collectively referred to as "Belviq").

29. Belviq XR was jointly launched by ARENA and EISAI in the United States in 2016, with ARENA manufacturing Belviq XR and EISAI as the exclusive distributor.

30. In 2017, EISAI purchased the global rights to develop and market Belviq from ARENA.

31. The aforementioned purchase identified in paragraph 30 was the subject of a press release by EISAI CO., LTD, in which it announced that, in association with Defendant EISAI, INC., it had reached an agreement with Defendant ARENA PHARMACEUTICALS, INC. to revise the previous marketing and supply agreement that it had concluded with Defendant ARENA PHARMACEUTICALS, INC's wholly-owned subsidiary, ARENA PHARMACEUTICALS GmbH, and under the new agreement, EISAI acquired rights to develop and market Belviq from both Defendant ARENA PHARMACEUTICALS, INC. and ARENA PHARMACEUTICALS GmbH. https://www.eisai.com/news/news201701.html.

32. Belviq is a first-in-class oral selective serotonin 5HT2c receptor agonist and is available by prescription only in oral tablets at doses of 10mg taken twice daily or 20mg extended release taken once daily.

33. During the preclinical trial program for Belviq, Defendants

conducted a two-year carcinogenicity study in rats (hereinafter referred to as the "two-year carcinogenicity rat study") in which lorcaserin was identified as a non-genotoxic carcinogen that induced multiple tumor types; this identification was primarily due to an increase in mammary tumors found in both sexes near clinical exposure and at all doses in female rats.

34. This same preclinical, two-year carcinogenicity rat study also revealed an increase in astrocytomas, malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skin squamous carcinoma, and thyroid follicular cell adenoma in male rats. Adenocarcinoma diagnosed in the lorcaserin groups were associated with increased tumor onset, multiplicity, and lung metastases. Fibroadenoma in the lorcaserin groups also demonstrated greater incidence and multiplicity.

35. While the two-year carcinogenicity rat study was ongoing, the FDA required bi-monthly updates from Defendants due to the consistently increased incidence of tumors and mortality that was being seen in the lorcaserin groups. However, in the final report of the study, Defendants reported that the incidence of adenocarcinoma was lower in the mid- and high-dose groups than that previously reported at week 96, and that it had increased in the control group. The final report also revealed that the incidence of fibroadenoma had increased across all doses from week 96, with notable variations in the mid- and high- dose groups. Due to the apparent increase in fibroadenoma accompanying the decrease in adenocarcinoma after week 96, the FDA suspected that study

investigators had reclassified tumor types.

36. Defendants attributed the increased incidence of tumors seen in the two-year carcinogenicity rat study to elevated prolactin levels induced by lorcaserin in rats, which they claim was a rodent-specific phenomenon.

37. In addition to two-year carcinogenicity rat study, during the preclinical trial program, Defendants also conducted a two-year carcinogenicity study in mice (hereinafter referred to as the "two- year carcinogenicity mouse study"), which demonstrated an increase in malignant hepatocellular carcinoma in males and schwannoma in females. Although the dosing levels were below the clinical dose, these findings provide further context and support for the potential carcinogenicity of lorcaserin, particularly in combination with the results of the two-year carcinogenicity rat study.

38. The two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or a combination of both, put Defendants on notice and/or should have put Defendants on notice that lorcaserin was a carcinogen and/or that further testing needed to be done, and was testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under Texas law.

39. In addition to the aforementioned studies, from September 2006 through February 2009, Defendants conducted the Behavioral modification and Lorcaserin for Overweight and Obesity Management (BLOOM) trial – a two-year, randomized, placebo-controlled, double-blind, multicenter clinical trial

involving 3,182 patients – to examine the efficacy of lorcaserin in reducing body weight in the United States. While weight reduction was seen in the first year, all treatment groups experienced weight regain during the second year. In July 2010, the results of the BLOOM trial were published in the New England Journal of Medicine (hereinafter referred to as "NEJM"). Smith S.R., et al. *Multicenter, Placebo- Controlled Trial of Lorcaserin for Weight Management*. N. Engl. J. Med 2010;363:245-56.

40. Additionally, from December 2007 to July 2009, Defendants conducted the Behavioral modification and Lorcaserin Second Study for Obesity Management (BLOSSOM) trial – a one-year randomized, placebo-controlled, double-blind, parallel arm trial involving 4,008 patients – to examine the effects of lorcaserin on body weight, cardiovascular risk, and safety in the United States. In July 2011, the results of the BLOSSOM trial were published in the Journal of Clinical Endocrinology and Metabolism. Fidler, M.C., et al. *A One-Year Randomized Trial of Lorcaserin for Weight Loss in Obese and Overweight Adults: the BLOSSOM trial*. J Clin Endocrinal Metab 2011;96:3067-3077.

41. Combined data from the BLOOM and BLOSSOM trials demonstrated only a 3.3% mean weight loss after one year with lorcaserin over that of the placebo group, demonstrating that lorcaserin failed to meet the mean efficacy criterion of FDA's obesity draft guidance.

42. On December 18, 2009, Defendant ARENA PHARMACEUTICALS, INC. submitted its first New Drug Application for Belviq seeking to market and

distribute Belviq in the United States.

43. On September 16, 2010, the Endocrinologic and Metabolic Drugs Advisory Committee (hereinafter referred to as "EMDAC") met to discuss approval of Belviq based on the results of preclinical trials and the BLOOM and BLOSSOM Phase 3 clinical trials. The EMDAC panel voted nine (9) to five (5) against approval of Belviq as the potential benefits did not outweigh the potential risks based on concerns about the preclinical carcinogenicity findings (i.e., increased mammary adenocarcinoma/fibroadenoma and brain astrocytomas in rats) and marginal weight loss demonstrated by the clinical trials.

44. On October 28, 2010, the FDA issued a Complete Response Letter (CRL) rejecting approval of Belviq. The bases for the CRL included uncertainty in diagnosis of mammary masses in rats, unresolved issues with the exposure-response relationship between lorcaserin and mammary adenocarcinoma, failure to identify a mode of action and a clear safety margin for brain astrocytoma, and marginal weight loss results.

45. In response to the CRL, Defendants convened a pathology working group (hereinafter referred to as "PWG") to blindly re-adjudicate the preclinical mammary tumor data in rats.

46. The CRL also requested that Defendants submit the final report from the third Phase 3 trial in overweight and obese patients with Type 2 Diabetes Mellitus.

47. From December 2007 to August 2010, Defendants conducted the

Behavioral modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus (BLOOM-DM) trial – a one- year, randomized, placebo-controlled trial involving 604 patients – to examine the efficacy and safety of lorcaserin for weight loss in patients with Type 2 Diabetes Mellitus in the United States. After one year, there was only a 3.1% mean weight loss with lorcaserin over that of the placebo group. In April 2012, the results of the BLOOM-DM trial were published in the journal of The Obesity Society. O'Neil, P.M., et al. *Randomized Placebo-Controlled Clinical Trial of Lorcaserin for Weight Loss in Type 2 Diabetes Mellitus: The BLOOM-DM Study*. Obesity 2012;20:1426-1436.

48. On December 27, 2011, in response to the CRL, Defendants submitted to the FDA the final report of the BLOOM-DM study and data from the PWG readjudication, as well as new studies Defendants claimed supported their continued assertion that the increase in tumors seen in the two-year carcinogenicity rat study was due to elevated prolactin levels induced by lorcaserin, again claiming it was a rodent-specific phenomenon.

49. As to the PWG re-adjudication, the PWG found a decreased number of adenocarcinoma and an increased number of fibroadenoma in both the control and the lorcaserin groups, which they claim was a rodent-specific phenomenon.

50. As to the PWG re-adjudication, for adenocarcinoma, the number decreased to a larger extent in the lorcaserin group compared to the control

group, but lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma, and the high-dose lorcaserin group maintained a statistically significant increase in adenocarcinomas compared to the control group. Regarding fibroadenoma, there was an increase in the incidence, tumor onset and multiplicity, and lethality across all lorcaserin dose groups compared to the control group; yet despite their relevance, these results were disregarded as irrelevant to risk of carcinoma in FDA's review of the readjudication data.

51. Upon information and belief, the PWG re-adjudication procedure and its results were mis-adjudicated, misapplied, misinterpreted and/or otherwise skewed in favor of Defendants and, particularly, a finding that lorcaserin was not a carcinogen; nevertheless, even if accepted as true, the results of the PWG re-adjudication, reviewed separately and/or in combination with the initial results of the two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or both, put Defendants on notice or should have put Defendants on notice that lorcaserin was a carcinogen and/or that further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under Texas law.

52. On May 10, 2012, a second EMDAC panel met to discuss approval of Belviq with a focus on the PWG readjudication of preclinical data to determine the drug's potential carcinogenicity risk, to determine a safety margin for

astrocytoma by looking at lorcaserin levels in human cerebrospinal fluid, and to discuss the results of the BLOOM-DM Phase 3 clinical trial to further determine efficacy. The panel voted 18 to four (4) (with one abstention) that the benefits of Belviq outweighed the risks for an overweight and obese population. The panel also recommended a post-approval assessment of risk for Belviq, with a focus on cardiovascular risk. Ultimately, the FDA required that Defendants conduct six (6) post-marketing studies, including a cardiovascular outcomes trial.

53. On June 26, 2012, in his Summary Review of Defendants' application for approval following submission of data in response to the CRL, the FDA Deputy Division Director, Dr. Eric Colman, indicated that the PWG's analysis addressed the concerns raised by the data in the original application, and that he did not believe Belviq posed a risk for mammary adenocarcinoma in humans. He also stated that the cerebrospinal fluid data provided an adequate safety margin for brain astrocytoma. However, regarding tumorigenic mechanism of action, Dr. Colman noted that the FDA Pharmacology/Toxicology reviewer, Dr. Fred Alavi, concluded that the prolactin studies, while supportive of a plausible role of prolactin in tumor formation, fell short of definitive proof that elevated prolactin levels were the reason increased tumors were seen during the two-year carcinogenicity rat study.

54. In stark contrast to the FDA's approval of Belviq despite the aforementioned testing, results and findings, on May 3, 2013, Defendants withdrew the application for marketing authorization for Belviq with the

European Medicines Agency (hereinafter referred to as "EMA").

55. In reviewing the data submitted by Defendants, the EMA Committee for Medicinal Products for Human Use (hereinafter referred to as "CHMP") determined that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG re-adjudication, the risk of carcinogenicity in humans needed further consideration and the overall clinical risk/benefit balance was negative in that the modest efficacy results did not outweigh safety concerns. The CHMP further stated that the increased occurrence of several tumor types in male rats was particularly concerning due to the lack of any persuasive mechanism of action that would provide assurance of safety in human use, which also undermined any discussion on exposure margins. Thus, the CHMP concluded that the clinical relevance of the tumors found in the two-year carcinogenicity rat study must be evaluated as part of the risk-benefit assessment.

56. From January 2014 to June 2018, Defendants conducted a post-marketing trial of lorcaserin - the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61).

57. CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving 12,000 patients conducted in the United States, Canada, Mexico, the Bahamas, Europe, South America, Australia, and New Zealand to evaluate the risk of heart-related issues

with Belviq. The primary safety outcome of major adverse cardiovascular events showed noninferiority. The results of CAMELLIA-TIMI 61 were published in September 2018 in NEJM. Bohula, E.A., et al. *Cardiovascular Safety of Lorcaserin in Overweight or Obese Patients*. N. Engl. J. Med. 2018;379:1107-17.

58. On January 14, 2020, the FDA issued a safety communication regarding clinical trial results showing a possible increased risk of cancer with Belviq. The FDA stated that its evaluation of the potential signal was ongoing and a causal association was at that time uncertain.

59. On February 13, 2020, the FDA announced that EISAI had submitted a request to voluntarily withdraw Belviq from the market. The FDA reported that analysis of the CAMELLIA-TIMI 61 data indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration, including pancreatic, colorectal, and lung cancer. Specifically, one additional cancer was observed per 470 patients treated for one year, with 462 (7.7%) Belviq patients diagnosed with 520 primary cancers compared to 423 (7.1%) with 470 cancers in the placebo group. The FDA further stated that the risks of Belviq outweigh its benefits and recommended that patients stop taking Belviq and dispose of any unused pills. The FDA also instructed all health care professionals to stop prescribing Belviq and to contact their patients taking Belviq to inform them of the increased risk of cancer and ask that they stop taking Belviq.

60. In the September 10, 2020 issue of the New England Journal of Medicine, the FDA submitted an article entitled: "**Cancer Risk Associated**

with Lorcaserin — The FDA's Review of the CAMELLIA-TIMI 61 Trial." The article makes clear that the FDA's decision to request the voluntary recall of the oral weight-loss drug lorcaserin (Belviq, Belviq XR) came after a careful analysis by the FDA (not by the Defendants) of the postmarketing safety data that revealed excess cancer risk and death. The FDA authors stated, in part, as follows:

> "On February 13, 2020, the Food and Drug Administration (FDA) announced that it had requested that the manufacturer of Belviq and Belviq XR (lorcaserin and extended-release lorcaserin) voluntarily withdraw the products from the U.S. market. The agency's request was based on its assessment of lorcaserin's benefits and risks after a review of a large postmarketing clinical trial that revealed a higher frequency of cancer diagnosis in the lorcaserin group than in the placebo group...*The FDA did not approve the original marketing application for lorcaserin, submitted in December 2009, in part because nonclinical carcinogenicity studies revealed an increased incidence of several tumor types in rats exposed to the drug...As a condition of approval, the FDA required Arena to conduct a postmarketing study focused on cardiovascular safety*...The randomized placebo-controlled CAMELLIA-TIMI 61 trial, conducted from 2014 through 2018, evaluated lorcaserin's effect on the incidence of major adverse cardiovascular events (MACE) in 12,000 patients randomly assigned to lorcaserin or placebo in a 1:1 ratio...*The published report identified no safety signal related to cancer. The FDA's initial safety analyses of the CAMELLIA study report identified a potential signal of increased cancers and cancer-related mortality. In contrast to the published study, when assessing cancer incidence, the FDA considered all postrandomization adverse events, not just "on treatment" events (those that occurred within 30 days after drug discontinuation)... The cancer-related safety signal from nonclinical studies supports the plausibility of an excess cancer risk from lorcaserin, and the consistency of cancer findings in CAMELLIA-TIMI 61 and the robustness of sensitivity analyses further support a causative effect. The increased risk of various cancer types associated with lorcaserin in the clinical study reflects the pattern seen in nonclinical studies*.5 ...Balancing the clinical importance of cancer and the difficulty of mitigating this risk against the uncertain clinical benefit of lorcaserin, however, we conclude that the therapy's benefits do not outweigh the risks for any identifiable patient population." (emphasis

provided) https://www.nejm.org/doi/full/10.1056/NEJMp2003873

FIRST CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(NEGLIGENT FAILURE TO WARN)

61. Defendants had a duty to use reasonable care, which is the care that a reasonably careful designer, manufacturer, seller, distributor or supplier would use under like circumstances.

62. Reasonable care on the part of Defendants required that they give appropriate warnings about particular risks of Belviq which Defendants knew or should have known were involved in the reasonably foreseeable use of Belviq.

63. Plaintiff used Belviq as intended for weight loss management.

64. Defendants knew or should have known that Belviq could cause cancer.

65. Specifically, as stated above, two preclinical studies, the two-year carcinogenicity rat study and the two-year carcinogenicity mouse study, demonstrated Belviq's propensity to cause cancer.[1]

66. The two-year carcinogenicity rat study, the two-year carcinogenicity mouse study, and/or a combination of both, put Defendants on notice and/or should have put Defendants on notice that lorcaserin was a carcinogen.

67. At the very least, these preclinical carcinogenicity studies should have put Defendants on notice that further testing needed to be done, testing that

[1] *See* ¶¶ 34-37

would have confirmed lorcaserin as a carcinogen.

68. The animal studies, combined with the marginal benefit seen in the clinical studies, were enough to place Defendants on notice of the foreseeable risk of cancer.[2] Indeed, this same evidence led the EDMAC panel to initially vote against approval of Belviq on September 16, 2010 and led the EMA to determine that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy.[3]

69. Under these circumstances, a reasonably careful designer, manufacturer, seller, distributor, or supplier would have provided adequate warnings to prescribing physicians and/or their patients that Belviq could cause cancer, that preclinical studies found cancer in rats and mice, and that adequate testing had not been performed to confirm Belviq's cancer propensity.

70. Despite the fact that Defendants knew or should have known that Belviq caused cancer, Defendants sold Belviq to Plaintiff and/or her prescribing physician without properly alerting physicians and their patients, including Plaintiff and her prescribing physician, of the cancer risk.

71. Defendants knew or should have known that consumers such as the Plaintiff, SHEJUAN McKIBBINS, would foreseeably suffer injury as a result of their failure to exercise ordinary care by warning about the risk of cancer or warning that Belviq had not been adequately tested.

---

[2] *See* ¶¶ 38-42
[3] *See* ¶¶ 43-56.

72. Defendants had a duty to warn Plaintiff's prescribing physicians of all safety risks associated with Belviq, including its increased risk of causing cancer.

73. Defendants had a duty to warn Plaintiff, SHEJUAN McKIBBINS, and her prescribing physician that Belviq had not been adequately and/or sufficiently tested regarding its carcinogenicity.

74. Defendants breached their duties to Plaintiff by failing to exercise reasonable care in warning her and her prescribing physician about the risk of cancer.

75. Upon information and belief, had Plaintiff's prescribing physician been warned of the increased cancer risk associated with Belviq, Belviq would not have been prescribed to Plaintiff and/or the prescribing physician would have relayed the risk of cancer to Plaintiff to allow her to make an informed decision regarding her use of Belviq and/or they would have instructed Plaintiff and her physician to closely monitor the patient to ensure early cancer detection.

76. Upon information and belief, had Plaintiff's prescribing physician been warned of the increased cancer risk associated with Belviq, they would not have prescribed Belviq to Plaintiff, or they would have provided Plaintiff with adequate warnings regarding the dangers of Belviq.

77. Had Plaintiff's physician warned her that Belviq can cause cancer, that it had not been adequately tested, or that she would need to be monitored closely for cancer, Plaintiff would not have used Belviq.

78. Defendants' negligence in failure to warn Plaintiff and/or her prescribing physician of the risk of cancer was the proximate cause of Plaintiff's use of Belviq and her subsequent Colorectal Cancer diagnosis.

79. Subsequent clinical studies conducted from January 2014 to June 2018 confirmed that Belviq causes cancer, including Colorectal Cancer.[4] These findings led to FDA action and ultimately, Defendants decided to voluntarily withdraw Belviq from the market on or about February 13, 2020.[5] This was too little, too late for Plaintiff.

80. Defendants' inadequate warnings of Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

81. By reason of the foregoing acts and omissions, Plaintiff, SHEJUAN McKIBBINS, was caused to suffer from Colorectal Cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

82. By reason of the foregoing, Plaintiff has been damaged as a result of Defendant's conduct as described herein.

SECOND CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

83. A product is defective when the foreseeable risks of harm from the product could have been reduced or avoided by providing reasonable

[4] *See* ¶ 57
[5] *See* ¶¶ 58-60

instructions or warnings, and the failure to provide those instructions or warnings makes the product unreasonably dangerous.

84. Under Texas law, a product may be considered defective if it has an unsafe design, diverges from its intended design or lacks proper instructions and warnings.[6]

85. The risk of cancer, including the risk of Colorectal Cancer, was a foreseeable risk that could have been avoided had Defendants provided reasonable instructions or warnings.

86. Specifically, based on the two-year carcinogenicity rat study, and the two-year carcinogenicity mouse study described above, it was known or should have been known by Eisai and Arena that Belviq had a propensity to cause cancer.[7]

87. At the very least, the above-referenced preclinical studies put Defendants on notice of the need to perform adequate testing to confirm the cancer risk.

88. The animal studies, combined with the marginal benefit seen in the clinical studies, was enough to place Defendants on notice of the foreseeable risk of cancer. Indeed, this same evidence led the EDMAC panel to initially vote against approval of Belviq on September 16, 2010 and led the EMA to determine

[6] Texas Stat. Sect 82.001, et seq.
[7] *See* ¶¶ 34-37.

that Belviq was not approvable due to its cancer risk and marginal efficacy.[8]

89. Moreover, this same evidence led the EMA to determine that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy.

90. Subsequent clinical studies conducted from January 2014 to June 2018 confirmed that Belviq causes cancer, including Colorectal Cancer.[9] These findings led to FDA action and ultimately Defendants decided to voluntarily withdraw Belviq from the market on or about February 13, 2020.[10] Again, this was too little, too late for Plaintiff.

91. Defendants failed to warn Plaintiff and her prescribing physician that Belviq could cause cancer, that careful monitoring after using Belviq was needed for early cancer detection or that it had not been adequately tested.

92. Upon information and belief, had Plaintiff's prescribing physicians been warned of the increased cancer risk associated with Belviq, Belviq would not have been prescribed to Plaintiff and/or the prescribing physician would have relayed the risk of cancer to Plaintiff to allow her to make an informed decision regarding her use of Belviq and/or they would have instructed Plaintiff and her physician to closely monitor the patient to ensure early cancer detection.

93. Upon information and belief, had Plaintiff's prescribing physician been warned of the increased cancer risk associated with Belviq, they would not

[8] *See* ¶¶ 43-56.
[9] *See* ¶ 57
[10] *See* ¶¶ 58-60

have prescribed Belviq to Plaintiff or they would have provided Plaintiff with adequate warnings regarding the dangers of Belviq.

94. Had Plaintiff's physician warned her that Belviq can cause cancer, that it had not been adequately tested or that she would need to be monitored closely for cancer, Plaintiff would not have used Belviq.

95. Defendants' failure to warn Plaintiff and/or her prescribing physician of the risk of cancer was the proximate cause of Plaintiff's use of Belviq and her subsequent Colorectal Cancer diagnosis.

96. Defendants' inadequate warnings for Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

97. As a result of the foregoing acts and omissions, Plaintiff, SHEJUAN McKIBBINS, was caused to suffer serious and dangerous side effects, including Colorectal Cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

98. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for failing to provide adequate warnings concerning the cancer risk which made Belviq unreasonably dangerous.

99. By reason of the foregoing, Plaintiff has been damaged as a result of Defendant's conduct as described herein.

THIRD CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(NEGLIGENT DESIGN DEFECT)

100. Defendants had a duty to use reasonable care, which is the care that a reasonably careful designer, manufacturer, seller, distributor or supplier would use under like circumstances.[11]

101. Reasonable care on the part of Defendants required that they use reasonable care with the design, inspection, testing, manufacturing, or other defect in a product, which Defendants knew or should have known were involved in the reasonably foreseeable use of Belviq.

102. Plaintiff used Belviq as intended for weight loss management.

103. Defendants knew or should have known that Belviq could cause cancer.

104. Specifically, as stated above, two preclinical studies, the two-year carcinogenicity rat study and the two-year carcinogenicity mouse study demonstrated Belviq's propensity to cause cancer.[12]

105. Belviq's propensity to cause cancer was a defect in the design of Belviq.

106. The two-year carcinogenicity rat study, the two-year carcinogenicity mouse study, and/or a combination of both, put Defendants on notice and/or should have put Defendants on notice that lorcaserin was a carcinogen.

107. At the very least, these preclinical carcinogenicity studies should

[11] Texas Stat. Sect 82.001, et seq.
[12] *See* ¶¶ 34-37

have put Defendants on notice that further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen.

108. The animal studies, combined with the marginal benefit seen in the clinical studies, were enough to place Defendants on notice of the foreseeable risk of cancer.[13] Indeed, this same evidence led the EDMAC panel to initially vote against approval of Belviq on September 16, 2010 and led the EMA to determine that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy.[14]

109. Under these circumstances, a reasonably careful designer, manufacturer, seller, distributor, or supplier would have changed the design or Belviq, disclosed the defective design of Belviq, or elected not to distribute Belviq.

110. Despite the fact that Defendants knew or should have known that Belviq caused cancer, Defendants sold Belviq to Plaintiff and/or her prescribing physician without properly alerting physicians and their patients, including Plaintiff and her prescribing physician, of the cancer risk asspciated with the defective desgon of Belviq.

111. Defendants knew or should have known that consumers such as Plaintiff, SHEJUAN MCKIBBINS, would foreseeably suffer injury as a result of their failure to exercise ordinary care in appropriately assessing the design,

[13] *See* ¶¶ 38-42
[14] *See* ¶¶ 43-56.

inspection, testing, manufacturing, or other defects in Belviq.

112. Defendants had a duty to exercise ordinary care in appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq.

113. Defendants breached their duties to Plaintiff by failing to exercise reasonable care in failing to exercise ordinary care in appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq.

114. Upon information and belief, had Defendants not fail to exercise ordinary care in appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq, Plaintiff's injuries would not have occured.

115. Defendants' negligence in failing to exercise ordinary care in appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq was the proximate cause of Plaintiff's use of Belviq and her subsequent Grade 1 Neuroendocrine tumors or more specifically, her Stomach Cancer diagnosis.

116. Subsequent clinical studies conducted from January 2014 to June 2018 confirmed that Belviq causes cancer, including Stomach Cancer.[15] These findings led to FDA action and ultimately, Defendants decided to voluntarily withdraw Belviq from the market on or about February 13, 2020.[16] Again, this

[15] *See* ¶ 57
[16] *See* ¶¶ 58-60

was too little, too late for Plaintiff.

117. Defendants' failure to exercise ordinary care in appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

118. By reason of the foregoing acts and omissions, the Plaintiff, SHEJUAN MCKIBBINS, was caused to suffer from Stomach Cancer, as well as other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

119. By reason of the foregoing, Plaintiff has been damaged as a result of Defendant's conduct as described herein.

FOURTH CAUSE OF ACTION
AS AGAINST ALL DEFENDANTS
(STRICT PRODUCTS LIABILITY – DESIGN DEFECT)

120. A product is defective when the foreseeable risks of harm from the product could have been reduced or avoided by appropriately assessing the design, inspection, testing, manufacturing, or other defects in Belviq and the design, inspection, testing, or manufacture of a product makes it unreasonably dangerous.

121. Under Texas law, a product is defective if it is unreasonably dangerous, even though the seller has exercised all possible care in the

preparation and sale of the product.[17]

122. The risk of cancer, including the risk of Stomach Cancer, was a foreseeable risk that could have been avoided, had Defendants appropriately assessed the design, inspection, testing, manufacturing, or other defects in Belviq.

123. Specifically, based on the two-year carcinogenicity rat study and the two-year carcinogenicity mouse study described above, it was known or should have been known by Eisai and Arena that Belviq had a propensity to cause cancer.[18]

124. At the very least, the above-referenced preclinical studies put Defendants on notice of the need to perform adequate testing to confirm the cancer risk.

125. The animal studies, combined with the marginal benefit seen in the clinical studies, was enough to place Defendants on notice of the foreseeable risk of cancer. Indeed, this same evidence led the EDMAC panel to initially vote against approval of Belviq on September 16, 2010 and led the EMA to determine that Belviq was not approvable due to its cancer risk and marginal efficacy.[19]

126. Moreover, this same evidence led the EMA to determine that

[17] Texas Stat. Sect 82.001, et seq.
[18] *See* ¶¶ 34-37.
[19] *See* ¶¶ 43-56.

Belviq was not approvable due to major objections regarding carcinogenicity and efficacy.

127. Subsequent clinical studies conducted from January 2014 to June 2018 confirmed that Belviq causes cancer, including Stomach Cancer.[20] These findings led to FDA action and ultimately Defendants decided to voluntarily withdraw Belviq from the market on or about February 13, 2020.[21] Again, this was too little, too late for Plaintiff.

128. Defendants failed to appropriately assessed the design, inspection, testing, manufacturing, or other defects in Belviq and more specifically, that Belviq could cause cancer, including also that careful monitoring after using Belviq was needed for early cancer detection.

129. Defendants' failure to appropriately assessed the design, inspection, testing, manufacturing, or other defects in Belviq was the proximate cause of Plaintiff's use of Belviq and her subsequent Stomach Cancer diagnosis.

130. Defendants' failure to appropriately assessed the design, inspection, testing, manufacturing, or other defects in Belviq for Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

131. As a result of the foregoing acts and omissions, the Plaintiff, TANYA ALANA CHAPLIN, was caused to suffer serious and dangerous side effects, including Grade 1 Neuroendocrine Tumors (Gastric Carcinoids), or

[20] *See* ¶ 57
[21] *See* ¶¶ 58-60

more specifically, Stomach Cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

132. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for failing to failure to appropriately assessed the design, inspection, testing, manufacturing, or other defects in Belviq, which made Belviq unreasonably dangerous.

133. By reason of the foregoing, Plaintiff has been damaged as a result of Defendant's conduct as described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above- referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, SHEJUAN McKIBBINS, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter

future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: January 14, 2021

CLARK von PLONSKI ANDERSON

By: */s/ Collen A. Clark*
COLLEN A. CLARK
State Bar No. 04309100
JACOB L. von PLONSKI
State Bar No. 24098554
3500 Maple Avenue, Suite 1250
Dallas, Texas 75219
214-780-0500/214-780-0501 Fax
eservice@cvpalaw.com

In association with:

Aylstock, Witkin, Kreis & Overholtz, PLLC

By: */s/ Daniel J. Thornburgh*
Daniel J. Thornburgh (motion for *pro hac vice* pending)
Florida Bar Number 42661
Nathan C. Bess (motion for *pro hac vice* pending)
Florida Bar Number 51945
17 E. Main Street, Suite 200
Pensacola, FL 32502
Phone: (850) 202-1010
Fax: (850) 916-7449
Email: dthornburgh@awkolaw.com
Email: nbess@awkolaw.com

ATTORNEYS FOR PLAINTIFF