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GRACIA PROFACI and JOSEPH PROFACI, Plaintiffs, v. EISAI, INC and ARENA PHARMACEUTICALS, INC., Defendants.	)	SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, BERGEN COUNTY CIVIL ACTION NUMBER **COMPLAINT AND JURY DEMAND**

Plaintiffs GRACIA PROFACI and JOSEPH PROFACI (hereinafter "Plaintiffs"), residents of the State of New Jersey, residing at 202 Summit Rd, Mt. Laurel, New Jersey 08054, by and through their undersigned attorney(s), **DOUGLAS & LONDON, P.C.**, hereby sue the Defendants named herein and alleges as follows:

BACKGROUND

1. This action is brought by Plaintiff, GRACIA PROFACI, 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.

2. This action is brought by Plaintiff, JOSEPH PROFACI, who suffered loss of consortium damages as a result of Plaintiff GRACIA PROFACI's use of Belviq and injuries related thereto.

3. 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.

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

5. When warning of 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.

6. Defendants concealed their knowledge of Belviq's inefficacy and safety risks from Plaintiff GRACIA PROFACI, her prescribing physicians, her healthcare providers, hospitals, pharmacists, the medical and healthcare community, and/or the public in general.

7. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff GRACIA PROFACI, her prescribing physicians, her healthcare providers, hospitals, pharmacists, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff GRACIA PROFACI, her prescribing physicians, hospitals, pharmacists, the public in general, and the medical community in particular, to recommend, dispense, prescribed, use 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 users of Belviq, including the Plaintiff GRACIA PROFACI.

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

pharmacists 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.

9. As a result of the acts and omissions of the Defendants, as set forth herein, the Plaintiff GRACIA PROFACI 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.

10. Plaintiff GRACIA PROFACI sustained the above health consequences due to her use of Belviq and Defendants' actions or omissions, as set forth herein, were a direct and proximate cause of her health consequences.

11. Consequently, Plaintiffs seek compensatory damages as a result of Plaintiff GRACIA PROFACI'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.

JURISDICTION AND VENUE

12. This Court has jurisdiction and venue over this action pursuant to R. 4:3-2(a) because Plaintiffs are citizens and residents of Burlington County, New Jersey, and Defendant EISAI, INC. is a citizen and resident of Bergen County, New Jersey with its principal place of business located in Woodcliff Lake, New Jersey. Venue in this Court is proper in that events or omissions giving rise to the claims asserted herein occurred in whole or in part in this County.

13. Defendants are subject to personal jurisdiction of this Court. Defendant EISAI, INC. maintains its principal place of business in Bergen County, New Jersey and each Defendant conducts substantial business in the State of New Jersey, committed torts in whole or in part in the State of New Jersey, have had systematic and continuous contacts with the State of New Jersey, specifically within this County of New Jersey, have agents and representatives which can be found in New Jersey, and/or have otherwise engaged in conduct subjecting the Defendants to the reach of the applicable long-arm statute. Defendants are amenable to service by a New Jersey court and the exercise of jurisdiction over them comports with due process.

14. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.* (hereinafter the "Products Liability Act") and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq.* (hereinafter the "Consumer Fraud Act"), among other state laws, to recover damages and other relief, and the costs of suit, including reasonable attorney and expert fees, for the damages Plaintiffs have sustained as a result of the Defendants' acts and omissions in violation of the Products Liability and Consumer Fraud Acts in excess of the jurisdictional limits of all lower courts in the State of New Jersey.

PARTY PLAINTIFFS

15. Plaintiff, GRACIA PROFACI, is a citizen of the United States of America, and is a citizen and resident of the State of New Jersey.

16. Plaintiff, GRACIA PROFACI, was born on July 15, 1964.

17. Plaintiff, GRACIA PROFACI, first began using Belviq in or about November 2018, and used Belviq up through approximately March 2019.

18. The Belviq used by Plaintiff GRACIA PROFACI was prescribed by her endocrinologist, Dr. Parveen Verma.

19. As result of using Defendants' Belviq, Plaintiff GRACIA PROFACI, was caused to suffer from breast cancer on or about July 23, 2019, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

20. The injuries and damages sustained by Plaintiff, GRACIA PROFACI, were caused by Defendants' Belviq and/or their misrepresentations relating to same.

21. Plaintiff GRACIA PROFACI is a citizen of the United States of America and is a citizen and resident of the State of New Jersey.

22. Plaintiff JOSEPH PROFACI is the lawful spouse of GRACIA PROFACI and was her lawful spouse at all relevant times.

23. Plaintiffs did not know and could not have known that the injuries they suffered were caused by Belviq until after the date Belviq was recalled from the market on February 13, 2020, and Plaintiffs came to learn of the recall.

PARTY DEFENDANTS

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

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

26. Defendant, EISAI, INC. has transacted and conducted business in the State of New Jersey.

27. Defendant, EISAI, INC. has derived substantial revenue from goods and products used in the State of New Jersey.

28. Defendant, EISAI, INC. expected or should have expected its acts to have consequence within New Jersey, and derived substantial revenue from interstate commerce within the United States, and the State of New Jersey, more particularly.

29. At all relevant times, Defendant, EISAI, INC., was in the business of and was responsible for the design, research manufacturing, testing, labeling advertising, promoting, marketing, selling, and distribution the drug Belviq for use which primary purpose is chronic weight management.

30. 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.

31. 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 distribution the drug Belviq for use which primary purpose is chronic weight management.

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

33. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., has transacted and conducted business in the State of New Jersey.

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

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

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

37. 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 distribution the drug Belviq for use which primary purpose is chronic weight management.

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

39. 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 distribution the drug Belviq for use which primary purpose is chronic weight management.

40. 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 ALLEGATIONS

A. FDA Approval of Belviq in the United States

41. 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.

42. 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.

43. 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.

44. 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]

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

46. 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.

47. 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.

48. 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.

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

50. 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.

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

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").

51. 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.

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

53. 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.

54. 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.

55. 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.

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

57. The aforementioned purchase identified in paragraph 53 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

58. 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.

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

60. 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.

61. While the two-year carcinogenicity rat study was ongoing, the FDA required bi-monthly updates from Defendants due to the consistently increased incidence of tumors and mortality that was being seen in the lorcaserin groups. However, in the final report of the study, Defendants reported that the

incidence of adenocarcinoma was lower in the mid- and high-dose groups than that previously reported at week 96, and that it had increased in the control group. The final report also revealed that the incidence of fibroadenoma had increased across all doses from week 96, with notable variations in the mid- and high-dose groups. Due to the apparent increase in fibroadenoma accompanying the decrease in adenocarcinoma after week 96, the FDA suspected that study investigators had reclassified tumor types.

62. 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.

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

64. 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 New Jersey law.

65. In addition to the two-year carcinogenicity rat study and the two-year carcinogenicity mouse study, scientific literature and publications existed that demonstrated that the serotonin pathway can cause or stimulate cancer and Defendants were aware or should have been aware of this literature before placing Belviq on the market.

66. These scientific literature and publications, the two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or a combination of the three, 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, Belviq is an unsafe product and unreasonably dangerous product under New Jersey law.

67. 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.

68. 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.

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

70. On December 18, 2009, Defendant ARENA PHARMACEUTICALS, INC. submitted its first New Drug Application for Belviq seeking to market and distribute Belviq in the United States.

71. 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.

72. 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.

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

74. 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.

75. 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.

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

77. 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.

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

79. 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, the medical literature and publications regarding the serotonin pathway and its causal link to cancer and/or all three, 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 New Jersey law.

80. On May 10, 2012, a second EMDAC panel met to discuss approval of Belviq with a focus on the PWG readjudication of preclinical data to determine the drug's potential carcinogenicity risk, to determine a safety margin for astrocytoma by looking at lorcaserin levels in human cerebrospinal fluid, and to discuss the results of the BLOOM-DM Phase 3 clinical trial to further determine efficacy. The panel voted 18 to four (4) (with one abstention) that the benefits of Belviq outweighed the risks for an overweight and obese population. The panel also recommended a post-approval assessment of risk for Belviq, with a focus on cardiovascular risk. Ultimately, the FDA required that Defendants conduct six (6) post-marketing studies, including a cardiovascular outcomes trial.

81. 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.

82. 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").

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

84. 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).

85. 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.

86. 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.

87. 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.

88. The aforementioned facts support that Belviq is not an effective drug to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

89. The aforementioned facts support that Belviq is not a safe drug to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

90. The aforementioned facts support that Belviq is associated with an increased risk of cancer.

91. The aforementioned facts support that the efficacy of Belviq is not outweighed by its safety risks, particularly its increased risk of cancer.

92. The aforementioned facts support that Belviq was not sufficiently and/or adequately tested for safety by Defendants.

93. 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.

94. 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 the New Drug Application for Belviq.

95. 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.

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

97. 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.

98. By reason of the foregoing acts and omissions, the Plaintiff GRACIA PROFACI 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.

99. Plaintiff GRACIA PROFACI 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.

100. By reason of the foregoing, Plaintiff GRACIA PROFACI 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.

COUNT I
PRODUCT LIABILITY ACT – DESIGN DEFECT
(N.J.S.A. 2A:58C-1 *et seq.*)

101. 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.

102. 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 GRACIA PROFACI.

103. At all times material to this action, Belviq was defective and unreasonably dangerous to consumers.

104. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants and was placed in the stream of commerce, it was not reasonably safe, not reasonably fit and not reasonably suitable for its intended purpose – a weight loss drug.

105. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, its foreseeable risks exceeded the benefits associated with its design and formulation.

106. At all times material to this action, given its lack of efficacy and increased safety risks Belviq, Belviq did not met the reasonable expectations of an ordinary consumer, particularly the Plaintiff GRACIA PROFACI.

107. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, it was more dangerous than an ordinary consumer would expect.

108. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, it was more dangerous than other weight loss drugs on the market

109. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, Defendants knew or should have known that the design of Belviq posed a substantial likelihood of harm (i.e. cancer) to Plaintiff and other users of Belviq.

110. At all times material to this action, Belviq was expected to reach, and did reach, consumers, handlers, and persons coming into contact with Belviq in the States of Indiana and New Jersey and throughout the United States, including the Plaintiff GRACIA PROFACI, without substantial change in the condition in which it was produced, manufactured, sold and/or distributed.

111. Belviq's defective design and/or formulation existed before it left the control of the Defendants.

112. At all times herein mentioned, Belviq was defective in design and/or formulation and Defendants knew or had reason to know that Belviq was defective in design and/or formulation, especially when used in the form and manner as provided by the Defendants.

113. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, was inherently dangerous and unsafe as it had the propensity to cause cancer.

114. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, had not been sufficiently tested for its safety risks, particularly as to its increased risk of cancer.

115. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, caused an increased risk of cancer that outweighed any potential efficacy the drug may have had.

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

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

118. Defendants had a duty to create and design a product that was not unreasonably dangerous for its normal, intended use.

119. Defendants created and designed a product unreasonably dangerous for its normal, intended use.

120. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design and formulation because there existed an economically and scientifically feasible, safer alternative design for Belviq that was capable of preventing Plaintiff GRACIA PROFACI'S injuries and damages – an alternative design that was and is in the exclusive possession, custody and control of Defendants.

121. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design and formulation because there existed an

economically and scientifically feasible, safer alternative design for Belviq, the utility of which outweighed the utility of the design that was actually used for Belviq.

122. Upon information and belief, the safer, feasible alternative design for Belviq was a pharmaceutical drug that was not a serotonin receptor agonist, but rather a pharmaceutical drug that did not affect the serotonin pathway.

123. Upon information and belief, the safer, feasible alternative design for Belviq would not have impaired the reasonably anticipated or intended function of the product.

124. Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, could not, by the exercise of reasonable care, have discovered Belviq's design defect and perceived its danger.

125. 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 GRACIA PROFACI in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff GRACIA PROFACI.

126. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiffs.

127. Defendants' defective design of Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

128. That said design defects in Defendants' drug Belviq were a substantial factor in causing Plaintiff GRACIA PROFACI'S injuries.

129. That said design defects in Defendants' drug Belviq were the direct and proximate cause of Plaintiff GRACIA PROFACI'S injuries.

130. As a direct and proximate result of the design defect, the Plaintiff GRACIA PROFACI 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.

131. As a direct and proximate result of the design defect, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PRODUCT LIABILITY ACT – FAILURE TO WARN
(N.J.S.A. 2A:58C-1 *et seq.*)

132. 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.

133. 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 GRACIA PROFACI.

134. At all relevant times, Defendants knew or should have known that Belviq created a risk of serious and dangerous side effects, particularly cancer, as well as other severe and personal injuries which are permanent and lasting in nature

135. At all relevant times, Defendants knew or should have known that they had failed to adequately and/or sufficiently test Belviq despite their clinical trials and/or other evidence demonstrating an increased risk of cancer associated with Belviq.

136. At all times material to this action, Belviq was defective and unreasonably dangerous to consumers.

137. At all times material to this action, Belviq was defective due to inadequate and/or insufficient warnings or instructions because Defendants failed to warn Plaintiff and her prescribing physician, Dr. Parveen Verma, of the of the increased risk of cancer associated with Belviq.

138. At all times material to this action, Belviq was defective due to inadequate and/or insufficient warnings or instructions because Defendants failed to warn Plaintiff and her prescribing physician, Dr. Parveen Verma, that they had failed to adequately and/or sufficiently test Belviq despite their clinical trials and/or other evidence demonstrating an increased risk of cancer associated with Belviq.

139. At all times material to this action, Belviq 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 associated with Belviq, including breast cancer, as well as other forms of cancer, they failed to provide adequate warnings to users or consumers of the product, such as Plaintiff and her prescribing physician, Dr. Parveen Verma, and continued to improperly advertise, market and/or promote Belviq.

140. The label for Belviq was inadequate because it did not warn and/or adequately warn of the increased cancer risk associated with Belviq.

141. The label for Belviq was inadequate because it did not warn and/or adequately warn that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

142. Given that Defendants knew or should have known of the increased risk of cancer associated with Belviq, the label for Belviq should have contained a warning that Belviq was associated with an increased risk of cancer.

143. Given that Defendants knew or should have known of the increased risk of cancer associated with Belviq, the label for Belviq should have contained a warning that Belviq had not been sufficiently and/or adequately tested for safety risks, particularly cancer.

144. Given that Defendants knew or should have known of the increased risk of cancer associated with Belviq, the label for Belviq should have contained a warning that given Belviq's association with cancer, the safety risks of Belviq outweighed any efficacy the drug may have had.

145. At all times material to this action, Defendants knew or should have known that Belviq created a risk of serious and dangerous side effects including breast cancer, as well as other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately or sufficiently warn of the drug's lack of testing and/or the need to conduct additional testing in light of its clinical studies demonstrating an increased risk of cancer.

146. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product without adequate warnings or instructions regarding its increased risk of cancer which created an unreasonable risk to the health of consumers and to the Plaintiff GRACIA PROFACI in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff GRACIA PROFACI.

147. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product without adequate warnings or instructions regarding its lack of adequate and sufficient testing which created an unreasonable risk to the health of consumers and to the Plaintiff GRACIA PROFACI in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff GRACIA PROFACI.

148. Defendants, as designers, manufacturers and/or distributors of Belviq, are held to the level of knowledge of an expert in the field.

149. Communications made by Defendants to Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, were inadequate and insufficient because Defendants failed to warn and/or adequately warn of the increased cancer risk associated with Belviq.

150. Communications made by Defendants to Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, were inadequate and insufficient because Defendants failed to warn and/or adequately warn that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

151. Plaintiff GRACIA PROFACI reasonably relied upon the skill, superior knowledge and judgement of the Defendants.

152. Upon information and belief, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, reasonably relied upon the skill, superior knowledge and judgement of the Defendants.

153. Defendants had a continuing duty to warn the Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, of the increased risk of cancer associated with Belviq and that its increased risk of cancer outweighed any benefits the drug may have.

154. Defendants had a continuing duty to warn the Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

155. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been warned of the increased cancer risk associated with Belviq, he would not have prescribed Belviq and/or would have provided Plaintiff GRACIA PROFACI with adequate warnings regarding the dangers of Belviq so as to allow her to make an informed decision regarding her use of Belviq.

156. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been warned that Belviq had not been sufficiently and/or adequately tested for safety risks,

including cancer, he would not have prescribed Belviq and/or would have provided Plaintiff GRACIA PROFACI with adequate warnings regarding the dangers of Belviq so as to allow her to make an informed decision regarding her use of Belviq.

157. Had Plaintiff GRACIA PROFACI been warned of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered breast cancer.

158. Had Plaintiff GRACIA PROFACI been warned that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer, she would not have used Belviq and/or suffered breast cancer.

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

160. Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, could not, by the exercise of reasonable care, have discovered Belviq's defect in its warnings and instructions and perceived its dangers.

161. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiffs.

162. Defendants' inadequate warnings with respect to Belviq were acts that amounted to willful, wanton, and/or reckless conduct by Defendants.

163. That said inadequate warnings with respect to Belviq were a substantial factor in causing Plaintiff GRACIA PROFACI'S injuries.

164. That said inadequate warnings with respect to Belviq were the direct and proximate cause of Plaintiff GRACIA PROFACI'S injuries.

165. As a direct and proximate result of the inadequate warnings defect, the Plaintiff GRACIA PROFACI 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.

166. As a direct and proximate result of the inadequate warnings defect, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

167. 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.

168. 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 GRACIA PROFACI.

169. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff GRACIA PROFACI would use, consume, or be affected by Belviq based upon their express warranties.

170. At all relevant times, Defendants reasonably anticipated and expected that physicians, such as the Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, would recommend, dispense or prescribe Belviq based upon their express warranties.

171. Defendants had a duty to use reasonable care in the research, development, design, testing, manufacturing, labeling distribution, marketing, promotion and/or sale of Belviq, including duties to ensure

that the product did not cause the user to suffer unreasonably dangerous side effects such as cancer, to warn of dangerous side effects and/or complications, such as cancer; and to disclose such adverse material facts when making representations and warranties to consumers and physicians.

172. At all relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff GRACIA PROFACI, and physicians such as the Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, without adequately warning them of the increased cancer risk associated with the use of Belviq.

173. All relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff GRACIA PROFACI, and physicians such as the Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, without adequately warning them that Belviq had not been adequately or sufficiently tested for safety risks, including the increased risk of cancer.

174. At all relevant times, Defendants expressly warranted to Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, 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).

175. At all relevant times, Defendants expressly warranted to Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, 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 BMI.

176. At all relevant times, Defendants expressly warranted to Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, that the effectiveness of Belviq outweighed any potential dangers and/or risks.

177. At all relevant times, Defendants expressly warranted to Plaintiff GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, and the medical community that any and all side effects Belviq did produce were accurately reflected in the warnings and instructions.

178. At all relevant times, Defendants expressly warranted to Plaintiff GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, and the medical community that Belviq had been adequately and sufficiently tested.

179. The aforementioned express warranties were made to Plaintiff GRACIA PROFACI by way of Belviq's product information sheet.

180. Upon information and belief, the aforementioned express warranties were made to Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, by way of Belviq's label.

181. In or about November 2018, Plaintiff GRACIA PROFACI presented to the office of her endocrinologist, Dr. Parveen Verma.

182. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed the drug Belviq with Plaintiff GRACIA PROFACI as well as other weight loss drugs on the market.

183. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed and compared with Plaintiff GRACIA PROFACI the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

184. At this visit, in or about November 2018, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, recommended Belviq as a safe and effective drug to use for weight loss, particularly when compared to other weight loss drugs on the market, and prescribed it to her.

185. Upon information and belief, Dr. Parveen Verma obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

186. Upon information and belief, Dr. Parveen Verma, obtained the information regarding the efficacy and side effects of Belviq from communications with Defendants' sale representatives.

187. Upon information and belief, Defendants expressly warranted to Dr. Parveen Verma, by way of the product's label, that Belviq was an effective drug to use for weight loss.

188. Upon information and belief, Defendants expressly warranted to Dr. Parveen Verma, by way of the product's label, that Belviq was a safe drug to use for weight loss.

189. Upon information and belief, Defendants expressly warranted to Dr. Parveen Verma, by way of communications with their sales representatives, that Belviq was an effective drug to use for weight loss.

190. Upon information and belief, Defendants expressly warranted to Dr. Parveen Verma, by way of communications with their sales representatives, that Belviq was a safe drug to use for weight loss.

191. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's product information sheet, that Belviq was an effective drug to use for weight loss.

192. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's product information sheet, that Belviq was a safe drug to use for weight loss.

193. As a result of Defendants' express warranties to her and Dr. Parveen Verma, Dr. Parveen Verma was induced to prescribe Belviq to Plaintiff GRACIA PROFACI, and Plaintiff GRACIA PROFACI was induced to use Belviq from November 2018 through March 2019.

194. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff GRACIA PROFACI, would use and/or consume Belviq based upon their express warranties.

195. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because of its increased risk of cancer, especially when the drug was used in the form and manner as provided by Defendants.

196. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because its warnings and instructions did not accurately reflect any and all side effects caused by Belviq, particularly cancer.

197. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because they had failed to adequately and sufficiently test Belviq regarding its propensity to cause cancer.

198. At all relevant times, Defendants knew or should have known 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 BMI.

199. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because its safety risk outweighed any efficacy the drug may have.

200. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff GRACIA PROFACI, with the ordinary knowledge common to the community as to the drug's characteristics.

201. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, with the ordinary knowledge common to the community as to the drug's characteristics.

202. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because Belviq was not safe to use as an adjunct to a reduced-calorie diet and increased

physical activity for chronic weight management in adults with certain initial BMI, in that it was associated with an increased risk of cancer.

203. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because its warnings and instructions did not accurately reflect any and all side effects caused by Belviq, particularly cancer.

204. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because they had failed to adequately or sufficiently test Belviq regarding its propensity to cause cancer.

205. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because Belviq was ineffective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

206. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because the effectiveness of Belviq does not outweigh any the dangers and/or risks associated with the drug.

207. The express warranties made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff GRACIA PROFACI to use the product and/or her prescribing physician, Dr. Parveen Verma, to prescribe the product.

208. Defendants knew and/or should have known that by making the express warranties to Plaintiff GRACIA PROFACI and/or her prescribing physician, Dr. Parveen Verma, it would be the natural tendency of Plaintiff to use Belviq and/or her prescribing physician, Dr. Parveen Verma, to prescribe Belviq.

209. Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, as well as members of the medical community, justifiably and detrimentally relied on the express warranties of the Defendants identified herein.

210. The express warranties made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff GRACIA PROFACI to use the product and/or her prescribing physician, Dr. Parveen Verma, to prescribe the product.

211. Had Defendants not made these express warranties, Plaintiff GRACIA PROFACI would not have used the product and/or, upon information and belief, her prescribing physician, Dr. Parveen Verma, would not have prescribed the product.

212. Plaintiff GRACIA PROFACI had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.

213. Upon information and belief, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.

214. Plaintiff GRACIA PROFACI's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

215. Plaintiff GRACIA PROFACI'S injuries and damages arose from a reasonably anticipated use of the product by Plaintiff GRACIA PROFACI.

216. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff GRACIA PROFACI.

217. As a direct and proximate result of the foregoing breach, the Plaintiff GRACIA PROFACI 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.

218. As a direct and proximate result of the foregoing breach, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental and related expenses.

WHEREFORE, Plaintiffs demands judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT
(N.J.S.A. 56:8-1 *et seq.*)

219. 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.

220. The subject product is considered "merchandise" as that term is defined by N.J.S.A. 56:8-1(c).

221. Defendants are designers, researchers, testers manufacturers, promoters, marketers, developers, sellers and/or distributors of Belviq.

222. Defendants knew, or should have known, that Belviq was unreasonably dangerous and defective in that it had a propensity to cause cancer, that it was not effective as a weight loss adjunct and/or that its safety risks outweighed any purported benefits the drug may have had.

223. Notwithstanding the foregoing, the Defendants omitted material facts in the disclosures it made to consumers, including the Plaintiff GRACIA PROFACI, the medical community, including Plaintiff GRACIA PROFACI's prescribing physician, the FDA and the public concerning the use and safety of Belviq.

224. Defendants falsely and fraudulently represented to consumers, including the Plaintiff GRACIA PROFACI, the medical community, including Plaintiff GRACIA PROFACI's prescribing

physician, the FDA and the public, that Belviq had been tested and was found to be safe and/or effective for chronic weight management.

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

226. These representations and omissions were made by Defendants with the intent of defrauding and deceiving the Plaintiff GRACIA PROFACI, her prescribing physician, the medical and healthcare community and the public in general, and were made with the intent of inducing the Plaintiff GRACIA PROFACI, her prescribing physician, the medical and healthcare community and the public in general to use, recommend, prescribe, dispense, and/or purchase 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 GRACIA PROFACI.

227. Defendants' representations and omissions were made with the intent that Plaintiff GRACIA PROFACI and her prescribing physician would rely upon such representations and omissions.

228. At the time the aforesaid representations and omissions were made by the Defendants and, at the time the Plaintiff GRACIA PROFACI used Belviq, the Plaintiff and her prescribing physician were unaware of the falsity of said representations and reasonably believed them to be true.

229. In reliance upon said representations and omissions, the Plaintiff GRACIA PROFACI was induced to and did use Belviq and/or her prescribing physician were induced to and did prescribe Belviq, thereby causing Plaintiff GRACIA PROFACI to sustain severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

230. Defendants have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1, *et seq.*) in that they made untrue, deceptive and/or misleading representations of material facts and omitted and/or

concealed material facts from the public, including the Plaintiffs herein, concerning the use and safety of Belviq.

231. Defendants' practice of promoting Belviq created and/or reinforced a false impression as to its safety and efficacy.

232. Defendants' practice of promoting Belviq placed all consumers of Belviq, including the Plaintiff GRACIA PROFACI, at risk for serious and potentially lethal side effects (i.e. cancer).

233. Defendants brought Belviq to the market, and acted fraudulently, wantonly, and maliciously to the detriment of the Plaintiffs.

234. Defendants have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*), in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiffs herein, concerning the use and safety of the subject product.

235. The aforesaid promotion, statements and/or omissions concerning Belviq by the Defendants constitute an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq.*

236. Plaintiff GRACIA PROFACI purchased and used the subject product for personal, family, or household purposes and suffered ascertainable losses of money and personal injury as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

237. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff GRACIA PROFACI 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.

238. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

239. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff GRACIA PROFACI has suffered ascertainable loss – economic loss that includes the purchases of the subject product and additional out-of-pocket healthcare related costs – for which the Defendants are liable to the Plaintiffs for treble her actual damages.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
FRAUDULENT MISREPRESENTATION AND CONCEALMENT

240. 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.

241. Prior to 2018 and through 2019, Defendants knew or should have known that Belviq was not effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

242. Nevertheless, in 2018 and through 2019, Defendants falsely represented on Belviq's label, product information sheet and/or through their sales representatives 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 BMI.

243. Prior to 2018 and through 2019, Defendants knew or should have known that Belviq was not safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI given its increased risk of cancer.

244. Nevertheless, in 2018 and through 2019, Defendants falsely represented on Belviq's label, product information sheet and/or through their sales representatives 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 BMI and concealed that Belviq was associated with an increased risk of cancer.

245. Prior to in 2018 and through 2019, Defendants knew or should have known that the effectiveness of Belviq, if any, did not outweigh the dangers and risks associated with Belviq.

246. Nevertheless, in 2018 and through 2019, Defendants falsely represented on Belviq's label, product information sheet and/or through their sales representatives that the effectiveness of Belviq outweighed the dangers and risks associated with Belviq.

247. Prior to 2018 and through 2019, Defendants knew or should have known that Belviq had not been adequately and/or sufficiently tested for safety.

248. Nevertheless, in 2018 and through 2019, Defendants falsely represented on Belviq's label, product information sheet and/or through their sales representatives 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 BMI and concealed that Belviq had not been adequately and/or sufficiently tested for safety.

249. Defendants' fraudulent representations and/or concealments as identified herein were done with the intent of defrauding and deceiving consumers, including the Plaintiff GRACIA PROFACI, and her prescribing physician, Dr. Parveen Verma, the public in general, and the medical and healthcare community in particular, which evinced a callous, reckless, willful, depraved indifference to the health, safety, and welfare of the Plaintiff GRACIA PROFACI.

250. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing consumers, including the Plaintiff GRACIA PROFACI, into using Belviq for chronic weight management, which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff GRACIA PROFACI.

251. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing prescribing physicians, including the Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, to recommend, dispense and/or prescribe Belviq for chronic weight management, which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff GRACIA PROFACI.

252. In or about November 2018, Plaintiff GRACIA PROFACI presented to the office of her endocrinologist, Dr. Parveen Verma.

253. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed the drug Belviq with Plaintiff GRACIA PROFACI as well as other weight loss drugs on the market.

254. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed and compared with Plaintiff GRACIA PROFACI the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

255. At this visit, in or about November 2018, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, recommended Belviq as a safe and effective drug to use for weight loss, particularly when compared to other weight loss drugs on the market, and prescribed it to her.

256. Upon information and belief, Dr. Parveen Verma obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

257. Upon information and belief, Dr. Parveen Verma, obtained the information regarding the efficacy and side effects of Belviq from communications with Defendants' sale representatives.

258. Upon information and belief, Defendants represented to Dr. Parveen Verma, by way of the product's label, that Belviq was an effective drug to use for weight loss.

259. Upon information and belief, Defendants represented to Dr. Parveen Verma, by way of the product's label, that Belviq was a safe drug to use for weight loss.

260. Upon information and belief, Defendants concealed from Dr. Parveen Verma by way of the product's label that Belviq was associated with an increased risk of cancer.

261. Upon information and belief, Defendants concealed from Dr. Parveen Verma by way of the product's label that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.

262. Upon information and belief, Defendants represented to Dr. Parveen Verma, by way of communications with their sales representatives, that Belviq was an effective drug to use for weight loss.

263. Upon information and belief, Defendants represented to Dr. Parveen Verma, by way of communications with their sales representatives, that Belviq was a safe drug to use for weight loss.

264. Upon information and belief, Defendants concealed from Dr. Parveen Verma by way of their sales representatives that Belviq was associated with an increased risk of cancer.

265. Upon information and belief, Defendants concealed from Dr. Parveen Verma by way of their sales representatives that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.

266. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's product information sheet, that Belviq was an effective drug to use for weight loss.

267. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's product information sheet, that Belviq was a safe drug to use for weight loss.

268. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of Belviq's product information sheet that Belviq was associated with an increased risk of cancer.

269. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of Belviq's product information sheet that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.

270. The aforementioned representations made in the product information sheet for Belviq in or about November 2018 through 2019 were false in that Belviq is not an effective drug to use for weight loss.

271. The aforementioned representations made in the product information sheet for Belviq in or about November 2018 through 2019 were fraudulently made in that that Defendants concealed that Belviq was associated with an increased risk of cancer despite their knowledge to the contrary.

272. The aforementioned representations made in the product information sheet for Belviq in or about November 2018 through 2019 were fraudulently made in that that Defendants concealed that Belviq had not been adequately and/or sufficiently tested for safety, including cancer.

273. Upon information and belief, as a result of the label for Belviq in or about November 2018, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff's prescribing physician, Dr. Parveen Verma, was induced to and did prescribe Belviq to Plaintiff GRACIA PROFACI from November 2018 through February 2019.

274. Upon information and belief, as a result of communications made by Defendants' sales representatives regarding Belviq prior to November 2018, and particularly as a result of Defendants'

fraudulent misrepresentation and concealments contained therein, Plaintiff's prescribing physician, Dr. Parveen Verma, was induced to and did prescribe Belviq to Plaintiff GRACIA PROFACI from November 2018 through February 2019.

275. As a result of the product information sheet for Belviq in or about November 2018, particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff GRACIA PROFACI was induced to and did use Belviq from in or about November 2018 through March 2019.

276. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been told of the increased cancer risk associated with Belviq, he would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

277. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been told of the lack of efficacy associated with Belviq, he would not have prescribed Belviq and/or would have provided Plaintiff with adequate information regarding the efficacy of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

278. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been told that the benefits of Belviq, if any, were outweighed by its safety risks, particularly cancer, he would not have prescribed Belviq and/or would have provided Plaintiff with adequate information regarding the efficacy and safety of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

279. Upon information and belief, had Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, been told that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer, he would not have prescribed Belviq and/or would have provided Plaintiff with adequate

warnings regarding the lack of sufficient and/or adequate testing of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

280. Had Plaintiff been told of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered breast cancer.

281. Had Plaintiff been told of the lack of efficacy associated with Belviq, she would not have used Belviq and/or suffered breast cancer.

282. Had Plaintiff been told that the benefits of Belviq, if any, were outweighed by its safety risks, particularly cancer, she would not have used Belviq and/or suffered breast cancer.

283. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Belviq for safety risks, including cancer, she would not have used Belviq and/or suffered breast cancer.

284. Plaintiff GRACIA PROFACI had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.

285. Upon information and belief, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.

286. Defendants had sole access to material facts concerning the ineffective nature of Belviq.

287. Defendants had sole access to material facts concerning the defective nature of Belviq, and, particularly, its increased risk of cancer.

288. Defendants had sole access to material facts concerning the lack of adequate and appropriate testing regarding the safety of Belviq.

289. At all relevant times, Defendants were under a duty to disclose to Plaintiff, GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, hospitals, and/or healthcare providers the defective nature of Belviq, including but not limited to the heightened risk of cancer.

290. At all relevant times, Defendants were under a duty to disclose to Plaintiff, GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, hospitals, and/or healthcare providers information regarding the ineffectiveness of Belviq.

291. At all relevant times, Defendants were under a duty to disclose to Plaintiff, GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, hospitals, and/or healthcare providers that the risks of Belviq outweighed any effectiveness it may have.

292. At all relevant times, Defendants were under a duty to disclose to Plaintiff, GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, hospitals, and/or healthcare providers that Belviq had not been adequately and/or sufficiently tested.

293. Defendants breached their duties to disclose Belviq's serious safety risks and lack of efficacy to Plaintiff GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, the medical and healthcare community, the FDA and the public in general.

294. Defendants could have and should have revealed the truth behind the safety and lack of efficacy of Belviq through various outlets, including the label and product information sheet for Belviq.

295. Defendants' misrepresentations and concealments concerning the safety and lack of efficacy of Belviq were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, 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.

296. Defendants knew that Plaintiff GRACIA PROFACI and her prescribing physician, Dr. Parveen Verma, had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Belviq, as set forth herein.

297. Plaintiff GRACIA PROFACI's injury and damages were proximately caused by Defendants' fraudulent misrepresentations and concealments as set forth herein.

298. Plaintiff GRACIA PROFACI's injury and damages were proximately caused by her reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

299. Plaintiff GRACIA PROFACI's injury and damages were proximately caused by her prescribing physician's reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

300. At all relevant times, Defendants knew or should have known that Belviq was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

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

302. As a direct and proximate result of Defendants foregoing misrepresentations and concealments, the Plaintiff GRACIA PROFACI 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.

303. As a direct and proximate result of Defendants foregoing misrepresentations and concealments, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISPRESENTATION

304. 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.

305. Defendants had a duty to make honest and accurate representations to the Plaintiff, her prescribing physician, Dr. Parveen Verma, the medical and healthcare community, the FDA and the public in general regarding the safety and efficacy of Belviq.

306. At all relevant times, Defendants represented to Plaintiff GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, and the medical community 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 BMI in that it did not cause an increased risk of cancer.

307. At all relevant times, Defendants represented to Plaintiff GRACIA PROFACI, her prescribing physician, Dr. Parveen Verma, and the medical community 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 BMI.

308. The aforementioned representations made by Defendants were, in fact, false because Belviq was not safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI given its increased risk of cancer.

309. The aforementioned representations made by Defendants were, in fact, false because Belviq is not an effective an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

310. When said representations were made by Defendants, they knew or should have known those representations to be false.

311. The representations made by Defendants were made to Plaintiff GRACIA PROFACI between November 2018 and March 2019 through the product information sheet for Belviq.

312. As a result of Defendants' representations between November 2018 and March 2019 on the product information sheet for Belviq, Plaintiff GRACIA PROFACI was induced to use Belviq.

313. Upon information and belief, as a result of Defendants' representations before November 2018 and through 2019 on the label of Belviq and through their sales representatives, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, was induced to prescribe, dispense and/or recommend Belviq to Plaintiff GRACIA PROFACI.

314. In or about November 2018, Plaintiff GRACIA PROFACI presented to the office of her prescribing physician, Dr. Parveen Verma, and they discussed her options for weight loss.

315. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed the drug Belviq with Plaintiff GRACIA PROFACI as well as other weight loss drugs on the market.

316. At this visit with Dr. Parveen Verma, in or about November 2018, Dr. Parveen Verma discussed and compared with Plaintiff GRACIA PROFACI the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

317. At this visit, in or about November 2018, Plaintiff GRACIA PROFACI's prescribing physician, Dr. Parveen Verma, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to her.

318. Upon information and belief, Dr. Parveen Verma, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

319. Upon information and belief, Dr. Parveen Verma, obtained the information regarding the efficacy and side effects of Belviq from their communications with Defendants' sales representatives relating to Belviq.

320. Upon information and belief, Defendants represented to Dr. Parveen Verma by way of the product's label that Belviq was an effective drug to use for weight loss.

321. Upon information and belief, Defendants represented to Dr. Parveen Verma by way of the product's label that Belviq was a safe drug to use for weight loss in that it was not associated with an increased risk of cancer.

322. Upon information and belief, Defendants represented to Dr. Parveen Verma by way of the product's label that Belviq was an effective drug to use for weight loss.

323. Upon information and belief, Defendants represented to Dr. Parveen Verma by way of their sales representatives that Belviq was a safe drug to use for weight loss in that it was not associated with an increased risk of cancer.

324. Upon information and belief, Defendants represented to Dr. Parveen Verma by way of their sales representatives that Belviq was an effective drug to use for weight loss.

325. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants represented to her by way of Belviq's product information sheet that Belviq was an effective drug to use for weight loss.

326. In or about November 2018, when Plaintiff GRACIA PROFACI began using Belviq and throughout her use of Belviq, Defendants represented to her by way of Belviq's product information sheet that Belviq was a safe drug to use for weight loss in that it was not associated with an increased risk of cancer.

327. When the aforementioned representations were made, Defendants were aware or should have been aware that their representations would induce Plaintiff GRACIA PROFACI and/or her prescribing physician, Dr. Parveen Verma, to use and/or prescribe Belviq.

328. When the representations were made, Defendants were aware or should have been aware that Belviq was to be used by Plaintiff GRACIA PROFACI and/or prescribed by Plaintiff's prescribing physician, Dr. Parveen Verma, in reliance upon their representations regarding the safety and efficacy of Belviq.

329. At the time the aforesaid representations were made by the Defendants and at the time Plaintiff GRACIA PROFACI used Belviq and her prescribing physician, Dr. Parveen Verma, prescribed Belviq to her, Plaintiff GRACIA PROFACI was unaware of the falsity of said representations and reasonably believed them to be true.

330. Upon information and belief, at the time the aforesaid representations were made by the Defendants and at the time Plaintiff GRACIA PROFACI used Belviq and her prescribing physician, Dr. Parveen Verma, prescribed Belviq to her, Plaintiff's prescribing physician, Dr. Parveen Verma, was unaware of the falsity of said representations and reasonably believed them to be true.

331. In reasonable and foreseeable reliance upon said representations, the Plaintiff GRACIA PROFACI was induced to and did use Belviq.

332. Upon information and belief, in reasonable and foreseeable reliance upon said representations, the Plaintiff's prescribing physician, Dr. Parveen Verma, was induced to and did prescribe Belviq.

333. Defendants failed to exercise ordinary care regarding their representations relating to the safety and efficacy of Belviq, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Defendants negligently misrepresented Belviq's safety, efficacy and/or the weighing of risk between the two.

334. Defendants breached their duty by misrepresenting Belviq's serious safety risks and efficacy to Plaintiff GRACIA PROFACI, her prescribing physician, the medical and healthcare community, the FDA and the public in general.

335. Upon information and belief, had Plaintiff's prescribing physician, Dr. Parveen Verma, known these representations regarding the safety and efficacy of Belviq to be false, he would not have prescribed Belviq to Plaintiff GRACIA PROFACI.

336. Had Plaintiff known these representations regarding the safety and efficacy of Belviq to be false, she would not have used Belviq.

337. Defendants' negligent misrepresentations proximately caused Plaintiffs' injuries and damages as alleged herein.

338. As a direct and proximate result of Defendants' foregoing misrepresentations, the Plaintiff GRACIA PROFACI 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.

339. As a direct and proximate result of Defendants' foregoing misrepresentations, the Plaintiff GRACIA PROFACI did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
LOSS OF CONSORTIUM

340. 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.

341. Plaintiff, JOSEPH PROFACI was, at all relevant times, and is the lawful spouse of Plaintiff GRACIA PROFACI, and as such, was and is entitled to the comfort, enjoyment, society, and services of his spouse.

342. As a direct and proximate result of the foregoing, Plaintiff JOSEPH PROFACI was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff GRACIA PROFACI, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured.

343. Plaintiff JOSEPH PROFACI's injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
PUNITIVE DAMAGES UNDER COMMON LAW, PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq.*) and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*)

344. 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.

345. At all times material hereto, Defendants' design, testing, manufacturing, marketing, promotion, distribution and sale of a defective product, and their failure to provide adequate warnings and instructions concerning its hazards were willful, wanton, reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiff GRACIA PROFACI and her prescribing physician, by making false representations about the safety of Belviq. Defendants downplayed, understated and/or disregarded their knowledge of the serious and

permanent side effects and risks associated with the use of Belviq despite available information demonstrating that Belviq was likely to cause serious and potentially fatal side effects to users.

346. At all times material hereto, Defendants knew of the defective nature of their Belviq product, and continued to design, manufacture, market, label, and sell Belviq so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by the product, including Plaintiff GRACIA PROFACI who did suffer such harm.

347. Defendants misled regulators, the medical community and the public at large, including Plaintiff and her prescribing physicians, by making false and misleading representations about the safety of Belviq. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiff GRACIA PROFACI.

348. Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff GRACIA PROFACI and her prescribing physician of necessary information to enable her to weigh the true risks of using Belviq against its benefits.

349. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

350. As a result of the foregoing acts and omissions, the Plaintiffs requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiffs will in the future be required to obtain further medical and/or hospital care, attention, and services.

351. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiffs demand judgment against each of the Defendants individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

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 Plaintiffs, 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.

Dated: July 19, 2021

DOUGLAS & LONDON, P.C.

By: */s/ Michael A. London*
MICHAEL A. LONDON (ML-7510)
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59 Maiden Lane, 6th Floor
New York, NY 10038
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Email: mlondon@douglasandlondon.com
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Dated: July 15, 2021

Respectfully submitted,

DOUGLAS & LONDON, P.C.

By: */s/ Michael A. London*
Michael A. London
Bar ID #: 048501997
59 Maiden Lane, 6th Floor
New York, New York 10038
Telephone: (212) 566-7500
Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO R. 4:5-1

The undersigned attorney for Plaintiffs certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;

2. No other action or arbitration proceeding is contemplated; and

3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of this action that should be joined pursuant to R. 4:28.

I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: July 15, 2021

Respectfully submitted,

DOUGLAS & LONDON, P.C.

By: */s/ Michael A. London*
Michael A. London
Bar ID #: 048501997
59 Maiden Lane, 6th Floor
New York, New York 10038
Telephone: (212) 566-7500
Attorneys for Plaintiffs

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, Michael A. London, is hereby designated as trial counsel for Plaintiffs in this action

Dated: July 15, 2021

Respectfully submitted,

DOUGLAS & LONDON, P.C.

By: */s/ Michael A. London*
Michael A. London
Bar ID #: 048501997
59 Maiden Lane, 6th Floor
New York, New York 10038
Telephone: (212) 566-7500
Attorneys for Plaintiffs

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiffs are mailing a copy of this Complaint and Jury Demand to the Office of the Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the filing of this Amended Complaint and Jury Demand.

Dated: July 15, 2021

Respectfully submitted,

DOUGLAS & LONDON, P.C.

By: */s/ Michael A. London*
Michael A. London
Bar ID #: 048501997
59 Maiden Lane, 6th Floor
New York, New York 10038
Telephone: (212) 566-7500
Attorneys for Plaintiffs

Civil Case Information Statement
(CIS)

Use for initial Law Division
Civil Part pleadings (not motions) under *Rule* 4:5-1
Pleading will be rejected for filing, under *Rule* 1:5-6(c), if information above the black bar is not completed or attorney's signature is not affixed

For Use by Clerk's Office Only
Payment type: ☐ ck ☐ cg ☐ ca
Chg/Ck Number:
Amount:
Overpayment:
Batch Number:

Attorney/Pro Se Name	Telephone Number	County of Venue
Michael A. London	(212) 566-7500	Bergen

Firm Name (if applicable)	Docket Number (when available)
Douglas & London, P.C.	

Office Address	Document Type
59 Maiden Lane, 6th Floor New York, NY 10038	Complaint and Jury Demand
	Jury Demand ☐ Yes ☐ No

Name of Party (e.g., John Doe, Plaintiff)	Caption
Gracia Profaci and Joseph Profaci	Profaci v. Eisai, Inc., et al.

Case Type Number (See reverse side for listing)	Are sexual abuse claims alleged?	Is this a professional malpractice case?
606	☐ Yes ■ No	☐ Yes ■ No If you have checked "Yes," see *N.J.S.A.* 2A:53A-27 and applicable case law regarding your obligation to file an affidavit of merit.

Related Cases Pending?	If "Yes," list docket numbers
■ Yes ☐ No	BER-L-004420-20; BER-L-007357-20

Do you anticipate adding any parties (arising out of same transaction or occurrence)?	Name of defendant's primary insurance company (if known)
☐ Yes ■ No	☐ None ■ Unknown

The Information Provided on This Form Cannot be Introduced into Evidence.

Case Characteristics for Purposes of Determining if Case is Appropriate for Mediation

Do parties have a current, past or recurrent relationship?	If "Yes," is that relationship:
☐ Yes ■ No	☐ Employer/Employee ☐ Friend/Neighbor ☐ Other (explain) ☐ Familial ☐ Business

Does the statute governing this case provide for payment of fees by the losing party? ■ Yes ☐ No

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition

Do you or your client need any disability accommodations?	If yes, please identify the requested accommodation:
☐ Yes ■ No	
Will an interpreter be needed?	If yes, for what language?
☐ Yes ■ No	

I certify that confidential personal identifiers have been redacted from documents now submitted to the court and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b).

Attorney Signature:

Side 2

Civil Case Information Statement
(CIS)

Use for initial pleadings (not motions) under *Rule* 4:5-1

CASE TYPES (Choose one and enter number of case type in appropriate space on the reverse side.)

Track I - 150 days discovery

151	Name Change
175	Forfeiture
302	Tenancy
399	Real Property (other than Tenancy, Contract, Condemnation, Complex Commercial or Construction)
502	Book Account (debt collection matters only)
505	Other Insurance Claim (including declaratory judgment actions)
506	PIP Coverage
510	UM or UIM Claim (coverage issues only)
511	Action on Negotiable Instrument
512	Lemon Law
801	Summary Action
802	Open Public Records Act (summary action)
999	Other (briefly describe nature of action)

Track II - 300 days discovery

305	Construction
509	Employment (other than Conscientious Employees Protection Act (CEPA) or Law Against Discrimination (LAD))
599	Contract/Commercial Transaction
603N	Auto Negligence – Personal Injury (non-verbal threshold)
603Y	Auto Negligence – Personal Injury (verbal threshold)
605	Personal Injury
610	Auto Negligence – Property Damage
621	UM or UIM Claim (includes bodily injury)
699	Tort – Other

Track III - 450 days discovery

005	Civil Rights
301	Condemnation
602	Assault and Battery
604	Medical Malpractice
606	Product Liability
607	Professional Malpractice
608	Toxic Tort
609	Defamation
616	Whistleblower / Conscientious Employee Protection Act (CEPA) Cases
617	Inverse Condemnation
618	Law Against Discrimination (LAD) Cases

Track IV - Active Case Management by Individual Judge / 450 days discovery

156	Environmental/Environmental Coverage Litigation
303	Mt. Laurel
508	Complex Commercial
513	Complex Construction
514	Insurance Fraud
620	False Claims Act
701	Actions in Lieu of Prerogative Writs

Multicounty Litigation (Track IV)

271	Accutane/Isotretinoin
274	Risperdal/Seroquel/Zyprexa
281	Bristol-Myers Squibb Environmental
282	Fosamax
285	Stryker Trident Hip Implants
286	Levaquin
289	Reglan
291	Pelvic Mesh/Gynecare
292	Pelvic Mesh/Bard
293	DePuy ASR Hip Implant Litigation
295	AlloDerm Regenerative Tissue Matrix
296	Stryker Rejuvenate/ABG II Modular Hip Stem Components
297	Mirena Contraceptive Device
299	Olmesartan Medoxomil Medications/Benicar
300	Talc-Based Body Powders
601	Asbestos
623	Propecia
624	Stryker LFIT CoCr V40 Femoral Heads
625	Firefighter Hearing Loss Litigation
626	Abilify
627	Physiomesh Flexible Composite Mesh
628	Taxotere/Docetaxel
629	Zostavax
630	Proceed Mesh/Patch
631	Proton-Pump Inhibitors
632	HealthPlus Surgery Center
633	Prolene Hernia System Mesh

If you believe this case requires a track other than that provided above, please indicate the reason on Side 1, in the space under "Case Characteristics.

Please check off each applicable category ☐ **Putative Class Action** ☐ **Title 59** ☐ **Consumer Fraud**

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-004782-21

Case Caption: PROFACI GRACIA VS EISAI, INC.
Case Initiation Date: 07/19/2021
Attorney Name: MICHAEL ANDREW LONDON
Firm Name: DOUGLAS & LONDON
Address: 59 MAIDEN LANE 6TH FLOOR
NEW YORK NY 10038
Phone: 2125667500
Name of Party: PLAINTIFF : Profaci, Gracia
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: 00735720 00442020
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Are sexual abuse claims alleged by: Gracia Profaci? NO

Are sexual abuse claims alleged by: Joseph Profaci? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** YES

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

07/19/2021
Dated

/s/ MICHAEL ANDREW LONDON
Signed