UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

REBECCA G. GOLDSTEIN,

Plaintiff,

v.

EISAI, INC., and ARENA PHARMACEUTICALS, INC.,

Defendants.

CASE NUMBER:

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, by their attorneys, **LEVIN, PAPANTONIO, RAFFERTY, PROCTOR, BUCHANAN, O'BRIEN, BARR & MOUGEY, P.A.** on behalf of themselves individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

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

NATURE OF THE CASE

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

3. Defendants, EISAI, INC., 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 and/or was not effective for its indicated use.

5. When warning of the safety and risks of Belviq, Defendants negligently misrepresented and/or fraudulently represented to Plaintiff, prescribing physicians, 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 defects from the Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, hospitals, pharmacists, the medical and healthcare community, the FDA, and/or the public in general.

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

8. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Belviq during clinical trials, forcing Plaintiff REBECCA G. GOLDSTEIN, and her prescribing physician, hospitals, and/or the FDA to rely on safety information that applies to other

chronic weight management treatments, which does not entirely and/or necessarily apply to Belviq whatsoever.

9. As a result of the foregoing acts and omissions of Defendants, the Plaintiff REBECCA G. GOLDSTEIN was and still is caused to suffer serious and dangerous side effects including, inter alia, colon 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 REBECCA G. GOLDSTEIN has sustained the above health consequences due to her use of Belviq and Defendants' actions or omissions were a direct and proximate cause of her health consequences.

11. Consequently, Plaintiff seek compensatory damages as a result of Plaintiff REBECCA G. GOLDSTEIN's use of Belviq, which has caused her to suffer from colon cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

12. Plaintiff, REBECCA G. GOLDSTEIN, is a citizen of the United States of America, and is a citizen of the State of New York.

13. Plaintiff, REBECCA G. GOLDSTEIN, was born on November 19, 1954.

14. Plaintiff, REBECCA G. GOLDSTEIN, first began using Belviq in or about January 2015, and used Belviq up through approximately November 2016.

15. The Belviq that was used by Plaintiff, REBECCA G. GOLDSTEIN was prescribed by Dr. Barbara Mandell.

16. As result of using Defendants' Belviq, Plaintiff REBECCA G. GOLDSTEIN, was caused to suffer from colon cancer on or about October 2019 and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

17. The injuries and damages sustained by Plaintiff, REBECCA G. GOLDSTEIN, were caused by Defendants' Belviq.

PARTY DEFENDANTS

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

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

20. Upon information and belief, Defendant, EISAI, INC., has transacted and conducted business in the State of New York.

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

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

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

24. 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.

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

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

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

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

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

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

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

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

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

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

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

FACTUAL BACKGROUND

A. FDA Approval of Belviq in the United States

35. 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.

36. 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.

37. 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.

38. 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]

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

40. 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.

41. 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.

42. 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.

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

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

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

45. 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.

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

47. 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.

48. 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.

49. 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.

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

51. 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

52. 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.

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

54. 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 breast 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.

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

56. 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.

57. In addition to the two-year carcinogenicity rat study, during the preclinical trial program, Defendants also conducted a two-year carcinogenicity study in mice (hereinafter referred to as the "two-year carcinogenicity mouse study"), which demonstrated an increase in malignant hepatocellular carcinoma in males and schwannoma in females. Although the dosing levels were

below the clinical dose, these findings provide context and support for the potential carcinogenicity of lorcaserin, particularly in combination with the results of the two-year carcinogenicity rat study.

58. 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 York law.

59. 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.

60. 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.

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

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

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

64. 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.

65. 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.

66. 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.

67. 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.

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

69. 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.

70. As to the PWG re-adjudication, for adenocarcinoma, the number decreased to a larger extent in the lorcaserin group compared to the control group, but lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma, and the high-dose lorcaserin group maintained a statistically significant increase in adenocarcinomas

compared to the control group. Regarding fibroadenoma, there was an increase in the incidence, tumor onset and multiplicity, and lethality across all lorcaserin dose groups compared to the control group; yet despite their relevance, these results were disregarded as irrelevant to risk of carcinoma in the FDA's review of the re-adjudication data.

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

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

73. 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.

74. 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").

75. In reviewing the data submitted by Defendants, the EMA Committee for Medicinal Products for Human Use (hereinafter referred to as "CHMP") determined that Belviq was not approvable due to major objections regarding its carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG 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 found that the increased occurrence of several tumor types in male rats was particularly concerning due to the lack of any persuasive mechanism of action that would provide assurance of safety in human use, which also undermined any discussion on exposure margins. Thus, the CHMP concluded that the

clinical relevance of the tumors found in the two-year carcinogenicity rat study must be evaluated as part of the risk-benefit assessment.

76. 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).

77. 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 non-inferiority. 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.

78. 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.

79. 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.

80. 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.

81. 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.

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

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

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

85. 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.

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

87. From the date Defendants received FDA approval to market Belviq, Defendants made, distributed, marketed, and/or sold Belviq without adequate warning to Plaintiff's prescribing physician and/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.

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

89. 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.

90. By reason of the foregoing acts and omissions, Plaintiff REBECCA G. GOLDSTEIN was and still is caused to suffer from colon 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.

91. Plaintiff REBECCA G. GOLDSTEIN has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has suffered serious and dangerous side effects from Belviq including, inter alia colon 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.

92. By reason of the foregoing, Plaintiff REBECCA G. GOLDSTEIN 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 –
NEGLIGENCE

93. Plaintiff repeats, reiterates and realleges 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.

94. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was not safe for human consumption because it caused unreasonably dangerous side effects, including cancer.

95. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that the safety risks of Belviq (i.e. its carcinogenicity) outweighed any benefits Belviq may have.

96. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq had not been properly, adequately and/or sufficiently tested for safety when they were in possession of information that signaled that Belviq could cause cancer and/or the cancer risk needed further testing and studies prior to its introduction to the market.

97. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was unreasonably dangerous because of inadequate warnings, because they did not adequately warn of its risks of cancer, especially when used in the form and manner as provided by Defendants.

98. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was unreasonably dangerous because of its design defects, especially when used in the form and manner as provided by Defendants.

99. At all relevant times and at the time Belviq left the Defendants' control, 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.

100. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design because there existed a feasible, safer alternative design for Belviq that was capable of preventing Plaintiff REBECCA G. GOLDSTEIN's injuries and damages – an alternative design that was and is in the exclusive possession, custody and control of Defendants.

101. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design because there existed a feasible, safer alternative design for Belviq, the utility of which outweighed the utility of the design that was actually used for Belviq.

102. 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.

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

104. Despite the fact that Defendants knew or should have known that Belviq caused unreasonably dangerous side effects, Defendants continued to market Belviq to prescribing

physicians, including the Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell.

105. Defendants knew or should have known that consumers such as the Plaintiff REBECCA G. GOLDSTEIN would foreseeably suffer injury as a result of their failure to exercise ordinary care, as set forth herein.

106. At all relevant times, given its lack of efficacy and increased safety risks, Belviq was not fit for the ordinary purpose for which it was intended – a weight loss drug.

107. At all relevant times, given its lack of efficacy and increased safety risks, Belviq did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff REBECCA G. GOLDSTEIN.

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

109. Defendants had a duty to warn Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, of all safety risks associated with Belviq, including its increased risk of causing cancer.

110. Defendants had a duty to warn Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, that Belviq had not been adequately and/or sufficiently tested regarding its carcinogenicity.

111. Defendants had a duty to adequately and/or sufficiently test Belviq.

112. Defendants had a duty to design Belviq in a manner that was safe to its users.

113. Defendants breached their duties to Plaintiff by failing to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Belviq into interstate commerce in that Defendants knew or should have known that using Belviq created a high risk of unreasonable, dangerous side effects, including cancer, that caused severe and personal injuries that 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.

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

(a) Promoting, formulating, creating and/or designing Belviq without thoroughly testing it;

(b) Promoting, formulating, creating, and/or designing Belviq XR without adequately testing it;

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

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

(e) Negligently failing to adequately and correctly warn the Plaintiff, her prescribing physician, the public, the medical and healthcare profession, and/or the FDA of the dangers of Belviq;

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

(g) Failing to test Belviq and/or failing to adequately, sufficiently, and properly test Belviq;

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

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

(j) Negligently representing that the benefits of Belviq outweigh its risks;

(k) Negligently representing that Belviq had equivalent safety and efficacy as other forms of treatment for chronic weight management;

(l) Negligently designing Belviq in a manner which was dangerous to its users;

(m) Concealing information concerning FDA warnings from the Plaintiff and her prescribing physician in knowing that Belviq was unsafe, dangerous, and/or non-conforming with FDA regulations; and

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

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

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

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

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

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

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

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

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

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

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

(h) Were otherwise careless and/or negligent.

118. The label for Belviq was inadequate because it did not warn of the increased cancer risk associated with Belviq.

119. The label for Belviq was inadequate because it did not warn that Belviq had not been adequately and/or sufficiently tested for safety.

120. Communications made by Defendants to Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, were inadequate because Defendants failed to warn of the increased cancer risk associated with Belviq and/or that Belviq had not been adequately and/or sufficiently tested for safety.

121. Upon information and belief, had Plaintiff's prescribing physician, Dr. Barbara Mandell, been warned of the increased cancer risk associated with Belviq, she 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.

122. Upon information and belief, had Plaintiff's prescribing physician, Dr. Barbara Mandell, been warned that Belviq had not been sufficiently and/or adequately tested for safety, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the inadequate and/or inappropriate testing of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

123. Had Plaintiff been warned of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered colon cancer.

124. Had Plaintiff been warned of the inadequate and/or inappropriate testing of Belviq, she would not have used Belviq and/or suffered colon cancer.

125. Defendants' negligence in failing to warn Plaintiff and/or her prescribing physician, Dr. Barbara Mandell, of the dangers associated with their Belviq was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

126. Defendants' negligence in failing to sufficiently and/or adequately test Belviq was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.

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

128. Plaintiff REBECCA G. GOLDSTEIN's injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by Plaintiff REBECCA G. GOLDSTEIN.

129. Plaintiff REBECCA G. GOLDSTEIN's injuries and damages as a result of her use of Belviq were foreseeable by Defendants.

130. As a result of the foregoing negligent acts and omissions, the Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

131. As a result of the foregoing negligent acts and omissions, Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff are informed and believes and further allege that Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

COUNT II -
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN AND FAILURE TO WARN

133. Plaintiff repeats, reiterates and realleges 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.

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

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

136. At those times, Belviq was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff REBECCA G. GOLDSTEIN.

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

138. At those times, given its lack of efficacy and increased safety risks, Belviq was not fit for the ordinary purpose for which it was intended – a weight loss drug.

139. At those times, given its lack of efficacy and increased safety risks, Belviq did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff REBECCA G. GOLDSTEIN.

140. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that,

when it left the hands of the Defendants' manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

141. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants' manufacturers and/or suppliers, 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.

142. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective in design and/or formulation, in that, upon information and belief, when it left the hands of the Defendant manufacturers and/or suppliers, a safer feasible alternative design existed that was capable of preventing Plaintiff REBECCA G. GOLDSTEIN's injuries and damages – an alternative design that was and is in the exclusive possession, custody and control of Defendants.

143. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design because there existed a feasible, safer alternative design for Belviq, the utility of which outweighed the utility of the design that was actually used for Belviq.

144. 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.

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

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

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

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

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

150. Defendants breached its duty by creating a product unreasonably dangerous for its normal, intended use.

151. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants reached Plaintiff REBECCA G. GOLDSTEIN in the same defective and unreasonably dangerous condition in which the Defendants' Belviq was designed.

152. 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 REBECCA G. GOLDSTEIN in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff REBECCA G. GOLDSTEIN.

153. The Plaintiff REBECCA G. GOLDSTEIN and/or her prescribing physician, Dr. Barbara Mandell, could not, by the exercise of reasonable care, have discovered Belviq's defects herein mentioned and perceived its danger.

154. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including cancer, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

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

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

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

158. 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.

159. Communications made by Defendants to Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, were inadequate because Defendants failed to warn and/or adequately warn of the increased cancer risk associated with Belviq.

160. Communications made by Defendants to Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, were inadequate because Defendants failed to

warn and/or adequately warn that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

161. Upon information and belief, had Plaintiff's prescribing physician, Dr. Barbara Mandell, been warned of the increased cancer risk associated with Belviq she 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.

162. Upon information and belief, had Plaintiff's prescribing physician, Dr. Barbara Mandell, been warned that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer, she 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.

163. Had Plaintiff been warned of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered colon cancer.

164. Had Plaintiff 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 colon cancer.

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

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

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

168. That said, defects in Defendants' drug Belviq were the proximate cause of Plaintiff's injuries.

169. As a result of the foregoing acts and omissions, the Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

170. As a result of the foregoing acts and omissions, the Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

COUNT III –
BREACH OF EXPRESS WARRANTY

172. Plaintiff repeats, reiterates and realleges 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.

173. 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, and distributed Belviq as hereinabove described that was used by Plaintiff REBECCA G. GOLDSTEIN.

174. At all relevant times, Defendants' expressly warranted to Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, 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 REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, 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 REBECCA G. GOLDSTEIN, and her prescribing physician, Dr. Barbara Mandell, that the effectiveness of Belviq outweighed any potential dangers and/or risks.

177. The aforementioned express warranties were made to Plaintiff REBECCA G. GOLDSTEIN by way Belviq's prescription information including, without limitation, the product label.

178. Upon information and belief, the aforementioned express warranties were made to Plaintiff REBECCA G. GOLDSTEIN's prescribing physician by way of Belviq's prescription information including, without limitation, the product label.

179. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that Belviq:

(a) was safe and fit for its intended purposes;

(b) was of merchantable quality;

(c) did not produce any dangerous side effects, and

(d) had been adequately tested and found to be safe and effective for weight loss as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

180. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with use of Belviq. In fact, Defendants knew or should have known that the risks identified in Belviq's prescribing information and package inserts do not accurately or adequately set forth the drug's true risks. Despite this, Defendants expressly warranted Belviq as safe and effective for use.

181. Defendants advertised, labeled, marketed, and promoted Belviq, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce Belviq's purchase or use, thereby making an express warranty that Belviq would conform to the representations. More specifically, the prescribing information for Belviq did not contain adequate information about the true risks of developing the injuries complained of herein.

182. On or about January 8, 2015, Plaintiff REBECCA G. GOLDSTEIN had a patient visit with Dr. Barbara Mandell at which time they discussed the drug Belviq.

183. At this visit, with Dr. Barbara Mandell discussed and compared with REBECCA G. GOLDSTEIN the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

184. Upon information and belief, Dr. Barbara Mandell obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

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

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

187. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was an effective drug to use for weight loss.

188. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was a safe drug to use for weight loss.

189. As a result of Defendants' express warranties to her and Dr. Barbara Mandell, Dr. Barbara Mandell was induced to prescribe Belviq to Plaintiff REBECCA G. GOLDSTEIN, and Plaintiff REBECCA G. GOLDSTEIN was induced to use Belviq from January 2015 through November 2016.

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

191. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as the Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, would recommend, prescribe and/or dispense Belviq based upon their express warranties.

192. 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.

193. 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.

194. 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.

195. At all relevant times, Defendants knew or should have known that Belviq had not been sufficiently and/or adequately tested for safety.

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

197. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by Plaintiff REBECCA G. GOLDSTEIN,'s prescribing physician, with the ordinary knowledge common to the community as to the drug's characteristics.

198. 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.

199. 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.

200. 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.

201. The express warranties made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff REBECCA G. GOLDSTEIN to use the product and/or her prescribing physician, Dr. Barbara Mandell, to prescribe the product.

202. Defendants knew and/or should have known that by making the express warranties to Plaintiff REBECCA G. GOLDSTEIN and/or her prescribing physician, Dr. Barbara Mandell, it would be the natural tendency of Plaintiff to use Belviq and/or her prescribing physician, Dr. Barbara Mandell, to prescribe Belviq.

203. Plaintiff and her prescribing physician, Dr. Barbara Mandell, as well as members of the medical community, relied on the express warranties of the Defendants identified herein.

204. The express warranties made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff REBECCA G. GOLDSTEIN to use the product and/or her prescribing physician, Dr. Barbara Mandell, to prescribe the product.

205. Had Defendants not made these express warranties, Plaintiff REBECCA G. GOLDSTEIN would not have used the product and/or, upon information and belief, her prescribing physician, Dr. Barbara Mandell, would not have prescribed the product.

206. Plaintiff REBECCA G. GOLDSTEIN's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

207. Plaintiff REBECCA G. GOLDSTEIN'S injuries and damages arose from a reasonably anticipated use of the product by Plaintiff REBECCA G. GOLDSTEIN.

208. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff REBECCA G. GOLDSTEIN.

209. As a result of the foregoing breaches, Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

210. By reason of the foregoing, Plaintiff REBECCA G. GOLDSTEIN 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.

211. As a result of the foregoing acts and omissions the Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

COUNT IV –
BREACH OF IMPLIED WARRANTIES

213. Plaintiff repeats, reiterates and realleges 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.

214. 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 REBECCA G. GOLDSTEIN.

215. At the time Defendants marketed, sold, and distributed Belviq for use by Plaintiff REBECCA G. GOLDSTEIN, Defendants knew of the use for which Belviq was intended – as a weight loss medication – and impliedly warranted the product to be of merchantable quality and safe and fit for ordinary use.

216. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as the Plaintiff REBECCA G. GOLDSTEIN, would use and/or consume Belviq for the purpose of weight loss.

217. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell would recommend, prescribe and/or dispense Belviq for use by their patients as a weight loss medication.

218. At all relevant times, Defendants' impliedly warranted to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, and the medical community that Belviq was of merchantable quality and safe and fit for ordinary use in that it 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").

219. At all relevant times, Defendants' impliedly warranted to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, and the medical community that Belviq was of merchantable quality, safe and fit, for ordinary use in that it 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.

220. At all relevant times, Defendants' impliedly warranted to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, and the medical community that Belviq was of merchantable quality, safe and fit, for ordinary use in that the effectiveness of Belviq outweighed any potential dangers and/or risks.

221. 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.

222. 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.

223. 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.

224. At all relevant times, Defendants knew or should have known that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

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

226. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by prescribing physicians, such as Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, with the ordinary knowledge common to the community as to the product's characteristics.

227. At all relevant times and at the time Belviq left the Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate 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 carried with it an increased risk of cancer.

228. At all relevant times and at the time Belviq left the Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate 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.

229. At all relevant times and at the time Belviq left the Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate because the effectiveness of Belviq did not outweigh any of the dangers and/or risks associated with the drug.

230. At all relevant times and at the time Belviq left the Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate because Belviq had not been sufficiently and/or adequately tested regarding its safety risks, including cancer.

231. Plaintiff REBECCA G. GOLDSTEIN relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.

232. Plaintiff REBECCA G. GOLDSTEIN reasonably relied upon the skill and judgment of Defendants as to whether Belviq was of merchantable quality and safe and fit for its intended use.

233. Upon information and belief, Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.

234. Upon information and belief, Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, reasonably relied upon the skill and judgment of Defendants as to whether Belviq was of merchantable quality and safe and fit for its intended use.

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

236. Defendants' herein breached the aforesaid implied warranties, as their drug Belviq was not merchantable nor fit for its intended purposes and uses.

237. Plaintiff REBECCA G. GOLDSTEIN would not have used Belviq and/or, upon information and belief, her prescribing physician, Dr. Barbara Mandell, would not have prescribed Belviq but for the aforesaid implied warranties.

238. Plaintiff REBECCA G. GOLDSTEIN's injuries and damages were directly caused by Defendants' breach of the aforementioned implied warranties.

239. Plaintiff REBECCA G. GOLDSTEIN's injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by Plaintiff REBECCA G. GOLDSTEIN.

240. As a result of the foregoing breaches, Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

241. As a result of the foregoing acts and omissions, the Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services. She did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

COUNT V –
FRAUDULENT MISRPRESENTATIOIN AND CONCEALMENT

243. Plaintiff repeats, reiterates and realleges 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.

244. Prior to 2015, 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.

245. Nevertheless, in 2015, Defendants falsely represented in television advertisements, other media platforms and on the label of Belviq 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.

246. Prior to 2015, 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.

247. Nevertheless, up to and including 2015, Defendants falsely represented in television advertisements, other media platforms and on the label of Belviq 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.

248. Prior to 2015, Defendants knew or should have known that the effectiveness of Belviq, if any, did not outweigh the dangers and risks associated with Belviq.

249. Nevertheless, up to and including 2015, Defendants falsely represented in television advertisements, other media platforms and on the label of Belviq that the effectiveness of Belviq outweighed the dangers and risks associated with Belviq.

250. Prior to 2015, Defendants knew or should have known that Belviq had not been adequately and/or sufficiently tested for safety.

251. Nevertheless, up to and including 2015, Defendants falsely represented in television advertisements, other media platforms and on the label of Belviq 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.

252. Defendants' fraudulent representations and/or concealments as identified herein were done with the intent of defrauding and deceiving consumers, including the Plaintiff REBECCA G. GOLDSTEIN, and prescribing physicians, including Dr. Barbara Mandell, 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 REBECCA G. GOLDSTEIN.

253. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing consumers, including the Plaintiff REBECCA G. GOLDSTEIN,

into using Belviq for chronic weight management, which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Plaintiff REBECCA G. GOLDSTEIN.

254. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing prescribing physicians, including the Plaintiff REBECCA G. GOLDSTEIN's prescribing physician Dr. Barbara Mandell, 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 REBECCA G. GOLDSTEIN.

255. Up to and including 2015, Plaintiff REBECCA G. GOLDSTEIN saw media advertisements relating to Belviq whereby Defendants represented that Belviq was an effective drug to use for weight loss.

256. The media advertisements seen by Plaintiff REBECCA G. GOLDSTEIN up to and including 2015 were created, drafted, finalized and approved by Defendants and/or individuals and entities working on their behalf.

257. Up to and including 2015, when Plaintiff REBECCA G. GOLDSTEIN saw these media advertisements relating to Belviq, Defendants represented that certain side effects were associated with the drug and did not indicate that these side effects included an increased risk of cancer.

258. Up to and including 2015, when Plaintiff REBECCA G. GOLDSTEIN saw these media advertisements relating to Belviq, Defendants concealed from her the fact that Belviq was associated with an increased risk of cancer.

259. Up to and including 2015, when Plaintiff REBECCA G. GOLDSTEIN saw these media advertisements relating to Belviq, Defendants concealed from her the fact that Belviq had not been adequately and/or sufficiently tested for safety.

260. The aforementioned representations made in the media advertisements seen by Plaintiff REBECCA G. GOLDSTEIN up to and including 2015 were false in that Belviq is not an effective drug to use for weight loss.

261. The aforementioned representations made in the media advertisements seen by Plaintiff REBECCA G. GOLDSTEIN up to and including 2015 were false and/or fraudulently made in that that Defendants concealed from Plaintiff REBECCA G. GOLDSTEIN that Belviq was associated with an increased risk of cancer.

262. The aforementioned representations made in the media advertisements seen by Plaintiff REBECCA G. GOLDSTEIN up to and including 2015 were false and/or fraudulently made in that that Defendants concealed from Plaintiff REBECCA G. GOLDSTEIN that Belviq had not been adequately and/or sufficiently tested for safety.

263. As a result of these advertisements up to and including 2015, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff REBECCA G. GOLDSTEIN was induced to want to use Belviq and she contacted her prescribing physician, Dr. Barbara Mandell, for the specific purpose of having her prescribe her Belviq.

264. As a result of these advertisements up to and including 2015, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff REBECCA G. GOLDSTEIN presented to the office of Dr. Barbara Mandell to request Belviq on or about January 8, 2015.

265. At this visit with Dr. Barbara Mandell on or about January 8, 2015, Dr. Barbara Mandell discussed the drug Belviq with Plaintiff REBECCA G. GOLDSTEIN.

266. At this visit with Dr. Barbara Mandell on or about January 8, 2015, Dr. Barbara Mandell discussed and compared with REBECCA G. GOLDSTEIN the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

267. Upon information and belief, Dr. Barbara Mandell obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

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

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

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

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

272. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product label that Belviq was an effective drug to use for weight loss.

273. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product label that Belviq was a safe drug to use for weight loss.

274. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of the product label that Belviq was associated with an increased risk of cancer.

275. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of the product label that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.

276. The aforementioned representations made in the label of Belviq on or about January 8, 2015 were false in that Belviq is not an effective drug to use for weight loss.

277. The aforementioned representations made in the label of Belviq on or about January 8, 2015 were fraudulently made in that Defendants concealed Belviq being associated with an increased risk of cancer despite their knowledge to the contrary.

278. The aforementioned representations made in the label of Belviq on or about January 8, 2015 were fraudulently made in that Defendants concealed that Belviq had not been adequately and/or sufficiently tested for safety, including cancer.

279. Upon information and belief, as a result of the label for Belviq on or about January 8, 2015, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff's prescribing physician, Dr. Barbara Mandell, was induced to and did prescribe Belviq to Plaintiff REBECCA G. GOLDSTEIN from January 2015 to November 2016.

280. As a result of the advertisements relating to Belviq up to and including 2015 and/or the label of Belviq itself, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff REBECCA G. GOLDSTEIN was induced to and did use Belviq from January 2015 to December 2016.

281. Upon information and belief, had Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, been told of the increased cancer risk associated with Belviq, she 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.

282. Upon information and belief, had Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, been told of the lack of efficacy associated with Belviq she 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.

283. Upon information and belief, had Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, been told that the benefits of Belviq, if any, were outweighed by its safety risks, particularly cancer, she 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.

284. Upon information and belief, had Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, been told that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer, she 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.

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

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

287. 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 colon cancer.

288. 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 colon cancer.

289. Plaintiff REBECCA G. GOLDSTEIN 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.

290. Plaintiff REBECCA G. GOLDSTEIN's prescribing physician, Dr. Barbara Mandell, 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.

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

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

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

294. At all relevant times, Defendants were under a duty to disclose to Plaintiff, REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, hospitals, and/or healthcare providers the defective nature of Belviq, including but not limited to the heightened risk of cancer.

295. At all relevant times, Defendants were under a duty to disclose to Plaintiff, REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, hospitals, and/or healthcare providers information regarding the ineffectiveness of Belviq.

296. At all relevant times, Defendants were under a duty to disclose to Plaintiff, REBECCA G. GOLDSTEIN, her prescribing physician, hospitals, and/or healthcare providers that the risks of Belviq outweighed any effectiveness it may have.

297. At all relevant times, Defendants were under a duty to disclose to Plaintiff, REBECCA G. GOLDSTEIN, her prescribing physician, hospitals, and/or healthcare providers that Belviq had not been adequately and/or sufficiently tested.

298. Defendants breached their duties to disclose Belviq's serious safety risks and lack of efficacy to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, the medical and healthcare community, the FDA and the public in general.

299. Defendants could have and should have revealed the truth behind the safety and lack of efficacy of Belviq through various outlets, including their media advertisements and the label for Belviq.

300. Defendants' misrepresentations and concealments concerning the safety and lack of efficacy of Belviq were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, 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.

301. Defendants knew that Plaintiff REBECCA G. GOLDSTEIN and her prescribing physician, Dr. Barbara Mandell, had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Belviq, as set forth herein.

302. Plaintiff REBECCA G. GOLDSTEIN's injury and damages were proximately caused by Defendants' fraudulent misrepresentations and concealments as set forth herein.

303. Plaintiff REBECCA G. GOLDSTEIN's injury and damages were proximately caused by her reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

304. Plaintiff REBECCA G. GOLDSTEIN's injury and damages were proximately caused by her prescribing physician's reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.

305. As a result of the foregoing acts and omissions, the Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

306. As a result of the foregoing acts and omissions the Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

COUNT IV – NEGLIGENT MISREPRESENTATION

308. Plaintiff repeats, reiterates and realleges 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.

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

310. At all relevant times, Defendants' represented to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell, 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.

311. At all relevant times, Defendants' represented to Plaintiff REBECCA G. GOLDSTEIN, her prescribing physician, Dr. Barbara Mandell 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.

312. 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.

313. 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.

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

315. The representations made by Defendants were made to Plaintiff REBECCA G. GOLDSTEIN up to and including 2015 through media advertisements and the label of Belviq.

316. At this visit with Dr. Barbara Mandell on or about January 8, 2015, Dr. Barbara Mandell discussed the drug Belviq with Plaintiff REBECCA G. GOLDSTEIN.

317. At this visit with Dr. Barbara Mandell on or about January 8, 2015, Dr. Barbara Mandell discussed and compared with REBECCA G. GOLDSTEIN the efficacy and side effects of the drug Belviq with the efficacy and side effects of other weight loss drugs on the market.

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

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

320. Upon information and belief, Defendants represented to Dr. Barbara Mandell 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.

321. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's label that Belviq was an effective drug to use for weight loss.

322. On or about January 8, 2015, when Plaintiff REBECCA G. GOLDSTEIN began using Belviq and throughout her use of Belviq, Defendants represented to her 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.

323. When the aforementioned representations were made, Defendants were aware or should have been aware that their representations would induce Plaintiff REBECCA G. GOLDSTEIN and/or her prescribing physician, Dr. Barbara Mandell, to use and/or prescribe Belviq.

324. When the representations were made, Defendants were aware or should have been aware that Belviq was to be used by Plaintiff REBECCA G. GOLDSTEIN and/or prescribed by Plaintiff's prescribing physician, Dr. Barbara Mandell, in reliance upon its representations regarding the safety and efficacy of Belviq.

325. At the time the aforesaid representations were made by the Defendants and at the time Plaintiff REBECCA G. GOLDSTEIN used Belviq and her prescribing physician, Dr. Barbara Mandell, prescribed Belviq to her, Plaintiff REBECCA G. GOLDSTEIN was unaware of the falsity of said representations and reasonably believed them to be true.

326. Upon information and belief, at the time the aforesaid representations were made by the Defendants and at the time Plaintiff REBECCA G. GOLDSTEIN used Belviq and her prescribing physician, Dr. Barbara Mandell, prescribed Belviq to her, Plaintiff's prescribing physician, Dr. Barbara Mandell, was unaware of the falsity of said representations and reasonably believed them to be true.

327. In reasonable and foreseeable reliance upon said representations, the Plaintiff REBECCA G. GOLDSTEIN was induced to and did use Belviq.

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

329. 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.

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

331. Upon information and belief, had Plaintiff's prescribing physician, Dr. Barbara Mandell, known these representations regarding the safety and efficacy of Belviq to be false, she would not have prescribed Belviq to Plaintiff REBECCA G. GOLDSTEIN.

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

333. Defendants' negligent misrepresentations proximately caused Plaintiff' injuries and damages as alleged herein.

334. As a result of their misrepresentations, the Plaintiff REBECCA G. GOLDSTEIN was caused to suffer serious and dangerous side effects including colon 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.

335. As a result of the foregoing acts and omissions the Plaintiff REBECCA G. GOLDSTEIN requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that

Plaintiff REBECCA G. GOLDSTEIN will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

PRAYER FOR RELIEF

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

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

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

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

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

Dated: September 30, 2021

By: */s/ Tate J. Kunkle*

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- AND -

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

/s/ Tate J. Kunkle
Tate J. Kunkle