UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

MARYANN KAYLOR and WILLARD KAYLOR, JR	*	**CIVIL ACTION**
	*	
VERSUS	*	**JUDGE**
	*	
EISAI, INC., EISAI CO., LTD, ARENA PHARMACEUTICALS GmbH, AND ARENA PHARMACEUTICALS, INC.	*	**Mag . Div.**
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* *

Plaintiffs, by their attorneys, **COSSICH, SUMICH, PARSIOLA & TAYLOR, L.L.C**. and **DOUGLAS & LONDON, P.C.** on behalf of themselves individually, 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 Plaintiffs 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 Plaintiffs reside.

NATURE OF THE CASE

2. This action is brought by Plaintiff MARYANN KAYLOR 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. This action is also brought by Plaintiff WILLARD KAYLOR, JR. who suffered loss of consortium damages as a result of Plaintiff MARYANN KAYLOR's use of Belviq and injuries related thereto.

4. Defendants, EISAI, INC., along with its parent company Eisai Co., Ltd. (hereinafter collectively referred to as "EISAI"), and Defendant ARENA PHARMACEUTICALS, INC., along with its wholly owned subsidiary Arena Pharmaceuticals GmbH (hereinafter collectively referred to as "ARENA")(collectively with EISAI, INC. referred to as "Defendants") were responsible for the design, research, manufacture, testing, advertisement, labeling, promotion, marketing, sale, and/or distribution of Belviq.

5. At all relevant times, Defendants knew or should have known that Belviq had not been property tested, was not safe and/or was not effective for its indicated use.

6. When warning of the safety and risks of Belviq, Defendants negligently misrepresented and/or fraudulently represented to Plaintiffs, the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA") and the public in general, that Belviq had been tested and was found to be safe and/or effective for its indicated use despite their knowledge to the contrary.

7. Defendants concealed their knowledge of Belviq's defects from the Plaintiff MARYANN KAYLOR, her physicians, hospitals, pharmacists, the medical and healthcare community, the FDA, and/or the public in general.

8. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff MARYANN KAYLOR, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Belviq for chronic weight management, all of which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff MARYANN KAYLOR.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Belviq during clinical trials, forcing Plaintiff MARYANN KAYLOR, and her physicians, hospitals,

and/or the FDA to rely on safety information that applies to other chronic weight management treatments, which does not entirely and/or necessarily apply to Belviq whatsoever.

10. As a result of the foregoing acts and omissions of Defendants, the Plaintiff MARYANN KAYLOR was and still is caused to suffer serious and dangerous side effects including, inter alia, breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff MARYANN KAYLOR herein has sustained the above health consequences due to her use of Belviq and Defendants' actions or omissions were a direct and proximate cause of her health consequences.

12. Consequently, Plaintiffs seek compensatory damages as a result of Plaintiff MARYANN KAYLOR's use of Belviq, which has caused her to suffer from breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

13. Plaintiff MARYANN KAYLOR is a citizen of the United States of America, and is a citizen and resident of the State of Louisiana.

14. Plaintiff MARYANN KAYLOR was born on October 16, 1961.

15. Plaintiff, MARYANN KAYLOR, first began using Belviq in or about September 2014, and used Belviq up through approximately March 2015.

16. As result of using Defendants' Belviq, Plaintiff MARYANN KAYLOR was caused to suffer from breast cancer on or about January 14, 2020 and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress related thereto.

17. The injuries and damages sustained by Plaintiff MARYANN KAYLOR were caused by Defendants' Belviq.

18. Plaintiff WILLARD KAYLOR, JR. is a citizen of the United States of America, and is a citizen and resident of the State of Louisiana.

19. Plaintiff WILLARD KAYLOR, JR. is the lawful spouse of MARYANN KAYLOR and was her lawful spouse at all relevant times.

PARTY DEFENDANTS

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

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

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

23. Upon information and belief, Defendant, EISAI, INC. has derived substantial revenue from goods and products sold and/or used in the State of Louisiana.

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

25. 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/or distribute the drug Belviq to be used for the primary purpose of chronic weight management.

26. Defendant, EISAI, INC. is a wholly-owned subsidiary of Eisai Corporation of North America, which in turn is a wholly-owned subsidiary of Eisai Co., Ltd., a Japanese company having a principal place of business located at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan.

27. At all relevant times, Eisai Co., Ltd., was in the business of and was responsible for the design, research, manufacturing, testing, labeling advertising, promoting, marketing, selling, and/or distribution of the drug Belviq for use which primary purpose is chronic weight management.

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

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

30. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of Louisiana.

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

32. At all relevant times Defendant ARENA PHARMACEUTICALS, INC. was a biopharmaceutical company focused on discovering, developing and commercializing oral drugs.

33. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC., was in the business of and was responsible for the design, research,

manufacturing, testing, labeling advertising, promoting, marketing, selling, and/or distribution of the drug Belviq for use which primary purpose is chronic weight management.

34. Defendant ARENA PHARMACEUTICALS, INC. is the parent/holding company of Arena Pharmaceuticals GmbH.

35. At all relevant times, Arena Pharmaceuticals GmbH was in the business of and was responsible for the design, research, manufacturing, testing, labeling, advertising, promoting, marketing, selling, and/or distribution of the drug Belviq for use which primary purpose is chronic weight management.

36. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC, exercised and exercises dominion and control over Arena Pharmaceuticals GmbH, including but not limited to, as it relates to Belviq.

FACTUAL BACKGROUND

A. FDA Approval of Belviq in the United States

37. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Belviq and lorcaserin hydrochloride for chronic weight management.

38. Defendant ARENA PHARMACEUTICALS, INC. submitted the New Drug Application for Belviq to the FDA on or about December 18, 2009 requesting that the FDA grant it approval to market and sell Belviq, also known as lorcaserin hydrochloride, in the United States 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.

39. On June 27, 2012, the FDA approved Defendant ARENA PHARMACEUTICALS, INC.'s request to market and sell Belviq in the United States as an adjunct to reduced-calorie diet and increased

physical activity for chronic weight management in adult patients with a 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.

40. ARENA and EISAI jointly launched Belviq in the United States in 2012, pursuant to the terms of the Amended and Restated Marketing and Supply Agreement, they entered into May 2012.[1]

41. The exact terms of the Amended and Restated Marketing and Supply Agreement are within the possession, custody and control of Defendants.

42. Defendant ARENA PHARMACEUTICALS, INC. entered into the Amended and Restated Marketing and Supply Agreement with EISAI to establish a collaboration to support Belviq's development, approval and commercialization.

43. Following the FDA's approval of Belviq, Defendant ARENA PHARMACEUTICALS, INC. announced on its website that its then current strategy was to first focus its efforts on the commercialization of Belviq in North and South America pursuant to the terms of the Amended and Restated Marketing and Supply Agreement with EISAI.

44. Following FDA approval, Defendant ARENA PHARMACEUTICALS, INC. promoted the safety, efficacy and sale of Belviq in the United States on its website, in press releases, through in-person presentations at conferences, in the drug's label, in print materials, through websites associated with Belviq, such as belviqnow.com, as well as other public outlets.

45. At all relevant times, Defendant ARENA PHARMACEUTICALS, INC. maintained responsibility with Defendant EISAI for the commercialization, marketing, distribution and sale of Belviq in the United States.

[1] The original Marketing and Supply Agreement was entered into in July 2010.

46. Four years later, on July 15, 2016, in response to an application submitted by Defendant ARENA PHARMACEUTICALS, INC to the FDA, Defendant ARENA PHARMACEUTICALS, INC. received additional FDA approval to market and sell Belviq XR, an extended release tablet of lorcaserin hydrochloride, in the United States for the same indication as Belviq (hereinafter Belviq and Belviq XR will be collectively referred to as "Belviq").

47. Belviq XR was jointly launched by ARENA and EISAI in the United States in 2016 pursuant to the terms of the Second Amended and Restated Marketing and Supply Agreement, they entered into in November 2013.

48. The exact terms of the Second Amended and Restated Marketing and Supply Agreement are within the possession, custody and control of Defendants.

49. Defendant ARENA PHARMACEUTICALS, INC. entered into the Second Amended and Restated Marketing and Supply Agreement with EISAI to establish a collaboration to support Belviq's development, approval and commercialization.

50. Following the FDA's approval of Belviq XR, Defendant ARENA PHARMACEUTICALS, INC. promoted the safety, efficacy and sale of Belviq XR in the United States on its website, in press releases, through in-person presentations at conferences, in the drug's label, in print materials, through websites associated with Belviq, such as belviqnow.com, as well as other public outlets.

51. At all relevant times, ARENA PHARMACEUTICALS, INC. maintained responsibility with Defendant EISAI for the commercialization, marketing, distribution and sale of Belviq XR in the United States.

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

53. The aforementioned purchase identified in paragraph 52 was the subject of a press release by Eisai Co., Ltd., in which Eisai Co., Ltd. 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 Defendant Arena Pharmaceuticals GmbH, and under the new agreement, EISAI acquired rights to develop and market Belviq from both Defendant ARENA PHARMACEUTICALS, INC. and Defendant Arena Pharmaceuticals GmbH. https://www.eisai.com/news/news201701.html.

B. Belviq's Clinical Trial Results and Recall by the FDA

54. 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.

55. 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 in female rats at all doses in female rats.

56. 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.

57. 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 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.

58. 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.

59. In addition to the 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 context and support for the potential carcinogenicity of lorcaserin, particularly in combination with the results of the two-year carcinogenicity rat study.

60. 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, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under the Louisiana Products Liability Act, La. R.S. 9:2800.51, *et. seq*. (hereinafter referred to as the "LPLA").

61. 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.

62. 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 Endocrinol Metab 2011;96:3067-3077.

63. Combined data from the BLOOM and BLOSSOM trials revealed 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.

64. On December 18, 2009, ARENA submitted its first New Drug Application for Belviq.

65. On September 16, 2010, the FDA's 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.

66. 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.

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

68. 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.

69. 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.

70. 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 re-adjudication, 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.

71. 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.

72. 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 the FDA's review of the re-adjudication data.

73. 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 the LPLA.

74. 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 the 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.

75. 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.

76. 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").

77. 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 its carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG readjudication, 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 found 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.

78. 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).

79. 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.

80. 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.

81. 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.

82. Prior to applying for and obtaining approval of Belviq, Defendants knew or should have known that human consumption of Belviq was associated with and/or would cause the induction of cancer, and Defendants possessed pre-clinical scientific studies, which Defendants knew or should have known were a signal that Belviq could cause cancer and/or the cancer risk needed further testing and studies prior to its introduction to the market.

83. Upon information and belief, despite cancer findings in animal carcinogenicity studies, Defendants failed to adequately conduct complete and proper testing of Belviq prior to filing their New Drug Application for Belviq.

84. From the date Defendants received FDA approval to market Belviq, Defendants made, distributed, marketed, and sold Belviq without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Belviq was associated with and/or could cause cancer, presented a risk of cancer in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Belviq with regard to carcinogenicity.

85. Upon information and belief, Defendants ignored the association between the use of Belviq and the risk of developing cancer.

86. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Belviq for cancer risk further rendered warnings for this medication inadequate.

87. By reason of the foregoing acts and omissions, Plaintiff MARYANN KAYLOR was and still is caused to suffer from breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

88. Plaintiff MARYANN KAYLOR has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered serious and dangerous side effects from Belviq including, inter alia breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

89. By reason of the foregoing, Plaintiff MARYANN KAYLOR has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Belviq drug.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(LOUISIANA PRODUCT LIABILITY ACT – INADEQUATE WARNINGS)

90. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

91. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed and distributed Belviq as hereinabove described that was used by Plaintiff MARYANN KAYLOR.

92. Plaintiff MARYANN KAYLOR's injuries and damages, particularly breast cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous – inadequate warnings.

93. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff MARYANN KAYLOR, with the ordinary knowledge common to the community as to the product's characteristics.

94. Plaintiff MARYANN KAYLOR's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff MARYANN KAYLOR.

95. At the time Belviq left the Defendants' control, Defendants, knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq posed danger, particularly cancer, to humans, and/or that they had not conducted sufficient and/or adequate testing regarding Belviq's carcinogenicity.

96. At the time Belviq left the Defendants' control, Belviq had inadequate warnings because Belviq possessed a characteristic that may cause damage, particularly cancer, to humans, and Defendants, who knew and/or should have known had they acted as a reasonably prudent manufacturer of said characteristic and its danger, failed to use reasonable care to provide an adequate warning of such characteristics and its danger to users and handlers of the product, such as the Plaintiff MARYANN KAYLOR and/or her prescribing physician, thereby rendering the product unreasonably dangerous.

97. Defendants knew or should have known that Belviq was unreasonably dangerous because of inadequate warnings, especially when used in the form and manner as provided by Defendants.

98. Defendants created a product unreasonably dangerous for its normal, intended use.

99. Had Defendants adequately warned of the risks and dangers associated with Belviq, Plaintiff's prescribing physician would not have prescribed Belviq and/or would have provided Plaintiff with adequate instructions regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding Belviq.

100. Had Defendants adequately warned of the risks and dangers associated with Belviq, Plaintiff would not have taken Belviq.

101. Accordingly, Defendants are liable unto the Plaintiffs as a result of their failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to users of the product, such as Plaintiff MARYANN KAYLOR, at the time Belviq left the Defendants' control.

102. Additionally, and/or in the alternative, Defendants, after Belviq left their control, acquired knowledge and/or should have acquired knowledge had they acted as a reasonably prudent manufacturer of a characteristic of Belviq that may cause damage, particularly cancer, to humans, yet they failed to use reasonable care to provide an adequate warning of such characteristics and its danger to users and handlers of the product, such as the Plaintiff MARYANN KAYLOR and/or her prescribing physician, thereby rendering the product unreasonably dangerous.

103. Accordingly, Defendants are liable unto the Plaintiffs as a result of their subsequent failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to users of the product, such as Plaintiff MARYANN KAYLOR.

104. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiff MARYANN KAYLOR was caused to suffer serious and dangerous side effects including breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

105. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR requires and/or will require more health care and services and Plaintiffs did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff MARYANN KAYLOR will in the future be required to obtain further medical and/or hospital care, attention, and services.

106. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(LOUISIANA PRODUCT LIABILITY ACT – BREACH OF EXPRESS WARRANTY)

107. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

108. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed and distributed Belviq as hereinabove described that was used by Plaintiff MARYANN KAYLOR.

109. Plaintiffs' injuries and damages, particularly breast cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous – Defendants' breach of express warranty.

110. Defendants knew or should have known that Belviq was unreasonably dangerous because of the breach of their express warranties, especially when the drug was used in the form and manner as provided by Defendants.

111. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff MARYANN KAYLOR, with the ordinary knowledge common to the community as to the product's characteristics.

112. Plaintiff MARYANN KAYLOR's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff MARYANN KAYLOR.

113. At the time Belviq left the Defendants' control, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq posed danger, particularly cancer, to humans.

114. At the time Belviq left the Defendants' control, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq was not an effective pharmaceutical drug to be used as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial body mass indexes (BMI).

115. At the time Belviq left the Defendants' control, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that the carcinogenic risks of Belviq far outweighed the benefits, if any, of Belviq.

116. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial body mass indexes (BMI).

117. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties that Belviq was effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial body mass indexes (BMI).

118. At the time Belviq left the Defendants' control, Belviq did not conform to its express warranties that the effectiveness of the pharmaceutical drug outweighed any potential dangers and/or risks.

119. Belviq was unreasonably dangerous because it did not conform to any of the express warranties made by the Defendants about the product.

120. Defendants created a product unreasonably dangerous for its normal, intended use.

121. The express warranties made by Defendants induced Plaintiff MARYANN KAYLOR to use the product and/or her prescribing physician to prescribe the product.

122. Had Defendants not made these express warranties, Plaintiff MARYANN KAYLOR would not have used the product and/or her prescribing physician would not have prescribed the product.

123. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff MARYANN KAYLOR relating to the characteristics of Belviq, particularly its efficacy and safety, at the time Belviq left their control.

124. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR was caused to suffer serious and dangerous side effects including breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

125. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR requires and/or will require more health care and services and Plaintiffs did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff MARYANN KAYLOR will in the future be required to obtain further medical and/or hospital care, attention, and services.

126. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(LOUISIANA PRODUCT LIABILITY ACT – DESIGN DEFECT)

127. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

128. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched,

manufactured, tested, advertised, promoted, marketed, sold, distributed and distributed Belviq as hereinabove described that was used by Plaintiff MARYANN KAYLOR.

129. Plaintiffs' injuries and damages, particularly breast cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous – design defect.

130. Defendants knew or should have known that Belviq was unreasonably dangerous because of its design defects, especially when used in the form and manner as provided by Defendants.

131. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff MARYANN KAYLOR, with the ordinary knowledge common to the community as to the product's characteristics

132. Plaintiff MARYANN KAYLOR's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff MARYANN KAYLOR.

133. At the time Belviq left the Defendants' control, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq posed danger, particularly cancer, to humans, and/or that they had not conducted sufficient and/or adequate testing regarding Belviq's carcinogenicity.

134. Upon information and belief, at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design because there existed an alternative design for the product that was capable of preventing the Plaintiffs' injuries and damages – an alternative design that was and is in the exclusive possession, custody and control of Defendants.

135. Upon information and belief, the alternative design was a pharmaceutical drug that was not a serotonin receptor agonist, but rather a pharmaceutical drug that did not affect the serotonin pathway.

136. Upon information and belief, Belviq was unreasonably dangerous in design because there existed an alternative design for the product that was capable of preventing the Plaintiffs' injuries and damage and the likelihood that Belviq's design would cause the Plaintiffs' injuries and damages and the gravity of those injuries and damages outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

137. At the time Belviq left Defendants' control, Defendants, in light of then existing reasonably available scientific and technological knowledge and testing, knew and/or should have known of the design characteristic that caused the damage and the danger of such characteristic.

138. At the time Belviq left the Defendants' control, the Defendants, in light of then existing reasonably available scientific and technological knowledge and testing, knew and/or should have known of the existing technologically and economically safer alternative design characteristic than that which caused the damage and the danger of such characteristic.

139. Belviq was unreasonably dangerous because of its defect in design.

140. Defendants created a product unreasonably dangerous for its normal, intended use.

141. Accordingly, Defendants are liable unto the Plaintiffs as a result of the defective design relating to the characteristics of Belviq at the time Belviq left their control.

142. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR was caused to suffer serious and dangerous side effects including breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

143. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR requires and/or will require more health care and services and Plaintiffs did incur medical, health,

incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff MARYANN KAYLOR will in the future be required to obtain further medical and/or hospital care, attention, and services.

144. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(LOUISIANA PRODUCT LIABILITY ACT – MANUFACTURING DEFECT)

145. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

146. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed and distributed Belviq as hereinabove described that was used by Plaintiff MARYANN KAYLOR.

147. Plaintiffs' injuries and damages, particularly breast cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous – manufacturing defect.

148. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff MARYANN KAYLOR, with the ordinary knowledge common to the community as to the product's characteristics.

149. Plaintiff MARYANN KAYLOR's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff MARYANN KAYLOR.

150. At the time Belviq left the Defendants' control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical

products manufactured by the Defendants and, as such, was unreasonably dangerous in construction or composition.

151. Belviq's material deviation from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the Defendants proximately caused Plaintiff MARYANN KAYLOR's injury by causing her to suffer breast cancer and all other injuries associated therewith.

152. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiff MARYANN KAYLOR was caused to suffer serious and dangerous side effects including breast 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, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

153. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff MARYANN KAYLOR requires and/or will require more health care and services and Plaintiffs did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

154. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (LOSS OF CONSORTIUM)

155. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. At all relevant times, Plaintiff WILLARD KAYLOR, JR. was the lawful spouse of Plaintiff MARYANN KAYLOR, and, as such, at all relevant times, he was entitled to the comfort, enjoyment, society, and services of his spouse.

157. As a direct and proximate result of the foregoing acts and omissions by Defendants, Plaintiff WILLARD KAYLOR, JR. was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff MARYANN KAYLOR, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff WILLARD KAYLOR, JR.'s injuries and damages are permanent and will continue into the future. Plaintiffs seek damages from the Defendants as alleged herein and as provided by law.

158. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

DEMAND FOR JURY TRIAL

159. Plaintiffs hereby demand trial by jury as to all issues.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering, mental anguish, disability, disfigurement, inconvenience, embarrassment, humiliation, loss of ability to enjoy life, loss of ability to pursue happiness, and personality change for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, rehabilitation expenses, together with interest and costs as provided by law;

2. Awarding Plaintiffs the costs of these proceedings; and

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

Dated: January 11, 2021

/s/ Philip F. Cossich, Jr.
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