UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA

PAMELA PUSKAS and MICHAEL PUSKAS, Plaintiffs, vs. EISAI, INC., EISAI CO., LTD, ARENA PHARMACEUTICALS GmbH, and ARENA PHARMACEUTICALS, INC., Defendants.	Case No. CIV-20-868-SLP

COMPLAINT

Plaintiffs, by their attorneys, **WALSH & FRANSEEN** 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 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 on behalf of Plaintiff, PAMELA PUSKAS, who used 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., EISAI CO., LTD. (hereinafter collectively referred to as "EISAI"), ARENA PHARMACEUTICALS GmbH, and ARENA PHARMACEUTICALS, INC. (hereinafter collectively referred to as "ARENA" and collectively with EISAI referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Belviq.

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

5. Defendants concealed their knowledge of Belviq's defects, from Plaintiff, the FDA, the public in general, and/or the medical community specifically.

6. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, 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 herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Belviq during clinical trials, forcing Plaintiff, and Plaintiff's 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.

8. As a result of the foregoing acts and omissions, the Plaintiff 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. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of Belviq.

9. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and/or the public in general.

10. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Belviq, which has caused Plaintiff 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

11. Plaintiff, PAMELA PUSKAS, is a citizen of the United States of America, and is a resident of the State of Oklahoma.

12. Plaintiff, PAMELA PUSKAS, was born on August 6, 1964.

13. Plaintiff, PAMELA PUSKAS, first began using Belviq in or about August 2018, and used Belviq up through approximately September 2018.

14. As result of using Defendants' Belviq, Plaintiff PAMELA PUSKAS, was caused to suffer from breast cancer on or about September 18, 2018, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

15. The injuries and damages sustained by Plaintiff, PAMELA PUSKAS, were caused by Defendants' Belviq.

16. Plaintiff, MICHAEL PUSKAS, is a citizen of the United States of America, and is a resident of the State of Oklahoma and is the lawful spouse of PAMELA PUSKAS.

PARTY DEFENDANTS

17. Upon information and belief, Defendant EISAI, INC. is a Delaware corporation, having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677. As part of its business, EISAI, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Belviq and lorcaserin hydrochloride.

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

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

20. Upon information and belief, Defendant, EISAI, INC., expected or should have expected its acts to have consequence within Oklahoma, and derived substantial revenue

from interstate commerce within the United States, and Oklahoma, more particularly.

21. 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 for use which primary purpose is chronic weight management.

22. Upon information and belief, Defendant, EISAI CO., LTD., is a Japanese corporation having a principal place of business located at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan and is the parent/holding company of EISAI, INC.

23. Upon information and belief, and at all relevant times, Defendant, EISAI CO., LTD., exercised and exercises dominion and control over Defendant EISAI, INC.

24. Upon information and belief, Defendant, EISAI CO., LTD., has transacted and conducted business in the State of Oklahoma.

25. Upon information and belief, Defendant, EISAI CO., LTD., has derived substantial revenue from goods and products used in the State of Oklahoma.

26. Upon information and belief, Defendant, EISAI CO., LTD., expected or should have expected its acts to have consequence within the United States of America, and the State of Oklahoma, and derived substantial revenue from interstate commerce within the United States of America and Oklahoma more particularly.

27. Upon information and belief, and at all relevant times, Defendant, EISAI CO., LTD., was in the business of and did manufacture, test, advertise, promote, market, sell, and distribute the drug Belviq for use which primary purpose is chronic weight management.

28. Upon information and belief, Defendant, ARENA PHARMACEUTICALS

GmbH, is a Swiss corporation having a principal place of business located at Theilerstrasse 1a, 6300 Zug, Switzerland. As part of its business, ARENA PHARMACEUTICALS GmbH, is involved in the research, development, sales, and marketing of pharmaceutical products including Belviq and lorcaserin hydrochloride.

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

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

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

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

33. 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 and is the parent/holding company of ARENA PHARMACEUTICALS GmbH. 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.

34. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC, exercised and exercises dominion and control over Defendant, ARENA PHARMACEUTICALS GmbH.

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

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

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

38. 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 for use which primary purpose is chronic weight management.

FACTUAL BACKGROUND

39. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Belviq and

lorcaserin hydrochloride for chronic weight management.

40. ARENA received FDA approval for Belviq, also known as lorcaserin hydrochloride, on June 27, 2012 as an adjunct to 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.

41. ARENA received additional FDA approval for Belviq XR, an extended release tablet of lorcaserin hydrochloride, on July 15, 2016 for the same indication as Belviq (hereinafter Belviq and Belviq XR will be collectively referred to as "Belviq").

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

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

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

45. During the preclinical trial program, Defendants conducted a two-year carcinogenicity study in rats in which lorcaserin was identified as a non-genotoxic carcinogen inducing multiple tumor types, primarily due to an increase in mammary tumors in both sexes near clinical exposure and at all doses in female rats. There was also 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 in the lorcaserin groups demonstrated increased tumor onset, multiplicity, and lung metastases. Fibroadenoma in the lorcaserin groups also demonstrated greater incidence and multiplicity. While the study was ongoing, FDA required bi-monthly updates due to the consistently increased incidence of tumors and mortality in the lorcaserin groups. However, in the final report the incidence of adenocarcinoma was lower in the mid- and high-dose groups than that reported at week 96 and had increased in the control group, while the incidence of fibroadenoma 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 reclassification of tumor types.

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

47. During the preclinical trial program, Defendants also conducted a two-year carcinogenicity study in mice, which demonstrated an increase in malignant hepatocellular carcinoma in males and schwannoma in females. Although the dosing levels were below the clinical dose and therefore likely inadequate, these findings provide further context for potential carcinogenicity in combination with the two-year rat study results.

48. 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 U.S. 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.

49. 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 U.S. 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.

50. 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, which failed to meet the mean efficacy criterion of FDA's obesity draft guidance.

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

52. 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.

53. 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.

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

55. 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.

56. 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 U.S. 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.

57. 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 to support their continued assertion that the increase in tumors seen in the two-year rat study was due to elevated prolactin levels induced by lorcaserin.

58. The PWG found a decreased number of adenocarcinoma and an increased number of fibroadenoma in both the control and the lorcaserin groups of the two-year rat study. 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, however these results were disregarded as irrelevant to risk of carcinoma in FDA's review of the readjudication data.

59. 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 potential carcinogenicity risk, lorcaserin levels in human cerebrospinal fluid to determine a safety

margin for astrocytoma, and 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.

60. 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.

61. In contrast, on May 3, 2013, Defendants withdrew the application for marketing authorization for Belviq with the European Medicines Agency (hereinafter referred to as "EMA"). 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 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 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 rat study must be evaluated as part of the risk-benefit assessment.

62. From January 2014 to June 2018, Defendants conducted a post-marketing trial, the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61). CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving 12,000 patients conducted in the U.S., 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.

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

64. On February 13, 2020, the FDA announced that EISAI had submitted a request to voluntarily withdraw Belviq from the market. 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. FDA further stated that the risks of Belviq outweigh its benefits and recommended that patients stop taking Belviq and dispose of any unused pills. 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.

65. 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 evidence Defendants knew or should have known was a signal that the cancer risk needed further testing and studies prior to its introduction to the market.

66. 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.

67. Upon information and belief, 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.

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

69. 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.

70. By reason of the foregoing acts and omissions, the Plaintiff 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.

71. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered 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 redeveloping cancer.

72. By reason of the foregoing, Plaintiff 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
(NEGLIGENCE)

73. 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.

74. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of Belviq into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

75. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Belviq into interstate commerce in that Defendants knew or should have known that using Belviq created a high risk of unreasonable, dangerous side effects, including, 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.

76. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing Belviq without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing Belviq without adequately testing it;

c. Not conducting sufficient testing programs to determine whether Belviq was safe for use; in that Defendants herein knew or should have known that Belviq was unsafe and unfit for use by reason of the dangers to its users;

d. Selling Belviq without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Belviq;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Belviq;

g. Failing to test Belviq and/or failing to adequately, sufficiently, and properly test Belviq.

h. Negligently advertising and recommending the use of Belviq without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that Belviq was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that Belviq had equivalent safety and efficacy as other forms of treatment for chronic weight management;

k. Negligently designing Belviq in a manner which was dangerous to its users;

l. Negligently manufacturing Belviq in a manner which was dangerous to its users;

m. Negligently producing Belviq in a manner which was dangerous to its users;

n. Negligently assembling Belviq in a manner which was dangerous to its users;

o. Concealing information concerning FDA warnings from the Plaintiff in knowing that Belviq was unsafe, dangerous, and/or non-conforming with FDA regulations;

p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Belviq compared to other forms of treatment for chronic weight management.

77. Defendants under-reported, underestimated and downplayed the serious dangers of Belviq.

78. Defendants negligently compared the safety risk and/or dangers of Belviq with other forms of treatment for chronic weight management.

79. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of Belviq in that they:

a. Failed to use due care in designing and manufacturing Belviq so as to avoid the aforementioned risks to individuals when Belviq was used for chronic weight management;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Belviq;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Belviq;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Belviq;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Belviq;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of Belviq, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

h. Were otherwise careless and/or negligent.

80. Despite the fact that Defendants knew or should have known that Belviq caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute, and/or sell Belviq to consumers, including the Plaintiff.

81. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

82. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

83. As a result of the foregoing acts and omissions, the Plaintiff 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.

84. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

85. 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
(STRICT PRODUCTS LIABILITY)

86. 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.

87. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Belviq as hereinabove described that was used by the Plaintiff.

88. That Belviq was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

89. At those times, Belviq was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

90. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Belviq.

91. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

92. At all times herein mentioned, Belviq was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

93. Defendants knew, or should have known, that at all times herein mentioned its Belviq was in a defective condition, and was and is inherently dangerous and unsafe.

94. At the time of the Plaintiff's use of Belviq, Belviq was being used for the purposes and in a manner normally intended, namely for chronic weight management.

95. Defendants with this knowledge voluntarily designed its Belviq in a dangerous condition for use by the public, and in particular the Plaintiff.

96. Defendants had a duty to create a product that was not unreasonably dangerous

for its normal, intended use.

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

98. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was manufactured defectively in that Belviq left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

99. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Belviq was manufactured.

100. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

101. The Plaintiff could not by the exercise of reasonable care, have discovered Belviq's defects herein mentioned and perceived its danger.

102. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including cancer, as well as other severe and personal

injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

103. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

104. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including cancer, as well as other severe and permanent health consequences from Belviq, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Belviq.

105. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Belviq.

106. Defendants' defective design, manufacturing defect, and inadequate warnings of Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

107. That said defects in Defendants' drug Belviq were a substantial factor in causing Plaintiff's injuries.

108. As a result of the foregoing acts and omissions, the Plaintiff 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.

109. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

110. 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
(BREACH OF EXPRESS WARRANTY)

111. 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.

112. Defendants expressly warranted that Belviq was safe and well accepted by users.

113. Belviq does not conform to these express representations because Belviq is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

114. Plaintiff did rely on the express warranties of the Defendants herein.

115. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Belviq in recommending, prescribing, and/or dispensing Belviq.

116. The Defendants herein breached the aforesaid express warranties, as their drug Belviq was defective.

117. Defendants expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that Belviq was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for chronic weight management, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

118. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Belviq was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

119. As a result of the foregoing acts and omissions, the Plaintiff 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.

120. By reason of the foregoing, Plaintiff 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.

121. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

122. 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
(BREACH OF IMPLIED WARRANTIES)

123. 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.

124. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold Belviq and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold Belviq as treatment for chronic weight management.

125. At the time Defendants marketed, sold, and distributed Belviq for use by Plaintiff, Defendants knew of the use for which Belviq was intended and impliedly warranted

the product to be of merchantable quality and safe and fit for such use.

126. The Defendants impliedly represented and warranted to the users of Belviq and their physicians, healthcare providers, and/or the FDA that Belviq was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

127. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Belviq was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

128. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

129. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Belviq was of merchantable quality and safe and fit for its intended use.

130. Belviq was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

131. The Defendants herein breached the aforesaid implied warranties, as their drug Belviq was not fit for its intended purposes and uses.

132. As a result of the foregoing acts and omissions, the Plaintiff 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.

133. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

134. 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 (FRAUDULENT MISREPRESENTATION)

135. 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.

136. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Belviq, had been tested and was found to be safe and/or effective for chronic weight management.

137. That representations made by Defendants were, in fact, false.

138. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the

representations were true.

139. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, 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 and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Belviq, for use in chronic weight management, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

140. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Belviq, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

141. In reliance upon said representations, the Plaintiff was induced to and did use Belviq, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

142. Said Defendants knew and were aware or should have been aware that Belviq had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

143. Defendants knew or should have known that Belviq had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

144. Defendants brought Belviq to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

145. As a result of the foregoing acts and omissions, the Plaintiff 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.

146. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

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

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

148. 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.

149. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Belviq for its intended use.

150. Defendants knew or were reckless in not knowing that its representations were false.

151. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. that Belviq was not as safe as other forms of treatment for chronic weight management;

b. that the risks of adverse events with Belviq were higher than those with other forms of treatment for chronic weight management;

c. that the risks of adverse events with Belviq were not adequately tested and/or known by Defendants;

d. that Defendants were aware of dangers in Belviq, in addition to and above and beyond those associated with other forms of treatment for chronic weight management;

e. that Belviq was defective, and that it caused dangerous side effects, including but not limited to cancer, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of treatment for chronic weight management;

f. that patients needed to be monitored more regularly than normal while using Belviq;

g. that Belviq was manufactured negligently

h. that Belviq was manufactured defectively;

i. that Belviq was manufactured improperly;

j. that Belviq was designed negligently;

k. that Belviq was designed defectively; and

l. that Belviq was designed improperly.

152. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Belviq, including but not limited to the heightened risk of cancer.

153. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Belviq, including the Plaintiff, in particular.

154. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Belviq was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Belviq, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Belviq and/or use the product.

155. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Belviq, as set forth herein.

156. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

157. As a result of the foregoing acts and omissions, the Plaintiff 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.

158. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

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

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

160. 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.

161. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, Belviq, had been tested and found to be safe and effective for chronic weight management.

162. The representations made by Defendants were, in fact, false.

163. Defendants failed to exercise ordinary care in the representation of Belviq, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or

distribution of said product into interstate commerce in that Defendants negligently misrepresented Belviq's high risk of unreasonable, dangerous side effects.

164. Defendants breached their duty in representing Belviq's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

165. As a result of the foregoing acts and omissions, the Plaintiff 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.

166. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

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

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

168. 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.

169. Defendants conducted research and used Belviq as part of their research.

170. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Belviq was safe and effective for use as a means of chronic weight management.

171. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

172. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

173. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

174. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Belviq was safe and effective for use in chronic weight management.

175. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Belviq carried the same risks, hazards, and/or dangers as other forms of treatment for chronic weight management.

176. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Belviq was not injurious to the health and/or safety of its intended users.

177. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Belviq was as potentially injurious to the health and/or safety of its intended as other forms of treatment for chronic weight management.

178. These representations were all false and misleading.

179. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Belviq was not safe as a means of chronic weight management and/or was not as safe as other means of chronic weight management.

180. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Belviq, specifically but not limited to Belviq not having dangerous and serious health and/or safety concerns.

181. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Belviq, specifically but not limited to Belviq being as safe a means of chronic weight management.

182. That it was the purpose of Defendants in making these representations to

deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Belviq and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Belviq.

183. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Belviq was fit and safe for use in chronic weight management.

184. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Belviq was fit and safe for use in chronic weight management and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of treatment for chronic weight management.

185. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Belviq did not present serious health and/or safety risks.

186. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Belviq did not present health and/or safety risks greater than other oral forms of treatment for chronic weight management.

187. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually

exist, and/or were made recklessly and without regard to the actual facts.

188. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Belviq.

189. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Belviq to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment for chronic weight management.

190. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Belviq by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Belviq.

191. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use, and rely on Belviq and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

192. Defendants, through their public relations efforts, which included but were not

limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

193. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Belviq.

194. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as Defendants' superior knowledge of chronic weight management and were thereby induced to purchase, use, and rely on Defendants' drug Belviq.

195. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Belviq.

196. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

197. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Belviq, Plaintiff would not have purchased, used, and/or relied on Defendants' drug Belviq.

198. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly, and/or purposefully on the Plaintiff.

199. As a result of the foregoing acts and omissions, the Plaintiff 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.

200. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and 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.

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

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS LOSS OF CONSORTIUM ON BEHALF OF PLAINTIFF MICHAEL PUSKAS)

202. 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.

203. Plaintiff, MICHAEL PUSKAS was and is the lawful spouse of Plaintiff PAMELA PUSKAS, and as such, was and is entitled to the comfort, enjoyment, society, and services of his spouse.

204. As a direct and proximate result of the foregoing, Plaintiff MICHAEL

PUSKAS was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff PAMELA PUSKAS, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiffs, PAMELA PUSKAS and MICHAEL PUSKAS'S injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

205. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

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 for severe and permanent personal injuries sustained by the Plaintiff, 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 Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiffs reasonable attorneys' fees;

4. Awarding Plaintiffs the costs of these proceedings; and

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

Respectfully submitted,
WALSH & FRANSEEN

s/Micky Walsh

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JURY TRIAL DEMANDED