

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

CHRISTINE JOHNSON and  
DENNIS JOHNSON

Plaintiffs,

v.

EISAI, INC.,  
EISAI CO., LTD,  
ARENA PHARMACEUTICALS, INC., and  
ARENA PHARMACEUTICALS GMBH,

Defendants.

Case No. 4:21-cv-876

JURY TRIAL DEMANDED

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**COMPLAINT**

Plaintiffs, by their attorneys, **WRIGHT & SCHULTE, LLC** on behalf of themselves individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

**JURISDICTION AND VENUE**

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

**NATURE OF THE CASE**

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

3. This action is also brought by Plaintiff DENNIS JOHNSON who suffered loss of consortium damages as a result of Plaintiff CHRISTINE JOHNSON's use of Belviq and injuries related thereto.

4. Defendant, EISAI, INC., along with its parent company Defendant EISAI CO., LTD.(hereinafter collectively referred to as "EISAI"), and Defendant ARENA PHARMACEUTICALS, INC., along with its wholly owned subsidiary Defendant ARENA PHARMACEUTICALS GMBH (hereinafter collectively referred to as "ARENA")(collectively with EISAI referred to as "Defendants") were, at all relevant times, responsible for the design, research, manufacture, testing, advertisement, labeling, promotion, marketing, sale, and/or distribution of Belviq.

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

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

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

8. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff CHRISTINE JOHNSON, 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 CHRISTINE JOHNSON.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Belviq during clinical trials, forcing Plaintiff CHRISTINE JOHNSON, and her prescribing physician, hospitals, and/or the FDA to rely on inaccurate safety and efficacy information relating to Belviq.

10. As a result of the acts and omissions of Defendants as identified herein, the Plaintiff CHRISTINE JOHNSON 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.

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

12. Consequently, Plaintiffs seek compensatory damages as a result of Plaintiff CHRISTINE JOHNSON'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**

13. Plaintiff CHRISTINE JOHNSON is a citizen of the United States of America and is a citizen and resident of the State of Ohio.

14. Plaintiff CHRISTINE JOHNSON was born on March 15, 1965.

15. Plaintiff, CHRISTINE JOHNSON, first began using Belviq in or about August 2016, and used Belviq up through approximately October 2016.

16. The Belviq that was used by Plaintiff, CHRISTINE JOHNSON was prescribed by her primary care physician, Dr. Denise Bobouynik.

17. As result of using Defendants' Belviq, Plaintiff CHRISTINE JOHNSON was caused to suffer from colon cancer on or about October 24, 2016 and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress related thereto.

18. The injuries and damages sustained by Plaintiff CHRISTINE JOHNSON were caused by Defendants' Belviq.

19. Plaintiff DENNIS JOHNSON is a citizen of the United States of America and is a citizen and resident of the State of Ohio.

20. Plaintiff DENNIS JOHNSON is the lawful spouse of CHRISTINE JOHNSON and was her lawful spouse at all relevant times.

21. Plaintiffs did not know and could not have known that the injuries they suffered were caused by Belviq until after the date Belviq was withdrawn from the market (i.e. February 2020) and after Plaintiffs came to learn of its withdrawal from the market and the reasons therefore.

**PARTY DEFENDANTS**

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

23. 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.

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

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

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

27. 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.

28. Defendant, EISAI, INC. is a wholly-owned subsidiary of Eisai Corporation of North America, which in turn is a wholly-owned subsidiary of Defendant EISAI CO., LTD.

29. Defendant EISAI CO., LTD. is a Japanese company having a principal place of business located at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan.

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

31. Upon information and belief, Defendant EISAI CO., LTD. has derived substantial revenue from goods and products sold and/or used in the State of Ohio.

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

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

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

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

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

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

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

39. 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.

40. Defendant ARENA PHARMACEUTICALS, INC. is the parent/holding company of Defendant ARENA PHARMACEUTICALS GMBH.

41. Defendant, ARENA PHARMACEUTICALS GMBH is a company organized under the laws of Switzerland with its principal place of business located at Untere Brühlstrasse 4, CH-4800 Zofingen, Switzerland.

42. Upon information and belief, Defendant, ARENA PHARMACEUTICALS GMBH has transacted and conducted business in the State of Ohio.

43. Upon information and belief, Defendant, ARENA PHARMACEUTICALS GMBH has derived substantial revenue from goods and products used in the State of Ohio.

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

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

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

## **FACTUAL BACKGROUND**

### **A. FDA Approval of Belviq in the United States**

47. 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.

48. 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<sup>2</sup> or adult patients with a BMI greater than or equal to 27 kg/m<sup>2</sup> and at least one weight-related comorbid condition.

49. 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<sup>2</sup> or adult patients with a BMI greater than or equal to 27 kg/m<sup>2</sup> and at least one weight-related comorbid condition.

50. 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.<sup>1</sup>

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

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<sup>1</sup> The original Marketing and Supply Agreement was entered into in July 2010.



52. 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.

53. 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.

54. 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 belvinqnow.com, as well as other public outlets.

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

56. 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").

57. 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.

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

59. 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.

60. 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 belviquow.com, as well as other public outlets.

61. 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.

62. In 2017, Eisai purchased the global rights to develop and market Belviq from ARENA.

63. The aforementioned purchase identified in paragraph 62 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**

64. Belviq is a first-in-class oral selective serotonin 5HT<sub>2c</sub> 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.

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

66. 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 colon 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.

67. 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.

68. 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.

69. 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.

70. 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 Ohio law.

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

72. These scientific literature and publications, the two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or a combination of the three, put Defendants on notice and/or should have put Defendants on notice that lorcaserin was a carcinogen and/or that

further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, Belviq is an unsafe product and unreasonably dangerous product under Ohio law.

73. 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.

74. 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.

75. 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.

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

77. 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.

78. 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.

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

80. 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.

81. 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'sNeil, 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.

82. 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.

83. 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.

84. 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.

85. Upon information and belief, the PWG re-adjudication procedure and its results were mis-adjudicated, misapplied, misinterpreted and/or otherwise skewed in favor of Defendants

and, particularly, a finding that lorcaserin was not a carcinogen; nevertheless, even if accepted as true, the results of the PWG re-adjudication, reviewed separately and/or in combination with the initial results of the two-year carcinogenicity rat study, the two-year carcinogenicity mouse study, the medical literature and publications regarding the serotonin pathway and its causal link to cancer and/or all three, put Defendants on notice or should have put Defendants on notice that lorcaserin was a carcinogen and/or that further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under Ohio law.

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

87. 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.

88. 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").

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

90. 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).

91. CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving 12,000 patients conducted in the United States,

Canada, Mexico, the Bahamas, Europe, South America, Australia and New Zealand to evaluate the risk of heart-related issues with Belviq. The primary safety outcome of major adverse cardiovascular events showed noninferiority. The results of CAMELLIA-TIMI 61 were published in November 2016 in NEJM. Bohula, E.A., et al. *Cardiovascular Safety of Lorcaserin in Overweight or Obese Patients*. N. Engl. J. Med. 2018;379:1107-17.

92. 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.

93. 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.

94. 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.

95. 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.

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

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

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

99. 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.

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

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

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

103. 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.

104. By reason of the foregoing acts and omissions, Plaintiff CHRISTINE JOHNSON 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.

105. Plaintiff CHRISTINE JOHNSON 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.

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

**FIRST CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**OHIO PRODUCTS LIABILITY ACT**  
**O.R.C. 2307.71, 2307.72, 2307.73 2307.75, 2307.76**  
**(DEFECTIVE DESIGN AND FAILURE TO WARN)**

107. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

108. The Defendants are manufacturers, as defined in O.R.C. 2307.71, and/or distributors that, at all times herein mentioned, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed, Belviq as hereinabove described that was used by the Plaintiff CHRISTINE JOHNSON.

109. Defendants' actions, as identified herein, violated statutes, ordinance and/or rules and regulations, and specifically Revised Code sections 2307.71, 2307.72, 2307.73, 2307.75 and 2307.76.

110. 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/or marketed by the Defendants.

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

112. 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.

113. 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 CHRISTINE JOHNSON.

114. 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 Defendants, the foreseeable risks of cancer associated with its design exceeded the benefits associated with the design or formulation of Belviq.

115. 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, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

116. 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 (cancer) to Plaintiff and other users of Belviq.

117. 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 CHRISTINE JOHNSON's injuries and damages – an alternative design that was and is in the exclusive possession, custody and control of Defendants.

118. 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 being used for Belviq.

119. 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.

120. 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.

121. 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.

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

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

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

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

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

127. 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 CHRISTINE JOHNSON in particular, and Defendants are therefore liable under the OPLA for the injuries sustained by the Plaintiff CHRISTINE JOHNSON.

128. The Plaintiff CHRISTINE JOHNSON and her prescribing healthcare provider, Dr. Denise Bobouynik, could not by the exercise of reasonable care have discovered Belviq's defects herein mentioned and perceived its danger.

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

130. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, testing, marketing, supplying, promotion, advertising, sale and/or distribution of Belviq into interstate commerce in that Defendants knew or should have known that using Belviq placed users at risk of developing serious and dangerous side effects, particularly cancer, and that Belviq had not been sufficiently and/or adequately tested, yet they placed the product into the stream of commerce anyway without adequate warnings.

131. 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 Belviq 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.



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

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

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

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

136. 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.

137. The patient information sheet for Belviq was inadequate because it did not warn and/or adequately warn of the increased cancer risk associated with Belviq.

138. The patient information sheet 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.

139. Communications made by Defendants to Plaintiff CHRISTINE JOHNSON and her prescribing healthcare provider, Dr. Denise Bobouynik, were inadequate because Defendants failed to warn and/or adequately warn them of the increased cancer risk associated with Belviq.

140. Communications made by Defendants to Plaintiff CHRISTINE JOHNSON and her prescribing healthcare provider, Dr. Denise Bobouynik, were inadequate because Defendants failed to warn and/or adequately warn them that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.

141. Upon information and belief, had Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, been warned of the increased cancer risk associated with Belviq she would not have prescribed Belviq and/or would have provided Plaintiff CHRISTINE JOHNSON with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff CHRISTINE JOHNSON to make an informed decision regarding her use of Belviq.

142. Upon information and belief, had Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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 CHRISTINE JOHNSON with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff CHRISTINE JOHNSON to make an informed decision regarding her use of Belviq.

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

144. Had Plaintiff CHRISTINE JOHNSON 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.

145. By reason of the foregoing, Defendants have become liable in tort to the Plaintiffs under the OPLA for the designing, marketing, promoting, distribution, and selling of a defective product, Belviq.

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

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

148. That said defects in Defendants' drug Belviq was the direct and proximate cause of Plaintiff CHRISTINE JOHNSON's injuries.

149. As a result of the foregoing acts and omissions, the Plaintiff CHRISTINE JOHNSON 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.

150. As a result of the foregoing acts and omissions the Plaintiff CHRISTINE JOHNSON 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 CHRISTINE JOHNSON will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

**SECOND CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**OHIO PRODUCTS LIABILITY ACT**  
**O.R.C. 2307.71, 2307.72, 2307.73, 2307.77**  
**(FAILURE TO CONFORM TO REPRESENTATIONS)**

152. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

153. 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 CHRISTINE JOHNSON.

154. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff CHRISTINE JOHNSON would use, consume, or be affected by Belviq.

155. Upon information and belief, at all relevant times, Defendants represented to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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) in that it did not cause an increased risk of cancer.

156. Upon information and belief, at all relevant times, Defendants represented to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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.

157. Upon information and belief, at all relevant times, Defendants represented to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, that the effectiveness of Belviq outweighed any potential dangers and/or risks.

158. Upon information and belief, at all relevant times, the aforementioned representations were made to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, by way of Belviq's label and information provided to her by Defendants' sales representatives.

159. In or about August 2016, Plaintiff CHRISTINE JOHNSON presented to the office of her prescribing healthcare provider, Dr. Denise Bobouynik, and discussed with her options for weight loss.

160. At this visit, in or about August 2016, Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to her.

161. Upon information and belief, Dr. Denise Bobouynik, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

162. Upon information and belief, Dr. Denise Bobouynik, obtained the information regarding the efficacy and side effects of Belviq from communications with Defendants' sale representatives.

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

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

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

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

167. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants represented to her, by way of Belviq's patient information sheet, that Belviq was an effective drug to use for weight loss.

168. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants represented to her, by way of Belviq's patient information sheet, that Belviq was a safe drug to use for weight loss.

169. As a result of Defendants' representations to her and Dr. Denise Bobouynik, Dr. Denise Bobouynik was induced to prescribe Belviq to Plaintiff CHRISTINE JOHNSON, and Plaintiff CHRISTINE JOHNSON was induced to use Belviq from August 2016 through approximately October 2016.

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

171. At all relevant times, Defendants reasonably anticipated and expected that prescribing healthcare providers, such as the Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, would recommend, prescribed and/or dispense Belviq based upon their express warranties.

172. 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.

173. 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.

174. 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.

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

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

177. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, with the ordinary knowledge common to the community as to the drug's characteristics.

178. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' representations 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.

179. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' representations 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.

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

181. The representations made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff CHRISTINE JOHNSON to use the product and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe the product.

182. Defendants knew and/or should have known that by making the representations to Plaintiff CHRISTINE JOHNSON and/or her prescribing healthcare provider, Dr. Denise Bobouynik, it would be the natural tendency of Plaintiff to use Belviq and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe Belviq.

183. Plaintiff and her prescribing healthcare provider, Dr. Denise Bobouynik, as well as members of the medical community, relied on the representations of the Defendants herein.

184. The representations made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff CHRISTINE JOHNSON to use the product and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe the product.

185. Had Defendants not made these representations, Plaintiff CHRISTINE JOHNSON would not have used the product and/or, upon information and belief, her prescribing healthcare provider, Dr. Denise Bobouynik, would not have prescribed the product.

186. Plaintiff CHRISTINE JOHNSON's injuries and damages were directly caused by Belviq's failure to conform to Defendants' representations regarding the safety and efficacy of Belviq.



187. Plaintiff CHRISTINE JOHNSON's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff CHRISTINE JOHNSON.

188. Accordingly, Defendants are liable under the OPLA to Plaintiff CHRISTINE JOHNSON because Belviq failed to conform to Defendants' representations.

189. As a result of the foregoing, Plaintiff CHRISTINE JOHNSON 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.

190. By reason of the foregoing, Plaintiff CHRISTINE JOHNSON 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.

191. As a result of the foregoing, the Plaintiff CHRISTINE JOHNSON 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 CHRISTINE JOHNSON will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

**THIRD CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**UNIFORM COMMERCIAL CODE**  
**O.R.C. 1302.26**  
**(BREACH OF EXPRESS WARRANTY)**

193. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

194. 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 CHRISTINE JOHNSON.

195. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff CHRISTINE JOHNSON would use, consume, or be affected by Belviq.

196. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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).

197. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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.

198. Upon information and belief, at all relevant times, Defendants expressly warranted to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, that the effectiveness of Belviq outweighed any potential dangers and/or risks.

199. Upon information and belief, at all relevant times, the aforementioned express warranties were made to Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, by way of Belviq's label and information provided to her by Defendants' sales representatives.

200. In or about August 2016, Plaintiff CHRISTINE JOHNSON presented to the office of her prescribing healthcare provider, Dr. Denise Bobouynik, and discussed with her options for weight loss.

201. At this visit, in or about August 2016, Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to her.

202. Upon information and belief, Dr. Denise Bobouynik, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.

203. Upon information and belief, Dr. Denise Bobouynik, obtained the information regarding the efficacy and side effects of Belviq from communications with Defendants' sale representatives.

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

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

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

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

208. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's patient information sheet, that Belviq was an effective drug to use for weight loss.

209. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of Belviq's patient information sheet, that Belviq was a safe drug to use for weight loss.

210. As a result of Defendants' express warranties to her and Dr. Denise Bobouynik, Dr. Denise Bobouynik was induced to prescribe Belviq to Plaintiff CHRISTINE JOHNSON, and Plaintiff CHRISTINE JOHNSON was induced to use Belviq from August 2016 through approximately October 2016.

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

212. At all relevant times, Defendants reasonably anticipated and expected that prescribing healthcare providers, such as the Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, would recommend, prescribe and/or dispense Belviq based upon their express warranties.

213. 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.

214. 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.

215. 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.

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

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

218. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, with the ordinary knowledge common to the community as to the drug's characteristics.

219. 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.

220. 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.

221. 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.

222. The express warranties made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff CHRISTINE JOHNSON to use the product and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe the product.

223. Defendants knew and/or should have known that by making the express warranties to Plaintiff CHRISTINE JOHNSON and/or her prescribing healthcare provider, Dr. Denise Bobouynik, it would be the natural tendency of Plaintiff to use Belviq and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe Belviq.

224. Plaintiff and her prescribing healthcare provider, Dr. Denise Bobouynik, as well as members of the medical community, relied on the express warranties of the Defendants herein.

225. The express warranties made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff CHRISTINE JOHNSON to use the product and/or her prescribing healthcare provider, Dr. Denise Bobouynik, to prescribe the product.

226. Had Defendants not made these express warranties, Plaintiff CHRISTINE JOHNSON would not have used the product and/or, upon information and belief, her prescribing healthcare provider, Dr. Denise Bobouynik, would not have prescribed the product.

227. Plaintiff CHRISTINE JOHNSON's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

228. Plaintiff CHRISTINE JOHNSON's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff CHRISTINE JOHNSON.

229. Defendants are therefore liable to Plaintiffs for their breaches of the aforementioned express warranties under the Uniform Commercial Code, R.S. 1302.26.

230. As a result of the foregoing breaches, Plaintiff CHRISTINE JOHNSON 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.

231. By reason of the foregoing, Plaintiff CHRISTINE JOHNSON 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.

232. As a result of the foregoing acts and omissions the Plaintiff CHRISTINE JOHNSON 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 CHRISTINE JOHNSON will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

**FOURTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**UNIFORM COMMERCIAL CODE**  
**O.R.C. 1302.27**  
**(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)**

234. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

235. 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 CHRISTINE JOHNSON.

236. At the time Defendants marketed, sold, and distributed Belviq for use by Plaintiff CHRISTINE JOHNSON, Defendants knew of the use for which Belviq was intended and impliedly warranted the product to be of merchantable quality and safe and fit for ordinary use.

237. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff CHRISTINE JOHNSON would use, consume, or be affected by Belviq.

238. At all relevant times, Defendants' impliedly warranted to Plaintiff CHRISTINE JOHNSON, her prescribing healthcare provider 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).

239. At all relevant times, Defendants' impliedly warranted to Plaintiff CHRISTINE JOHNSON, her prescribing healthcare provider and the medical community that Belviq was of merchantable quality and 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.

240. At all relevant times, Defendants' impliedly warranted to Plaintiff CHRISTINE JOHNSON, her prescribing healthcare provider and the medical community that Belviq was of



merchantable quality and safe and fit for ordinary use in that the effectiveness of Belviq outweighed any potential dangers and/or risks.

241. 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.

242. 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.

243. 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.

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

245. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by an ordinary healthcare provider, such as Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, with the ordinary knowledge common to the community as to the product's characteristics.

246. 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.

247. 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.

248. 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 the dangers and/or risks associated with the drug.

249. Plaintiff CHRISTINE JOHNSON did rely on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.

250. Plaintiff CHRISTINE JOHNSON 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.

251. Upon information and belief, Plaintiff CHRISTINE JOHNSON's prescribing physician did rely on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.

252. Upon information and belief, Plaintiff CHRISTINE JOHNSON's prescribing physician 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.

253. As a result of Plaintiff CHRISTINE JOHNSON's reasonable reliance upon Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq, she used Belviq.

254. Upon information and belief, as a result of Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider's reasonable reliance upon Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq, she prescribed Belviq to Plaintiff CHRISTINE JOHNSON.

255. 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.

256. Defendants herein breached the aforesaid implied warranties, as their drug Belviq was not merchantable nor fit for its intended purposes and uses in that it had not been properly or sufficiently tested for cancer, it was associated with an increased risk of cancer, it was ineffective as a weight loss drug and/or any benefits the drug did have were outweighed by its risks, particularly its increased risk of cancer.

257. Plaintiff CHRISTINE JOHNSON's injuries and damages were directly caused by Defendants' breach of the aforementioned implied warranties.

258. Plaintiff CHRISTINE JOHNSON's injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by Plaintiff CHRISTINE JOHNSON.

259. Defendants are therefore liable to Plaintiffs for their breaches of the implied warranty of merchantability under the Uniform Commercial Code, R.S. 1302.27.

260. As a result of the foregoing breaches, Plaintiff CHRISTINE JOHNSON 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.

261. As a result of the foregoing acts and omissions the Plaintiff CHRISTINE JOHNSON 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 CHRISTINE JOHNSON will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

**FIFTH CAUSE OF ACTION AS  
AGAINST THE DEFENDANTS  
(FRAUDULENT MISREPRESENTATION)**

263. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

264. At all relevant times, Defendants were under a duty not to deceive the Plaintiff, CHRISTINE JOHNSON, her prescribing physician, Dr. Denise Bobouynik, hospitals, and/or healthcare providers regarding the efficacy and safety of Belviq.

265. Defendants breached this duty not to deceive by falsely and fraudulently representing to Plaintiff CHRISTINE JOHNSON's prescribing physician, Dr. Denise Bobouynik, through the label of Belviq and their sales representatives, that Belviq had been adequately and sufficiently tested and was found to be safe and effective.

266. Defendants breached this duty not to deceive by falsely and fraudulently representing to Plaintiff CHRISTINE JOHNSON, through the patient information sheet for Belviq and through her prescribing physicians, that Belviq had been adequately and sufficiently tested and was found to be safe and effective.

267. Prior to 2016, 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.

268. Nevertheless, in 2016, Defendants falsely represented on the patient information sheet for Belviq, the label of Belviq and through their sales representatives that Belviq was effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

269. Prior to 2016, 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.

270. Nevertheless, in 2016, Defendants falsely represented on the patient information sheet for Belviq, the label of Belviq and through their sales representatives that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.

271. Prior to 2016, Defendants knew or should have known that the effectiveness of Belviq, if any, did not outweigh the dangers and risks associated with Belviq.

272. Nevertheless, in 2016, Defendants falsely represented on the patient information sheet for Belviq, on the label of Belviq and through their sales representatives that the effectiveness of Belviq outweighed the dangers and risks associated with Belviq.

273. Prior to 2016, Defendants knew or should have known that Belviq had not been adequately and/or sufficiently tested for safety.

274. Nevertheless, in 2016, Defendants falsely represented on the patient information sheet for Belviq, that Belviq had been adequately and/or sufficiently tested for safety.

275. Defendants' fraudulent representations as identified herein were done with the intent of defrauding and deceiving consumers, including the Plaintiff CHRISTINE JOHNSON, and prescribing healthcare providers, including Dr. Denise Bobouynik, 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 CHRISTINE JOHNSON.

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

277. Defendants' fraudulent representations as identified herein were done with the intent of inducing prescribing healthcare providers, including the Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, 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 CHRISTINE JOHNSON.

278. In or about August 2016, Plaintiff CHRISTINE JOHNSON presented to the office of Dr. Denise Bobouynik to discuss, among other things, her options for weight loss.

279. At this visit with Dr. Denise Bobouynik in or about August 2016, Dr. Denise Bobouynik discussed and recommended the drug Belviq for Plaintiff CHRISTINE JOHNSON.

280. Upon information and belief, Dr. Denise Bobouynik obtained information regarding the efficacy and side effects of Belviq from the label of Belviq.

281. Upon information and belief, Dr. Denise Bobouynik obtained information regarding the efficacy and side effects of Belviq from communications with Defendants' sales representatives.

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

283. Upon information and belief, Defendants represented to Dr. Denise Bobouynik 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.

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

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

286. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's patient information sheet that Belviq was an effective drug to use for weight loss.

287. In or about August 2016, when Plaintiff CHRISTINE JOHNSON began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's patient information sheet that Belviq was a safe drug to use for weight loss in that it was not associated with an increased risk of cancer.

288. The aforementioned representations made in the patient information sheet and label for Belviq as well as by Defendants' sales representatives were false and deceptively made in that Belviq was not an effective drug to use for weight loss.

289. The aforementioned representations made in the patient information sheet and label for Belviq as well as by Defendants' sales representatives were false and deceptively made in that Belviq was not a safe drug to use for weight loss given its increased risks of cancer.

290. Upon information and belief, in or about August 2016, as a result of the label for Belviq, and particularly as a result of Defendants' fraudulent misrepresentations contained therein,

Plaintiff's prescribing healthcare provider, Dr. Denise Bobouynik, was induced to and did prescribe Belviq to Plaintiff CHRISTINE JOHNSON in August 2016.

291. Upon information and belief, as a result of the fraudulent misrepresentations made by Defendants through their sales representatives, Plaintiff's prescribing healthcare provider, Dr. Denise Bobouynik, was induced to and did prescribe Belviq to Plaintiff CHRISTINE JOHNSON in August 2016.

292. As a result of the patient information sheet for Belviq in or about August 2016, and particularly as a result of Defendants' fraudulent misrepresentations contained therein, Plaintiff CHRISTINE JOHNSON was induced to and did use Belviq between August and approximately October 2016.

293. Upon information and belief, had Defendants not deceived Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, regarding the safety, efficacy and lack of sufficient testing of Belviq, Dr. Denise Bobouynik would not have prescribed Belviq to Plaintiff and/or would have provided Plaintiff with accurate information regarding the efficacy and dangers of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

294. Had Defendants not deceived Plaintiff CHRISTINE JOHNSON regarding the safety, efficacy and lack of sufficient testing of Belviq, Plaintiff would not have used Belviq and/or suffered colon cancer.

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



296. Plaintiff CHRISTINE JOHNSON's prescribing healthcare provider, Dr. Denise Bobouynik, had no way to determine the truth behind Defendants' misrepresentations as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.

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

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

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

300. Defendants could have and should have made accurate representations regarding the safety of Belviq, the lack of efficacy of Belviq and the lack of sufficient testing of Belviq for safety risks through various outlets, including their patient information sheet for Belviq, the label for Belviq and their sales representatives.

301. Defendants' misrepresentations concerning the safety of Belviq, the lack of efficacy of Belviq and the lack of sufficient testing of Belviq for safety risks were made intentionally, purposefully, willfully, wantonly, and/or recklessly, to mislead and deceive Plaintiff CHRISTINE JOHNSON and her prescribing healthcare provider, Dr. Denise Bobouynik, 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.

302. Defendants knew that Plaintiff CHRISTINE JOHNSON and her prescribing healthcare provider, Dr. Denise Bobouynik, had no way to determine the truth behind Defendants' misrepresentations surrounding Belviq, as set forth herein.

303. Plaintiff CHRISTINE JOHNSON's injury and damages were proximately caused by Defendants' fraudulent misrepresentations as set forth herein.

304. Plaintiff CHRISTINE JOHNSON's injury and damages were proximately caused by her reasonable reliance on Defendants' fraudulent misrepresentations as set forth herein.

305. Plaintiff CHRISTINE JOHNSON's injury and damages were proximately caused by her prescribing healthcare provider's reasonable reliance on Defendants' fraudulent misrepresentations as set forth herein.

306. As a result of the foregoing misrepresentations, the Plaintiff CHRISTINE JOHNSON 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.

307. As a result of the foregoing misrepresentations, the Plaintiff CHRISTINE JOHNSON 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 CHRISTINE JOHNSON will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

**SIXTH CAUSE OF ACTION AS  
AGAINST THE DEFENDANTS  
(LOSS OF CONSORTIUM)**

309. Plaintiffs repeat, reiterate and reallege paragraphs 1 through 106 of this Complaint with the same force and effect as if more fully set forth herein.

310. Plaintiff, DENNIS JOHNSON was, at all relevant times, and is the lawful spouse of Plaintiff CHRISTINE JOHNSON, and as such, was and is entitled to the comfort, enjoyment, society, and services of his spouse.

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

312. Plaintiff DENNIS JOHNSON's injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

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

#### **PRAYER FOR RELIEF**

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

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

2. Punitive and/or exemplary damages as allowed for by law, including but not limited to R.S. 3207.80, for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the

general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiffs reasonable attorneys' fees;
4. Awarding Plaintiffs the costs of these proceedings;
5. Pre and post-judgment interest;
6. Trial by Jury; and
7. Such other and further relief as this Court deems just and proper.

### **JURY DEMAND**

Plaintiffs demands a trial by jury of all claims asserted in this Complaint.

Respectfully submitted,

/s/ Richard W. Schulte

**Richard W. Schulte (0066031)**

**WRIGHT & SCHULTE, LLC**

865 S. Dixie Dr.

Vandalia, OH 45377

(937) 435-7500

(937) 435-7511 facsimile

[rschulte@yourlegalhelp.com](mailto:rschulte@yourlegalhelp.com)

*Counsel for Plaintiffs*

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

Christine Johnson and Dennis Johnson

(b) County of Residence of First Listed Plaintiff Mahoning, OH  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Richard W. Schulte  
Wright & Schulte, LLC  
865 S. Dixie Dr., Vandalia, Ohio 45377 937-435-7500

**DEFENDANTS**

EISAI, Inc., et al.

County of Residence of First Listed Defendant Bergen, NJ  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF  
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question  
(U.S. Government Not a Party)
- ☒ 4 Diversity  
(Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input type="checkbox"/> 2            | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice <b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education <b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**V. ORIGIN** (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding    ☐ 2 Removed from State Court    ☐ 3 Remanded from Appellate Court    ☐ 4 Reinstated or Reopened    ☐ 5 Transferred from Another District (specify)    ☐ 6 Multidistrict Litigation - Transfer    ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 U.S.C. § 1332 (Diversity)

Brief description of cause:

Severe and permanent personal injuries caused by Belvig

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$  
75,000.01

CHECK YES only if demanded in complaint:  
JURY DEMAND: ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

04/27/2021

SIGNATURE OF ATTORNEY OF RECORD

/s/ Richard W. Schulte

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
  - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
  - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
- United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

CHRISTINE JOHNSON, ET AL.

*Plaintiff(s)*

v.

EISAI, INC.

*Defendant(s)*

Civil Action No. 4:21-cv-876

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

EISAI Inc.  
100 Tice Blvd.  
Woodcliffe, NJ 07677

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Richard W. Schulte  
Wright & Schulte, LLC  
865 S. Dixie Dr.  
Vandalia, OH 45377

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

Civil Action No. 4:21-cv-876

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*:

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:



Northern District of Ohio

CHRISTINE JOHNSON, ET AL.

Plaintiff(s)

V.

EISAI, INC.

Defendant(s)

Civil Action No. 4:21-cv-876

# SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Arena Pharmaceuticals, Inc.  
c/o Corporation Service Company  
251 Little Falls Dr.  
Wilmington DE, 19808

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Richard W. Schulte  
Wright & Schulte, LLC  
865 S. Dixie Dr.  
Vandalia, OH 45377

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: \_\_\_\_\_

Signature of Clerk or Deputy Clerk

Civil Action No. 4:21-cv-876

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_ .

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_ , and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_ , who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
\_\_\_\_\_ on *(date)* \_\_\_\_\_ ; or

☐ I returned the summons unexecuted because \_\_\_\_\_ ; or

☐ Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: