Michael A. London **DOUGLAS & LONDON, P.C.** 59 Maiden Lane, 6th Floor New York, New York 10038

Telephone: (212) 566-7500

Fax: (212) 566-7501

#### **Attorney for Plaintiffs**

DEBORAH CRAWFORD and BRADLEY TREY	)	SUPERIOR COURT OF NEW
CRAWFORD,	)	JERSEY, LAW DIVISION,
	)	BERGEN COUNTY
Plaintiffs,	)	
	)	CIVIL ACTION NUMBER
v.	)	
EISAI, INC and ARENA PHARMACEUTICALS, INC.,	)	COMPLAINT AND JURY DEMAND
	j i	
Defendants.	,	

Plaintiffs DEBORAH CRAWFORD and BRADLEY TREY CRAWFORD (hereinafter "Plaintiffs"), residents of the State of Louisiana, residing at 7440 C. Jones Lane, Denham Springs, Louisiana 70706, by and through their undersigned attorney(s), **DOUGLAS & LONDON, P.C.**, hereby sue the Defendants named herein and alleges as follows:

#### **BACKGROUND**

- 1. This action is brought by Plaintiff, DEBORAH CRAWFORD, who was injured as a result of her use of Belviq, also known as lorcaserin hydrochloride, as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management.
- 2. This action is brought by Plaintiff, BRADLEY TREY CRAWFORD, who suffered loss of consortium damages as a result of Plaintiff DEBORAH CRAWFORD's use of Belviq and injuries related thereto.
- 3. Defendants, EISAI, INC., along with its parent company Eisai Co., Ltd. (hereinafter collectively referred to as "EISAI"), and Defendant ARENA PHARMACEUTICALS, INC., along with its

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

- 4. At all relevant times, Defendants knew or should have known that Belviq had not been property tested, was not safe because it could cause cancer and/or was not effective for its indicated use.
- 5. When warning of safety and risks of Belviq, Defendants negligently misrepresented and/or fraudulently represented to Plaintiffs, the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), and the public in general, that Belviq had been tested and was found to be safe and/or effective for its indicated use despite their knowledge to the contrary.
- 6. Defendants concealed their knowledge of Belviq's inefficacy and safety risks from Plaintiff DEBORAH CRAWFORD, her prescribing physicians, her healthcare providers, hospitals, pharmacists, the medical and healthcare community, and/or the public in general.
- 7. Defendants' representations and/or omissions were done with the intent of defrauding and deceiving Plaintiff DEBORAH CRAWFORD, her prescribing physicians, her healthcare providers, hospitals, pharmacists, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing Plaintiff DEBORAH CRAWFORD, her prescribing physicians, hospitals, pharmacists, the public in general, and the medical community in particular, to recommend, dispense, prescribed, use and/or purchase Belviq for chronic weight management, all of which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the users of Belviq, including the Plaintiff DEBORAH CRAWFORD.
- 8. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Belviq during clinical trials, forcing Plaintiff DEBORAH CRAWFORD and her physicians, hospitals,

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

- 9. As a result of the acts and omissions of the Defendants, as set forth herein, the Plaintiff DEBORAH CRAWFORD was and still is caused to suffer serious and dangerous side effects including, inter alia, parotid gland cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.
- 10. Plaintiff DEBORAH CRAWFORD sustained the above health consequences due to her use of Belviq and Defendants' actions or omissions, as set forth herein, were a direct and proximate cause of her health consequences.
- 11. Consequently, Plaintiffs seek compensatory damages as a result of Plaintiff DEBORAH CRAWFORD's use of Belviq, which has caused her to suffer from parotid gland cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

#### **JURISDICTION AND VENUE**

- 12. This Court has jurisdiction and venue over this action pursuant to  $\underline{R}$ . 4:3-2(a) because Defendant EISAI, INC. is a citizen and resident of Bergen County, New Jersey with its principal place of business located in Woodcliff Lake, New Jersey. Venue in this Court is proper in that events or omissions giving rise to the claims asserted herein occurred in whole or in part in this County.
- 13. Defendants are subject to personal jurisdiction of this Court. Defendant EISAI, INC. maintains its principal place of business in Bergen County, New Jersey and each Defendant conducts

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

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

#### **PARTY PLAINTIFFS**

- 15. Plaintiff DEBORAH CRAWFORD is a citizen of the United States of America, and is a citizen and resident of the State of Louisiana.
  - 16. Plaintiff DEBORAH CRAWFORD was born on March 18, 1972.
- 17. Plaintiff DEBORAH CRAWFORD first began using Belviq in or about December 2017, and used Belviq up through approximately August 2018.
- 18. The Belviq used by Plaintiff DEBORAH CRAWFORD was prescribed by Dr. Martha Paterson.
- 19. As a result of using Defendants' Belviq, Plaintiff DEBORAH CRAWFORD was caused to suffer from parotid gland cancer on or about August 23, 2018 and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress related thereto.

- 20. The injuries and damages sustained by Plaintiff, DEBORAH CRAWFORD, were caused by Defendants' Belviq.
- 21. Plaintiff BRADLEY TREY CRAWFORD is a citizen of the United States of America, and is a citizen and resident of the State of Louisiana.
- 22. Plaintiff BRADLEY TREY CRAWFORD is the lawful spouse of DEBORAH CRAWFORD and was her lawful spouse at all relevant times.
- 23. Plaintiffs did not know and could not have known that the injuries they suffered were caused by Belviq until after the date Belviq was recalled from the market on February 13, 2020 and Plaintiffs came to learn of the recall.

### **PARTY DEFENDANTS**

- 24. Defendant EISAI, INC. is a Delaware corporation, having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
- 25. As part of its business, EISAI, INC. is involved in the research, development, sales, and marketing of pharmaceutical products including Belviq and lorcaserin hydrochloride.
  - 26. Defendant, EISAI, INC. has transacted and conducted business in the State of New Jersey.
- 27. Defendant, EISAI, INC. has derived substantial revenue from goods and products used in the State of New Jersey.
- 28. Defendant, EISAI, INC. expected or should have expected its acts to have consequence within New Jersey, and derived substantial revenue from interstate commerce within the United States, and the State of New Jersey, more particularly.
- 29. At all relevant times, Defendant, EISAI, INC., was in the business of and was responsible for the design, research manufacturing, testing, labeling advertising, promoting, marketing, selling, and distribution the drug Belviq for use which primary purpose is chronic weight management.

- 30. Defendant, EISAI, INC. is a wholly-owned subsidiary of Eisai Corporation of North America, which in turn is a wholly-owned subsidiary of Eisai Co., Ltd., a Japanese company having a principal place of business located at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan.
- 31. At all relevant times, Eisai Co., Ltd., was in the business of and was responsible for the design, research, manufacturing, testing, labeling advertising, promoting, marketing, selling, and distribution the drug Belviq for use which primary purpose is chronic weight management.
- 32. Defendant, ARENA PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business located at 6154 Nancy Ridge Drive, San Diego, California 92121.
- 33. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., has transacted and conducted business in the State of New Jersey.
- 34. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., has derived substantial revenue from goods and products used in the State of New Jersey.
- 35. Upon information and belief, Defendant, ARENA PHARMACEUTICALS, INC., expected or should have expected its acts to have consequence within New Jersey, and derived substantial revenue from interstate commerce within the United States, and New Jersey, more particularly.
- 36. At all relevant times Defendant ARENA PHARMACEUTICALS, INC. was a biopharmaceutical company focused on discovering, developing and commercializing oral drugs.
- 37. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC., was in the business of and was responsible for the design, research, manufacturing, testing, labeling advertising, promoting, marketing, selling, and distribution the drug Belviq for use which primary purpose is chronic weight management.
- 38. Defendant ARENA PHARMACEUTICALS, INC. is the parent/holding company of Arena Pharmaceuticals GmbH.

- 39. At all relevant times, Arena Pharmaceuticals GmbH was in the business of and was responsible for the design, research, manufacturing, testing, labeling advertising, promoting, marketing, selling, and distribution the drug Belviq for use which primary purpose is chronic weight management.
- 40. Upon information and belief, and at all relevant times, Defendant, ARENA PHARMACEUTICALS, INC, exercised and exercises dominion and control over Arena Pharmaceuticals GmbH, including but not limited to, as it relates to Belviq.

#### **FACTUAL ALLEGATIONS**

#### A. FDA Approval of Belvig in the United States

- 41. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Belviq and lorcaserin hydrochloride for chronic weight management.
- 42. Defendant ARENA PHARMACEUTICALS, INC. submitted the New Drug Application for Belviq to the FDA on or about December 18, 2009 requesting that the FDA grant it approval to market and sell Belviq, also known as lorcaserin hydrochloride, in the United States as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a body mass index (hereinafter referred to as "BMI") greater than or equal to 30 kg/m² or adult patients with a BMI greater than or equal to 27 kg/m² and at least one weight-related comorbid condition.
- 43. On June 27, 2012, the FDA approved Defendant ARENA PHARMACEUTICALS, INC.'s request to market and sell Belviq in the United States as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a BMI greater than or equal to 30 kg/m<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.

- 44. ARENA and EISAI jointly launched Belviq in the United States in 2012, pursuant to the terms of the Amended and Restated Marketing and Supply Agreement, they entered into May 2012.<sup>1</sup>
- 45. The exact terms of the Amended and Restated Marketing and Supply Agreement are within the possession, custody and control of Defendants.
- 46. Defendant ARENA PHARMACEUTICALS, INC. entered into the Amended and Restated Marketing and Supply Agreement with EISAI to establish a collaboration to support Belviq's development, approval and commercialization.
- 47. Following the FDA's approval of Belviq, Defendant ARENA PHARMACEUTICALS, INC. announced on its website that its then current strategy was to first focus its efforts on the commercialization of Belviq in North and South America pursuant to the terms of the Amended and Restated Marketing and Supply Agreement with EISAI.
- 48. Following FDA approval, Defendant ARENA PHARMACEUTICALS, INC. promoted the safety, efficacy and sale of Belviq in the United States on its website, in press releases, through in-person presentations at conferences, in the drug's label, in print materials, through websites associated with Belviq, such as belviqnow.com, as well as other public outlets.
- 49. At all relevant times, ARENA PHARMACEUTICALS, INC. maintained responsibility with Defendant EISAI for the commercialization, marketing, distribution and sale of Belviq in the United States.
- 50. Four years later, on July 15, 2016, in response to an application submitted by Defendant ARENA PHARMACEUTICALS, INC to the FDA, Defendant ARENA PHARMACEUTICALS, INC. 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").

8

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

- 51. Belviq XR was jointly launched by ARENA and EISAI in the United States in 2016 pursuant to the terms of the Second Amended and Restated Marketing and Supply Agreement, they entered into in November 2013.
- 52. The exact terms of the Second Amended and Restated Marketing and Supply Agreement are within the possession, custody and control of Defendants.
- 53. Defendant ARENA PHARMACEUTICALS, INC. entered into the Second Amended and Restated Marketing and Supply Agreement with EISAI to establish a collaboration to support Belviq's development, approval and commercialization.
- 54. Following the FDA's approval of Belviq XR, Defendant ARENA PHARMACEUTICALS, INC. promoted the safety, efficacy and sale of Belviq XR in the United States on its website, in press releases, through in-person presentations at conferences, in the drug's label, in print materials, through websites associated with Belviq, such as belviqnow.com, as well as other public outlets.
- 55. At all relevant times, ARENA PHARMACEUTICALS, INC. maintained responsibility with Defendant EISAI for the commercialization, marketing, distribution and sale of Belviq XR in the United States.
  - 56. In 2017, EISAI purchased the global rights to develop and market Belviq from ARENA.
- 57. The exact terms of the purchase identified in paragraph 56 are within the possession, custody and control of Defendants.
- 58. The aforementioned purchase identified in paragraph 56 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. <a href="https://www.eisai.com/news/news201701.html">https://www.eisai.com/news/news201701.html</a>.

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

- 59. Belviq is a first-in-class oral selective serotonin 5HT2c receptor agonist and is available by prescription only in oral tablets at doses of 10mg taken twice daily or 20mg extended release taken once daily.
- 60. During the preclinical trial program for Belviq, Defendants conducted a two-year carcinogenicity study in rats (hereinafter referred to as the "two-year carcinogenicity rat study") in which lorcaserin was identified as a non-genotoxic carcinogen that induced multiple tumor types; this identification was primarily due to an increase in mammary tumors found in both sexes near clinical exposure and at all doses in female rats.
- 61. This same preclinical, two-year carcinogenicity rat study also revealed an increase in astrocytomas, malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skin squamous carcinoma, and thyroid follicular cell adenoma in male rats. Adenocarcinoma diagnosed in the lorcaserin groups were associated with increased tumor onset, multiplicity, and lung metastases. Fibroadenoma in the lorcaserin groups also demonstrated greater incidence and multiplicity.
- 62. While the two-year carcinogenicity rat study was ongoing, the FDA required bi-monthly updates from Defendants due to the consistently increased incidence of tumors and mortality that was being seen in the lorcaserin groups. However, in the final report of the study, Defendants reported that the incidence of adenocarcinoma was lower in the mid- and high-dose groups than that previously reported at week 96, and that it had increased in the control group. The final report also revealed that the incidence of fibroadenoma had increased across all doses from week 96, with notable variations in the mid- and high-

dose groups. Due to the apparent increase in fibroadenoma accompanying the decrease in adenocarcinoma after week 96, the FDA suspected that study investigators had reclassified tumor types.

- 63. 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.
- 64. In addition to two-year carcinogenicity rat study, during the preclinical trial program, Defendants also conducted a two-year carcinogenicity study in mice (hereinafter referred to as the "two-year carcinogenicity mouse study"), which demonstrated an increase in malignant hepatocellular carcinoma in males and schwannoma in females. Although the dosing levels were below the clinical dose, these findings provide further context and support for for the potential carcinogenicity of lorcaserin, particularly in combination with the results of the two-year carcinogenicity rat study.
- 65. The two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or a combination of both, put Defendants on notice and/or should have put Defendants on notice that lorcaserin was a carcinogen and/or that further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under New Jersey law.
- 66. 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.

- 67. 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.
- 68. Combined data from the BLOOM and BLOSSOM trials demonstrated only a 3.3% mean weight loss after one year with lorcaserin over that of the placebo group, demonstrating that lorcaserin failed to meet the mean efficacy criterion of FDA's obesity draft guidance.
- 69. On December 18, 2009, Defendant ARENA PHARMACEUTICALS, INC. submitted its first New Drug Application for Belviq seeking to market and distribute Belviq in the United States.
- 70. On September 16, 2010, the Endocrinologic and Metabolic Drugs Advisory Committee (hereinafter referred to as "EMDAC") met to discuss approval of Belviq based on the results of preclinical trials and the BLOOM and BLOSSOM Phase 3 clinical trials. The EMDAC panel voted nine (9) to five (5) against approval of Belviq as the potential benefits did not outweigh the potential risks based on concerns about the preclinical carcinogenicity findings (i.e., increased mammary adenocarcinoma/fibroadenoma and brain astrocytomas in rats) and marginal weight loss demonstrated by the clinical trials.
- 71. 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.

- 72. In response to the CRL, Defendants convened a pathology working group (hereinafter referred to as "PWG") to blindly re-adjudicate the preclinical mammary tumor data in rats.
- 73. 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.
- 74. From December 2007 to August 2010, Defendants conducted the Behavioral modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus (BLOOM-DM) trial a one-year, randomized, placebo-controlled trial involving 604 patients to examine the efficacy and safety of lorcaserin for weight loss in patients with Type 2 Diabetes Mellitus in the United States. After one year, there was only a 3.1% mean weight loss with lorcaserin over that of the placebo group. In April 2012, the results of the BLOOM-DM trial were published in the journal of The Obesity Society. O'Neil, P.M., et al. *Randomized Placebo-Controlled Clinical Trial of Lorcaserin for Weight Loss in Type 2 Diabetes Mellitus: The BLOOM-DM Study*. Obesity 2012;20:1426-1436.
- 75. On December 27, 2011, in response to the CRL, Defendants submitted to the FDA the final report of the BLOOM-DM study and data from the PWG readjudication, as well as new studies Defendants claimed supported their continued assertion that the increase in tumors seen in the two-year carcinogenicity rat study was due to elevated prolactin levels induced by lorcaserin, again claiming it was a rodent-specific phenomenon.
- 76. 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.

- 77. As to the PWG re-adjudication, for adenocarcinoma, the number decreased to a larger extent in the lorcaserin group compared to the control group, but lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma, and the high-dose lorcaserin group maintained a statistically significant increase in adenocarcinomas compared to the control group. Regarding fibroadenoma, there was an increase in the incidence, tumor onset and multiplicity, and lethality across all lorcaserin dose groups compared to the control group; yet despite their relevance, these results were disregarded as irrelevant to risk of carcinoma in FDA's review of the readjudication data.
- 78. Upon information and belief, the PWG re-adjudication procedure and its results were misadjudicated, misapplied, misinterpreted and/or otherwise skewed in favor of Defendants and, particularly, a finding that lorcaserin was not a carcinogen; nevertheless, even if accepted as true, the results of the PWG re-adjudication, reviewed separately and/or in combination with the initial results of the two-year carcinogenicity rat study, the two-year carcinogenicity mouse study and/or both, put Defendants on notice or should have put Defendants on notice that lorcaserin was a carcinogen and/or that further testing needed to be done, testing that would have confirmed lorcaserin as a carcinogen. Based upon the foregoing, this is an unsafe product and unreasonably dangerous product under New Jersey law.
- 79. On May 10, 2012, a second EMDAC panel met to discuss approval of Belviq with a focus on the PWG readjudication of preclinical data to determine the drug's potential carcinogenicity risk, to determine a safety margin for astrocytoma by looking at lorcaserin levels in human cerebrospinal fluid, and to discuss the results of the BLOOM-DM Phase 3 clinical trial to further determine efficacy. The panel voted 18 to four (4) (with one abstention) that the benefits of Belviq outweighed the risks for an overweight and obese population. The panel also recommended a post-approval assessment of risk for Belviq, with a focus on cardiovascular risk. Ultimately, the FDA required that Defendants conduct six (6) post-marketing studies, including a cardiovascular outcomes trial.

- 80. 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.
- 81. 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").
- 82. In reviewing the data submitted by Defendants, the EMA Committee for Medicinal Products for Human Use (hereinafter referred to as "CHMP") determined that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG re-adjudication, the risk of carcinogenicity in humans needed further consideration and the overall clinical risk/benefit balance was negative in that the modest efficacy results did not outweigh safety concerns. The CHMP further stated that the increased occurrence of several tumor types in male rats was particularly concerning due to the lack of any persuasive mechanism of action that would provide assurance of safety in human use, which also undermined any discussion on exposure margins. Thus, the CHMP concluded that the clinical relevance of the tumors found in the two-year carcinogenicity rat study must be evaluated as part of the risk-benefit assessment.

- 83. 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).
- 84. CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving 12,000 patients conducted in the United States, Canada, Mexico, the Bahamas, Europe, South America, Australia, and New Zealand to evaluate the risk of heart-related issues with Belviq. The primary safety outcome of major adverse cardiovascular events showed noninferiority. The results of CAMELLIA-TIMI 61 were published in September 2018 in NEJM. Bohula, E.A., et al. *Cardiovascular Safety of Lorcaserin in Overweight or Obese Patients*. N. Engl. J. Med. 2018;379:1107-17.
- 85. 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.
- 86. 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.

- 87. 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.
- 88. 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.
  - 89. The aforementioned facts support that Belviq is associated with an increased risk of cancer.
- 90. The aforementioned facts support that the efficacy of Belviq is not outweighed by its safety risks, particularly its increased risk of cancer.
- 91. The aforementioned facts support that Belviq was not sufficiently and/or adequately tested for safety by Defendants.
- 92. 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.
- 93. Upon information and belief, despite cancer findings in animal carcinogenicity studies, Defendants failed to adequately conduct complete and proper testing of Belviq prior to filing the New Drug Application for Belviq.
- 94. From the date Defendants received FDA approval to market Belviq, Defendants made, distributed, marketed, and sold Belviq without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Belviq was associated with and/or could cause cancer, presented a risk of cancer in patients

who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Belviq with regard to carcinogenicity.

- 95. Upon information and belief, Defendants ignored the association between the use of Belviq and the risk of developing cancer.
- 96. 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.
- 97. By reason of the foregoing acts and omissions, the Plaintiff DEBORAH CRAWFORD was and still is caused to suffer from parotid gland 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.
- 98. Plaintiff DEBORAH CRAWFORD has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff has suffered serious and dangerous side effects including, <u>inter alia</u> parotid gland 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.
- 99. By reason of the foregoing, Plaintiff DEBORAH CRAWFORD 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.

## <u>COUNT I</u> <u>PRODUCT LIABILITY ACT – DESIGN DEFECT</u> (N.J.S.A. 2A:58C-1 et seq.)

- 100. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 101. 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 DEBORAH CRAWFORD.
- 102. At all times material to this action, Belviq was defective and unreasonably dangerous to consumers.
- 103. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants and was placed in the stream of commerce, it was not reasonably safe, not reasonably fit and not reasonably suitable for its intended purpose a weight loss drug.
- 104. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, its foreseeable risks exceeded the benefits associated with its design and formulation.
- 105. At all times material to this action, given its lack of efficacy and increased safety risks Belviq, Belviq did not met the reasonable expectations of an ordinary consumer, particularly the Plaintiff DEBORAH CRAWFORD.
- 106. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, it was more dangerous than an ordinary consumer would expect.

- 107. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, it was more dangerous than other weight loss drugs on the market.
- 108. At all times material to this action, Belviq was defective in design and/or formulation, in that, when it left the hands of the Defendants' and was placed in the stream of commerce, Defendants knew or should have known that the design of Belviq posed a substantial likelihood of harm (i.e. cancer) to Plaintiff and other users of Belviq.
- 109. At all times material to this action, Belviq was expected to reach, and did reach, consumers, handlers, and persons coming into contact with Belviq in the State of New Jersey and throughout the United States, including the Plaintiff DEBORAH CRAWFORD, without substantial change in the condition in which it was produced, manufactured, sold and/or distributed.
- 110. Belviq's defective design and/or formulation existed before it left the control of the Defendants.
- 111. At all times herein mentioned, Belviq was defective in design and/or formulation and Defendants knew or had reason to know that Belviq was defective in design and/or formulation, especially when used in the form and manner as provided by the Defendants.
- 112. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, was inherently dangerous and unsafe as it had the propensity to cause cancer.
- 113. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, had not been sufficiently tested for its safety risks, particularly as to its increased risk of cancer.

- 114. At all times herein mentioned, Defendants knew, or should have known, that Belviq, as designed and formulated, caused an increased risk of cancer that outweighed any potential efficacy the drug may have had.
- 115. Defendants, with this knowledge, voluntarily designed its Belviq in a dangerous condition for use by the public, and in particular the Plaintiff DEBORAH CRAWFORD.
- 116. At the time of the Plaintiff DEBORAH CRAWFORD'S use of Belviq, Belviq was being used for the purposes and in a manner normally intended, namely for chronic weight management.
- 117. Defendants had a duty to create and design a product that was not unreasonably dangerous for its normal, intended use.
- 118. Defendants created and designed a product unreasonably dangerous for its normal, intended use.
- 119. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design and formulation because there existed an economically and scientifically feasible, safer alternative design for Belviq that was capable of preventing Plaintiff DEBORAH CRAWFORD'S injuries and damages an alternative design that was and is in the exclusive possession, custody and control of Defendants.
- 120. Upon information and belief, at all relevant times and at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design and formulation because there existed an economically and scientifically feasible, safer alternative design for Belviq, the utility of which outweighed the utility of the design that was actually used for Belviq.
- 121. 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.

- 122. Upon information and belief, the safer, feasible alternative design for Belviq would not have impaired the reasonably anticipated or intended function of the product.
- 123. Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, could not, by the exercise of reasonable care, have discovered Belviq's design defect and perceived its danger.
- 124. 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 DEBORAH CRAWFORD in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff DEBORAH CRAWFORD.
- 125. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiffs.
- 126. Defendants' defective design of Belviq were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 127. That said design defects in Defendants' drug Belviq were a substantial factor in causing Plaintiff DEBORAH CRAWFORD'S injuries.
- 128. That said design defects in Defendants' drug Belviq were the direct and proximate cause of Plaintiff DEBORAH CRAWFORD'S injuries.
- 129. As a direct and proximate result of the design defect, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.

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

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

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

- 131. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 132. 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 DEBORAH CRAWFORD.
- 133. At all relevant times, Defendants knew or should have known that Belviq created a risk of serious and dangerous side effects, particularly cancer, as well as other severe and personal injuries which are permanent and lasting in nature
- 134. At all relevant times, Defendants knew or should have known that they had failed to adequately and/or sufficiently test Belviq despite their clinical trials and/or other evidence demonstrating an increased risk of cancer associated with Belviq.
- 135. At all times material to this action, Belviq was defective and unreasonably dangerous to consumers.

- 136. At all times material to this action, Belviq was defective due to inadequate and/or insufficient warnings or instructions because Defendants failed to warn Plaintiff and her prescribing physician, Dr. Martha Paterson, of the of the increased risk of cancer associated with Belviq.
- 137. At all times material to this action, Belviq was defective due to inadequate and/or insufficient warnings or instructions because Defendants failed to warn Plaintiff and her prescribing physician, Dr. Martha Paterson, that they had failed to adequately and/or sufficiently test Belviq despite their clinical trials and/or other evidence demonstrating an increased risk of cancer associated with Belviq.
- 138. At all times material to this action, Belviq was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects associated with Belviq, including parotid gland cancer, as well as other forms of cancer, they failed to provide adequate warnings to users or consumers of the product, such as Plaintiff and her prescribing physician, Dr. Martha Paterson, and continued to improperly advertise, market and/or promote Belviq.
- 139. The label for Belviq was inadequate because it did not warn and/or adequately warn of the increased cancer risk associated with Belviq.
- 140. 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.
- 141. At all times material to this action, Defendants knew or should have known that Belviq created a risk of serious and dangerous side effects including parotid gland cancer, as well as other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately or sufficiently warn of the drug's lack of testing and/or the need to conduct additional testing in light of its clinical studies demonstrating an increased risk of cancer.

- 142. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product without adequate warnings or instructions regarding its increased risk of cancer which created an unreasonable risk to the health of consumers and to the Plaintiff DEBORAH CRAWFORD in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff DEBORAH CRAWFORD.
- 143. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product without adequate warnings or instructions regarding its lack of adequate and sufficient testing which created an unreasonable risk to the health of consumers and to the Plaintiff DEBORAH CRAWFORD in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff DEBORAH CRAWFORD.
- 144. Defendants, as designers, manufacturers and/or distributors of Belviq, are held to the level of knowledge of an expert in the field.
- 145. Communications made by Defendants to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, were inadequate and insufficient because Defendants failed to warn and/or adequately warn of the increased cancer risk associated with Belviq.
- 146. Communications made by Defendants to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, were inadequate and insufficient because Defendants failed to warn and/or adequately warn that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.
- 147. Plaintiff DEBORAH CRAWFORD reasonably relied upon the skill, superior knowledge and judgement of the Defendants.
- 148. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, reasonably relied upon the skill, superior knowledge and judgement of the Defendants.

- 149. Defendants had a continuing duty to warn the Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, of the increased risk of cancer associated with Belviq and that its increased risk of cancer outweighed any benefits the drug may have.
- 150. Defendants had a continuing duty to warn the Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer.
- 151. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, been warned of the increased cancer risk associated with Belviq, she would not have prescribed Belviq and/or would have provided Plaintiff DEBORAH CRAWFORD with adequate warnings regarding the dangers of Belviq so as to allow her to make an informed decision regarding her use of Belviq.
- 152. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, 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 DEBORAH CRAWFORD with adequate warnings regarding the dangers of Belviq so as to allow her to make an informed decision regarding her use of Belviq.
- 153. Had Plaintiff DEBORAH CRAWFORD been warned of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered parotid gland cancer.
- 154. Had Plaintiff DEBORAH CRAWFORD 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 parotid gland cancer.
- 155. At the time of the Plaintiff DEBORAH CRAWFORD's use of Belviq, Belviq was being used for the purposes and in a manner normally intended, namely for chronic weight management.

- 156. Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, could not, by the exercise of reasonable care, have discovered Belviq's defect in its warnings and instructions and perceived its dangers.
  - 157. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiffs.
- 158. Defendants' inadequate warnings with respect to Belviq were acts that amounted to willful, wanton, and/or reckless conduct by Defendants.
- 159. That said inadequate warnings with respect to Belviq were a substantial factor in causing Plaintiff DEBORAH CRAWFORD'S injuries.
- 160. That said inadequate warnings with respect to Belviq were the direct and proximate cause of Plaintiff DEBORAH CRAWFORD'S injuries.
- 161. As a direct and proximate result of the inadequate warnings defect, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotic gland 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.
- 162. As a direct and proximate result of the inadequate warnings defect, the Plaintiff DEBORAH CRAWFORD did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

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

# COUNT III BREACH OF EXPRESS WARRANTY (New Jersey Law)

- 163. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 164. 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 DEBORAH CRAWFORD.
- 165. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff DEBORAH CRAWFORD would use, consume, or be affected by Belviq based upon their express warranties.
- 166. At all relevant times, Defendants reasonably anticipated and expected that physicians, such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, would recommend, dispense or prescribe Belviq based upon their express warranties.
- 167. Defendants had a duty to use reasonable care in the research, development, design, testing, manufacturing, labeling distribution, marketing, promotion and/or sale of Belviq, including duties to ensure that the product did not cause the user to suffer unreasonably dangerous side effects such as cancer, to warn of dangerous side effects and/or complications, such as cancer; and to disclose such adverse material facts when making representations and warranties to consumers and physicians.
- 168. At all relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff DEBORAH CRAWFORD, and physicians such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, without adequately warning them of the increased cancer risk associated with the use of Belviq.

- 169. All relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff DEBORAH CRAWFORD, and physicians such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, without adequately warning them that Belviq had not been adequately or sufficiently tested for safety risks, including the increased risk of cancer.
- 170. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, 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).
- 171. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, 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.
- 172. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, that the effectiveness of Belviq outweighed any potential dangers and/or risks.
- 173. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physicians and the medical community that any and all side effects Belviq did produce were accurately reflected in the warnings and instructions.
- 174. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physicians and the medical community that Belviq had been adequately and sufficiently tested.

- 175. The aforementioned express warranties were made to Plaintiff DEBORAH CRAWFORD by way of Belviq's label.
- 176. Upon information and belief, the aforementioned express warranties were made to Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, by way of Belviq's label.
- 177. In or about December 2017, Plaintiff DEBORAH CRAWFORD presented to the office of her prescribing physician, Dr. Martha Paterson, and they discussed her need for weight loss.
- 178. At this visit, in or about December 2017, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to her.
- 179. Upon information and belief, Dr. Martha Paterson, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.
- 180. Upon information and belief, Defendants expressly warranted to Dr. Martha Paterson, by way of the product's label, that Belviq was an effective drug to use for weight loss.
- 181. Upon information and belief, Defendants expressly warranted to Dr. Martha Paterson, by way of the product's label, that Belviq was a safe drug to use for weight loss.
- 182. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was an effective drug to use for weight loss.
- 183. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was a safe drug to use for weight loss.

- 184. As a result of Defendants' express warranties to her and Dr. Martha Paterson, Dr. Martha Paterson was induced to prescribe Belviq to Plaintiff DEBORAH CRAWFORD, and Plaintiff DEBORAH CRAWFORD was induced to use Belviq from December 2017 through August 2018.
- 185. 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.
- 186. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because its warnings and instructions did not accurately reflect any and all side effects caused by Belviq, particularly cancer.
- 187. At all relevant times, Defendants knew or should have known that Belviq was unreasonably dangerous because they had failed to adequately and sufficiently test Belviq regarding its propensity to cause cancer.
- 188. 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.
- 189. 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.
- 190. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD, with the ordinary knowledge common to the community as to the drug's characteristics.
- 191. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, with the ordinary knowledge common to the community as to the drug's characteristics.

- 192. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because Belviq was not safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI, in that it was associated with an increased risk of cancer.
- 193. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because its warnings and instructions did not accurately reflect any and all side effects caused by Belviq, particularly cancer.
- 194. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because they had failed to adequately or sufficiently test Belviq regarding its propensity to cause cancer.
- 195. 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.
- 196. 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.
- 197. The express warranties made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff DEBORAH CRAWFORD to use the product and/or her prescribing physician, Dr. Martha Paterson, to prescribe the product.
- 198. Defendants knew and/or should have known that by making the express warranties to Plaintiff DEBORAH CRAWFORD and/or her prescribing physician, Dr. Martha Paterson,, it would be the natural tendency of Plaintiff to use Belviq and/or her prescribing physician, Dr. Martha Paterson, to prescribe Belviq.

- 199. Plaintiff and her prescribing physician, Dr. Martha Paterson, as well as members of the medical community, justifiably and detrimentally relied on the express warranties of the Defendants identified herein.
- 200. The express warranties made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff DEBORAH CRAWFORD to use the product and/or her prescribing physician, Dr. Martha Paterson, to prescribe the product.
- 201. Had Defendants not made these express warranties, Plaintiff DEBORAH CRAWFORD would not have used the product and/or, upon information and belief, her prescribing physician, Dr. Martha Paterson, would not have prescribed the product.
- 202. Plaintiff DEBORAH CRAWFORD had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.
- 203. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.
- 204. Plaintiff DEBORAH CRAWFORD's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.
- 205. Plaintiff DEBORAH CRAWFORD'S injuries and damages arose from a reasonably anticipated use of the product by Plaintiff DEBORAH CRAWFORD.
- 206. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff DEBORAH CRAWFORD.
- 207. As a direct and proximate result of the foregoing breach, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.

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

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

## <u>COUNT IV</u> <u>PRODUCT LIABILITY – BREACH OF IMPLIED WARRANTY</u> (N.J.S.A. 2A:58C-1 et seq.)

- 209. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 210. 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 DEBORAH CRAWFORD.
- 211. At the time Defendants designed, manufactured, marketed, sold, and/or distributed Belviq for use by Plaintiff DEBORAH CRAWFORD, 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.
- 212. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff DEBORAH CRAWFORD would use, consume, or be affected by Belviq.

- 213. At all relevant times, Defendants reasonably anticipated and expected that physicians, such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, would recommend, prescribe and/or dispense Belviq for use by their patients as a weight loss medication.
- 214. At all relevant times, Defendants' impliedly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, 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 BMI.
- 215. At all relevant times, Defendants' impliedly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, 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.
- 216. At all relevant times, Defendants' impliedly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, 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.
- 217. 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.
- 218. 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.

- 219. 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.
- 220. At all relevant times, Defendants knew or should have known that Belviq had not been sufficiently and/or adequately tests for safety risks, including cancer.
- 221. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD, with the ordinary knowledge common to the community as to the product's characteristics.
- 222. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary physician such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, with the ordinary knowledge common to the community as to the product's characteristics.
- 223. 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.
- 224. 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.
- 225. 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.

- 226. At all relevant times and at the time Belviq left the Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate because Belviq had not been sufficiently and/or adequately tested regarding its safety risks, including cancer.
- 227. Plaintiff DEBORAH CRAWFORD relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.
- 228. Plaintiff DEBORAH CRAWFORD relied upon the skill and judgment of Defendants as to whether Belviq was of merchantable quality and safe and fit for its intended use.
- 229. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to Belviq.
- 230. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, relied upon the skill and judgment of Defendants as to whether Belviq was of merchantable quality and safe and fit for its intended use.
- 231. 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.
- 232. Defendants herein breached the aforesaid implied warranties, as their drug Belviq was not merchantable nor fit for its intended purposes and uses.
- 233. Plaintiff DEBORAH CRAWFORD would not have used Belviq and/or, upon information and belief, her prescribing physician, Dr Martha Paterson, would not have prescribed Belviq but for the aforesaid implied warranties.

- 234. Plaintiff DEBORAH CRAWFORD's injuries and damages were directly and proximately caused by Defendants' breach of the aforementioned implied warranties.
- 235. Plaintiff DEBORAH CRAWFORD'S injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by Plaintiff DEBORAH CRAWFORD.
- 236. As a direct and proximate result of the foregoing breach, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.
- 237. As a direct and proximate result of the foregoing breach, the Plaintiff DEBORAH CRAWFORD did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

### <u>COUNT V</u> <u>PRODUCT LIABILITY – NEGLIGENCE</u> (N.J.S.A. 2A:58C-1 et seq.)

- 238. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 239. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was not safe for human consumption because it caused unreasonably dangerous side effects, including cancer.

- 240. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that the safety risks of Belviq (i.e. its carcinogenicity) outweighed any benefits Belviq may have.
- 241. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq had not been properly, adequately or sufficiently tested for safety when they were in possession of information that signaled that Belviq could cause cancer and/or the cancer risk needed further testing and studies prior to its introduction to the market.
- 242. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was unreasonably dangerous because of inadequate warnings, because they did not adequately warn of its risks of cancer, especially when used in the form and manner as provided by Defendants.
- 243. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that Belviq was unreasonably dangerous because of its design defects, especially when used in the form and manner as provided by Defendants.
- 244. At all relevant times and at the time Belviq left the Defendants' control, Defendants knew or should have known that the design of Belviq posed a substantial likelihood of harm (i.e. cancer) to Plaintiff DEBORAH CRAWFORD and other users of Belviq.
- 245. 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 an economically and scientifically feasible, safer alternative design for Belviq that was capable of preventing Plaintiff DEBORAH CRAWFORD's injuries and damages an alternative design that was and is in the exclusive possession, custody and control of Defendants.

- 246. 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 an economically and scientifically feasible, safer alternative design for Belviq, the utility of which outweighed the utility of the design that was actually used for Belviq.
- 247. 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.
- 248. Upon information and belief, the safer, feasible alternative design for Belviq would not have impaired the reasonably anticipated or intended function of the product.
- 249. Despite the fact that Defendants knew or should have known that Belviq caused unreasonably dangerous side effects, Defendants continued to design, manufacture, market, distribute, and/or sell Belviq to consumers, including the Plaintiff DEBORAH CRAWFORD.
- 250. Despite the fact that Defendants knew or should have known that Belviq caused unreasonably dangerous side effects, Defendants continued to, market Belviq to prescribing physicians, including Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson.
- 251. Defendants knew or should have known that consumers such as the Plaintiff DEBORAH CRAWFORD would foreseeably suffer injury as a result of their failure to exercise ordinary care, as set forth herein.
- 252. At all relevant times, given its lack of efficacy and increased safety risks, Belviq was not fit for the ordinary purpose for which it was intended a weight loss drug.
- 253. At all relevant times, given its lack of efficacy and increased safety risks, Belviq did not meet the reasonable expectations of an ordinary consumer, particularly the Plaintiff DEBORAH CRAWFORD.

- 254. Defendants had a duty to exercise reasonable care in the designing, researching, testing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Belviq into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.
- 255. Defendants had a duty to warn Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, of all safety risks associated with Belviq, including its increased risk of causing cancer.
- 256. Defendants had a duty to warn Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, that Belviq had not been adequately and/or sufficiently tested regarding its carcinogenicity.
  - 257. Defendants had a duty to adequately and sufficiently test Belviq.
  - 258. Defendants had a duty to design Belviq in a manner that was safe to its users.
- 259. Defendants breached their duties to Plaintiffs by failing to exercise ordinary care in the designing, researching, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Belviq into interstate commerce in that Defendants knew or should have known that using Belviq created a high risk of unreasonable, dangerous side effects, including, cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.
- 260. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:
  - (a) Promoting, formulating, creating and/or designing Belviq without thoroughly testing it;

- (b) Promoting, formulating, creating and/or designing Belviq without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether Belviq was safe for use, in that Defendants herein knew or should have known that Belviq was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling Belviq without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Plaintiff, her prescribing physician, the public, the medical and healthcare profession, and/or the FDA of the dangers of Belviq;
- (f) Failing to provide adequate instructions to Plaintiff and her prescribing physician regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Belviq;
- (g) Failing to test Belviq and/or failing to adequately, sufficiently, and properly test Belviq;
- (h) Negligently advertising and recommending the use of Belviq without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that Belviq was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently representing that the benefits of Belviq outweigh its risks;
- (k) Negligently representing that Belviq had equivalent safety and efficacy as other forms of treatment for chronic weight management;
- (l) Negligently designing Belviq in a manner which was dangerous to its users;
- (m) Concealing information concerning FDA warnings from the Plaintiff and her prescribing physician in knowing that Belviq was unsafe, dangerous, and/or non-conforming with FDA regulations; and

- (n) Improperly concealing and/or misrepresenting information from the Plaintiff, her prescribing physician, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Belviq compared to other forms of treatment for chronic weight management.
- 261. Defendants under-reported, underestimated and downplayed the serious dangers of Belviq.
- 262. Defendants negligently compared the safety risk and/or dangers of Belviq with other forms of treatment for chronic weight management.
- 263. Defendants were negligent in the designing, researching, supplying, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of Belviq in that they:
  - (a) Failed to use due care in designing Belviq so as to avoid the aforementioned risks to individuals when Belviq was used for chronic weight management;
  - (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Belviq;
  - (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Belviq;
  - (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Belviq;
  - (e) Failed to warn Plaintiff and her prescribing physician of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
  - (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Belviq;
  - (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Belviq, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and
  - (h) Were otherwise careless and/or negligent.

- 264. The label for Belviq was inadequate because it did not warn of the increased cancer risk associated with Belviq.
- 265. The label for Belviq was inadequate because it did not warn that Belviq had not been adequately and/or sufficiently tested for safety.
- 266. Communications made by Defendants to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, were inadequate because Defendants failed to warn of the increased cancer risk associated with Belviq.
- 267. Communications made by Defendants to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, were inadequate because Defendants failed to warn that Belviq had not been adequately and/or sufficiently tested for safety risks, including the increased risk of cancer.
- 268. Upon information and belief, had Plaintiff's prescribing physician Dr. Martha Paterson, been warned of the increased cancer risk associated with Belviq, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.
- 269. Upon information and belief, had Plaintiff's prescribing physician, Dr. Martha Paterson, been warned that Belviq had not been adequately and/or sufficiently tested for safety risks, including the increased risk of cancer, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.
- 270. Had Plaintiff been warned of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered parotid gland cancer.

- 271. Had Plaintiff been warned that Belviq had not been adequately and/or sufficiently tested for safety risks, including the increased risk of cancer, she would not have used Belviq and/or suffered parotid gland cancer.
- 272. Defendants' negligence in failing to warn Plaintiff and/or her prescribing physician, Dr. Martha Paterson, of the dangers associated with their Belviq was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.
- 273. Defendants' negligence in failing to sufficiently and/or adequately test Belviq was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.
- 274. Defendants' negligence in defectively designing Belviq was the proximate cause of Plaintiff's injuries, harm, and economic loss which Plaintiff suffered and/or will continue to suffer.
- 275. Plaintiff DEBORAH CRAWFORD's injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by Plaintiff DEBORAH CRAWFORD.
- 276. Defendants' negligence was the proximate cause of Plaintiff DEBORAH CRAWFORD's injuries, harm and economic loss which Plaintiffs suffered and/or will continue to suffer.
- 277. As a direct and proximate result of the foregoing negligence, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.
- 278. As a direct and proximate result of the foregoing negligence, the Plaintiff DEBORAH CRAWFORD did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

# VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:8-1 et seg.)

- 279. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 280. The subject product is considered "merchandise" as that term is defined by N.J.S.A. 56:8-1(c).
- 281. Defendants are designers, researchers, testers manufacturers, promoters, marketers, developers, sellers and/or distributors of Belviq.
- 282. Defendants knew, or should have known, that Belviq was unreasonably dangerous and defective in that it had a propensity to cause cancer, that it was not effective as a weight loss adjunct and/or that its safety risks outweighed any purported benefits the drug may have had.
- 283. Notwithstanding the foregoing, the Defendants omitted material facts in the disclosures it made to consumers, including the Plaintiff DEBORAH CRAWFORD, the medical community, including Plaintiff DEBORAH CRAWFORD's prescribing physician, the FDA and the public concerning the use and safety of Belviq.
- 284. Defendants falsely and fraudulently represented to consumers, including the Plaintiff DEBORAH CRAWFORD, the medical community, including Plaintiff DEBORAH CRAWFORD's prescribing physician, the FDA and the public, that Belviq had been tested and was found to be safe and/or effective for chronic weight management.

- 285. The representations were made to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, the medical community and the public by way of the product's label.
- 286. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly, and recklessly disregarded whether the representations were true.
- 287. These representations and omissions were made by Defendants with the intent of defrauding and deceiving the Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, the medical and healthcare community and the public in general, and were made with the intent of inducing the Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, the medical and healthcare community and the public in general to use, recommend, prescribe, dispense, and/or purchase Belviq for use in chronic weight management, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff DEBORAH CRAWFORD.
- 288. Defendants' representations and omissions were made with the intent that Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, would rely upon such representations and omissions.
- 289. At the time the aforesaid representations and omissions were made by the Defendants and, at the time the Plaintiff DEBORAH CRAWFORD used Belviq, the Plaintiff and her prescribing physician, Dr. Martha Paterson, were unaware of the falsity of said representations and reasonably believed them to be true.
- 290. In reliance upon said representations and omissions, the Plaintiff DEBORAH CRAWFORD was induced to and did use Belviq and, upon information and belief, her prescribing physician, Dr. Martha Paterson, was induced to and did prescribe Belviq, thereby causing Plaintiff DEBORAH CRAWFORD to sustain severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

- 291. Defendants have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1, et seq.) in that they made untrue, deceptive and/or misleading representations of material facts and omitted and/or concealed material facts from the public, including the Plaintiffs herein, concerning the use and safety of Belviq.
- 292. Defendants' practice of promoting Belviq created and/or reinforced a false impression as to its safety and efficacy.
- 293. Defendants' practice of promoting Belviq placed all consumers of Belviq, including the Plaintiff DEBORAH CRAWFORD, at risk for serious and potentially lethal side effects (i.e. cancer).
- 294. Defendants brought Belviq to the market, and acted fraudulently, wantonly, and maliciously to the detriment of the Plaintiffs.
- 295. Defendants have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*), in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiffs herein, concerning the use and safety of the subject product.
- 296. The aforesaid promotion, statements and/or omissions concerning Belviq by the Defendants constitute an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendants, in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.
- 297. Plaintiff DEBORAH CRAWFORD purchased and used the subject product for personal, purposes and suffered ascertainable losses of money and personal injury as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

298. As a direct and proximate result of the Defendants' acts of consumer fraud, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.

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

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

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

# COUNT VII FRAUDULENT MISREPRESENTATION AND CONCEALMENT (New Jersey Law)

- 301. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 302. Prior to 2017 and 2018, 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.

- 303. Nevertheless, in 2017 and 2018, Defendants falsely represented on the label of Belviq that Belviq was effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.
- 304. Prior to 2017 and 2018, 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.
- 305. Nevertheless, in 2017 and 2018, Defendants falsely represented on the label of Belviq that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI and concealed that Belviq was associated with an increased risk of cancer.
- 306. Prior to 2017 and 2018, Defendants knew or should have known that the effectiveness of Belviq, if any, did not outweigh the dangers and risks associated with Belviq.
- 307. Nevertheless, in 2017 and 2018, Defendants falsely represented on the label of Belviq that the effectiveness of Belviq outweighed the dangers and risks associated with Belviq.
- 308. Prior to 2017 and 2018, Defendants knew or should have known that Belviq had not been adequately and/or sufficiently tested for safety.
- 309. Nevertheless, in 2017 and 2018Defendants falsely represented on the label of Belviq that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI and concealed that Belviq had not been adequately and/or sufficiently tested for safety.
- 310. Defendants' fraudulent representations and/or concealments as identified herein were done with the intent of defrauding and deceiving consumers, including the Plaintiff DEBORAH CRAWFORD, and prescribing physician, Dr. Martha Paterson, 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 DEBORAH CRAWFORD.

- 311. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing consumers, including the Plaintiff DEBORAH CRAWFORD, into using Belviq for chronic weight management, which evinced a callous, reckless, willful, deprayed indifference to health, safety, and welfare of the Plaintiff DEBORAH CRAWFORD.
- 312. Defendants' fraudulent representations and/or omissions as identified herein were done with the intent of inducing prescribing physicians, including the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, 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 DEBORAH CRAWFORD.
- 313. In or about December 2017, Plaintiff DEBORAH CRAWFORD presented to the office of her prescribing physician, Dr. Martha Paterson, and they discussed her need for weight loss.
- 314. At this visit, in or about December 2017, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to Plaintiff DEBORAH CRAWFORD.
- 315. Upon information and belief, Dr. Martha Paterson, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.
- 316. Upon information and belief, Defendants represented to Dr. Martha Paterson by way of the product's label that Belviq was an effective drug to use for weight loss.
- 317. Upon information and belief, Defendants represented to Dr. Martha Paterson by way of the product's label that Belviq was a safe drug to use for weight loss.

- 318. Upon information and belief, Defendants concealed from Dr. Martha Paterson by way of the product's label that Belviq was associated with an increased risk of cancer.
- 319. Upon information and belief, Defendants concealed from Dr. Martha Paterson by way of the product's label that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.
- 320. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's label that Belviq was an effective drug to use for weight loss.
- 321. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's label that Belviq was a safe drug to use for weight loss.
- 322. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of the product's label that Belviq was associated with an increased risk of cancer.
- 323. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants concealed from her by way of the product's label that Belviq had not been tested sufficiently and/or adequately for increased safety risks, including cancer.
- 324. The aforementioned representations made in the label of Belviq in or about December 2017 through August 2018 were false in that Belviq is not an effective drug to use for weight loss.
- 325. The aforementioned representations made in the label of Belviq in or about December 2017 through August 2018 were fraudulently made in that that Defendants concealed that Belviq was associated with an increased risk of cancer despite their knowledge to the contrary.

- 326. The aforementioned representations made in the label of Belviq in or about December 2017 through August 2018 were fraudulently made in that that Defendants concealed that Belviq had not been adequately and/or sufficiently tested for safety, including cancer.
- 327. Upon information and belief, as a result of the label for Belviq in or about December 2017, and particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff's prescribing physician, Dr. Martha Paterson, was induced to and did prescribe Belviq to Plaintiff DEBORAH CRAWFORD from December 2017 through August 2018.
- 328. As a result of the label for Belviq in or about December 2017, particularly as a result of Defendants' fraudulent misrepresentation and concealments contained therein, Plaintiff DEBORAH CRAWFORD was induced to and did use Belviq from December 2017 through August 2018.
- 329. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, been told of the increased cancer risk associated with Belviq, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.
- 330. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, been told of the lack of efficacy associated with Belviq, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate information regarding the efficacy of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.
- 331. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, been told that the benefits of Belviq, if any, were outweighed by its safety risks, particularly cancer, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate information regarding the efficacy and safety of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.

- 332. Upon information and belief, had Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, been told that Belviq had not been sufficiently and/or adequately tested for safety risks, including cancer, she would not have prescribed Belviq and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Belviq so as to allow Plaintiff to make an informed decision regarding her use of Belviq.
- 333. Had Plaintiff been told of the increased cancer risk associated with Belviq, she would not have used Belviq and/or suffered parotid gland cancer.
- 334. Had Plaintiff been told of the lack of efficacy associated with Belviq, she would not have used Belviq and/or suffered parotid gland cancer.
- 335. Had Plaintiff been told that the benefits of Belviq, if any, were outweighed by its safety risks, particularly cancer, she would not have used Belviq and/or suffered parotid gland cancer.
- 336. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Belviq for safety risks, including cancer, she would not have used Belviq and/or suffered parotid gland cancer.
- 337. Plaintiff DEBORAH CRAWFORD had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.
- 338. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, had no way to determine the truth behind Defendants' misrepresentations and concealments as identified herein, and her reliance upon Defendants' representations and concealments was reasonable.
  - 339. Defendants had sole access to material facts concerning the ineffective nature of Belviq.
- 340. Defendants had sole access to material facts concerning the defective nature of Belviq, and, particularly, its increased risk of cancer.

- 341. Defendants had sole access to material facts concerning the lack of adequate and appropriate testing regarding the safety of Belviq.
- 342. At all relevant times, Defendants were under a duty to disclose to Plaintiff, DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, hospitals, and/or healthcare providers the defective nature of Belviq, including but not limited to the heightened risk of cancer.
- 343. At all relevant times, Defendants were under a duty to disclose to Plaintiff, DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, hospitals, and/or healthcare providers information regarding the ineffectiveness of Belviq.
- 344. At all relevant times, Defendants were under a duty to disclose to Plaintiff, DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, hospitals, and/or healthcare providers that the risks of Belviq outweighed any effectiveness it may have.
- 345. At all relevant times, Defendants were under a duty to disclose to Plaintiff, DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, hospitals, and/or healthcare providers that Belviq had not been adequately and/or sufficiently tested.
- 346. Defendants breached their duties to disclose Belviq's serious safety risks and lack of efficacy to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, the medical and healthcare community, the FDA and the public in general.
- 347. Defendants could have and should have revealed the truth behind the safety and lack of efficacy of Belviq through various outlets, including the label for Belviq.
- 348. Defendants' misrepresentations and concealments concerning the safety and lack of efficacy of Belviq were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, 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.

- 349. Defendants knew that Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, had no way to determine the truth behind Defendants' misrepresentations and concealments surrounding Belviq, as set forth herein.
- 350. Plaintiff DEBORAH CRAWFORD's injury and damages were proximately caused by Defendants' fraudulent misrepresentations and concealments as set forth herein.
- 351. Plaintiff DEBORAH CRAWFORD's injury and damages were proximately caused by her reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.
- 352. Plaintiff DEBORAH CRAWFORD's injury and damages were proximately caused by her prescribing physician's reasonable reliance on Defendants' fraudulent misrepresentations and concealments as set forth herein.
- 353. At all relevant times, Defendants knew or should have known that Belviq was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.
- 354. Defendants brought Belviq to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff DEBORAH CRAWFORD.
- 355. As a direct and proximate result of Defendants foregoing misrepresentations, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.
- 356. As a direct and proximate result of Defendants foregoing misrepresentations, the Plaintiff DEBORAH CRAWFORD did require and will require more health care and services and did incur medical, health, incidental, and related expenses.

# COUNT VIII NEGLIGENT MISPRESENTATION (New Jersey Law)

- 357. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 358. Defendants had a duty to make honest and accurate representations to the Plaintiff, her prescribing physician, Dr. Martha Paterson, the medical and healthcare community, the FDA and the public in general regarding the safety and efficacy of Belviq.
- 359. At all relevant times, Defendants' represented to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, and the medical community that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI in that it did not cause an increased risk of cancer.
- 360. At all relevant times, Defendants' represented to Plaintiff DEBORAH CRAWFORD, her prescribing physician, Dr. Martha Paterson, and the medical community that Belviq was effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.
- 361. The aforementioned representations made by Defendants were, in fact, false because Belviq was not safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI given its increased risk of cancer.

- 362. The aforementioned representations made by Defendants were, in fact, false because Belviq is not an effective an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.
- 363. When said representations were made by Defendants, they knew or should have known those representations to be false.
- 364. The representations made by Defendants were made to Plaintiff DEBORAH CRAWFORD between 2017 and 2018 through the label of Belviq.
- 365. As a result of Defendants' representations between 2017 and 2018 on the label of Belviq, Plaintiff DEBORAH CRAWFORD was induced to use Belviq.
- 366. Upon information and belief, as a result of Defendants' representations between 2017 and 2018 on the label of Belviq, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, was induced to prescribe, dispense and/or recommend Belviq to Plaintiff DEBORAH CRAWFORD.
- 367. In or about December 2017, Plaintiff DEBORAH CRAWFORD presented to the office of her prescribing physician, Dr. Martha Paterson, and they discussed her need for weight loss.
- 368. At this visit, in or about December 2017, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to Plaintiff DEBORAH CRAWFORD.
- 369. Upon information and belief, Dr. Martha Paterson obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.
- 370. Upon information and belief, Defendants represented to Dr. Martha Paterson by way of the product's label that Belviq was an effective drug to use for weight loss.

- 371. Upon information and belief, Defendants represented to Dr. Martha Paterson 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.
- 372. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's label that Belviq was an effective drug to use for weight loss.
- 373. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants represented to her by way of the product's label that Belviq was a safe drug to use for weight loss in that it was not associated with an increased risk of cancer.
- 374. When the aforementioned representations were made, Defendants were aware or should have been aware that their representations would induce Plaintiff DEBORAH CRAWFORD and/or her prescribing physician, Dr. Martha Paterson, to use and/or prescribe Belviq.
- 375. When the representations were made, Defendants were aware or should have been aware that Belviq was to be used by Plaintiff DEBORAH CRAWFORD and/or prescribed by Plaintiff's prescribing physician, Dr. Martha Paterson, in reliance upon their representations regarding the safety and efficacy of Belviq.
- 376. At the time the aforesaid representations were made by the Defendants and at the time Plaintiff DEBORAH CRAWFORD used Belviq and her prescribing physician, Dr. Martha Paterson, prescribed Belviq to her, Plaintiff DEBORAH CRAWFORD was unaware of the falsity of said representations and reasonably believed them to be true.
- 377. Upon information and belief, at the time the aforesaid representations were made by the Defendants and at the time Plaintiff DEBORAH CRAWFORD used Belviq and her prescribing physician,

Dr. Martha Paterson, prescribed Belviq to her, Plaintiff's prescribing physician, Dr. Martha Paterson, was unaware of the falsity of said representations and reasonably believed them to be true.

- 378. In reasonable and foreseeable reliance upon said representations, the Plaintiff DEBORAH CRAWFORD was induced to and did use Belviq.
- 379. Upon information and belief, in reasonable and foreseeable reliance upon said representations, the Plaintiff's prescribing physician, Dr. Martha Paterson, was induced to and did prescribe Belviq.
- 380. Defendants failed to exercise ordinary care regarding their representations relating to the safety and efficacy of Belviq, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Defendants negligently misrepresented Belviq's safety, efficacy and/or the weighing of risk between the two.
- 381. Defendants breached their duty by misrepresenting Belviq's serious safety risks and efficacy to Plaintiff DEBORAH CRAWFORD, her prescribing physician, the medical and healthcare community, the FDA and the public in general.
- 382. Upon information and belief, had Plaintiff's prescribing physician, Dr. Martha Paterson, known these representations regarding the safety and efficacy of Belviq to be false, she would not have prescribed Belviq to Plaintiff DEBORAH CRAWFORD.
- 383. Had Plaintiff known these representations regarding the safety and efficacy of Belviq to be false, she would not have used Belviq.
- 384. Defendants' negligent misrepresentations proximately caused Plaintiffs' injuries and damages as alleged herein.
- 385. As a direct and proximate result of Defendants' foregoing misrepresentations, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland

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.

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

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

# COUNT IX INADEQUATE WARNINGS (LOUISIANA PRODUCT LIABILITY ACT)

- 387. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 388. 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 DEBORAH CRAWFORD.
- 389. Plaintiff DEBORAH CRAWFORD's injuries and damages, particularly parotid gland cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous inadequate warnings.
- 390. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD, with the ordinary knowledge common to the community as to the product's characteristics.

- 391. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary prescriber such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, with the ordinary knowledge common to the community as to the product's characteristics.
- 392. Plaintiff DEBORAH CRAWFORD's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff DEBORAH CRAWFORD.
- 393. At the time Belviq left the Defendants' control, Defendants, knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq posed danger, particularly cancer, to humans, and/or that they had not conducted sufficient and/or adequate testing regarding Belviq's carcinogenicity.
- 394. At the time Belviq left the Defendants' control, Belviq had inadequate warnings because Belviq possessed a characteristic that may cause damage, particularly cancer, to humans, and Defendants, who knew and/or should have known had they acted as a reasonably prudent manufacturer of said characteristic and its danger, failed to use reasonable care to provide an adequate warning of such characteristics and its danger to users and handlers of the product, such as the Plaintiff DEBORAH CRAWFORD and/or her prescribing physician, Dr. Martha Paterson, thereby rendering the product unreasonably dangerous.
- 395. Defendants knew or should have known that Belviq was unreasonably dangerous because of inadequate warnings, especially when used in the form and manner as provided by Defendants.
  - 396. Defendants created a product unreasonably dangerous for its normal, intended use.
- 397. Had Defendants adequately warned of the risks and dangers associated with Belviq, upon information and belief, Plaintiff's prescribing physician, Dr. Martha Paterson, would not have prescribed

Belviq and/or would have provided Plaintiff DEBORAH CRAWFORD with adequate instructions regarding the dangers of Belviq so as to allow Plaintiff to make an informed decision regarding Belviq.

- 398. Had Defendants adequately warned of the risks and dangers associated with Belviq, Plaintiff DEBORAH CRAWFORD would not have taken Belviq.
- 399. Accordingly, Defendants are liable unto the Plaintiffs as a result of their failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to users of the product, such as Plaintiff DEBORAH CRAWFORD, at the time Belviq left the Defendants' control.
- 400. Accordingly, Defendants are liable unto the Plaintiffs as a result of their failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to prescribing physicians, such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, at the time Belviq left the Defendants' control.
- 401. Additionally, and/or in the alternative, Defendants, after Belviq left their control, acquired knowledge and/or should have acquired knowledge had they acted as a reasonably prudent manufacturer of a characteristic of Belviq that may cause damage, particularly cancer, to humans, yet they failed to use reasonable care to provide an adequate warning of such characteristics and its danger to users and handlers of the product, such as the Plaintiff DEBORAH CRAWFORD and/or her prescribing physician, Dr. Martha Paterson, thereby rendering the product unreasonably dangerous.
- 402. Accordingly, Defendants are liable unto the Plaintiffs as a result of their subsequent failure to use reasonable care to provide an adequate warning of such a characteristic and its dangers to users of the product, such as Plaintiff DEBORAH CRAWFORD, and their prescribing physicians, such as Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson.
- 403. As a direct and proximate cause of the Defendants' aforesaid actions, the Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland

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.

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

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

# COUNT X BREACH OF EXPRESS WARRANTY (LOUISIANA PRODUCT LIABILITY ACT)

- 405. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 406. 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 DEBORAH CRAWFORD.
- 407. Plaintiffs' injuries and damages, particularly parotid gland cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous Defendants' breach of express warranty.

- 408. At all relevant times, Defendants reasonably anticipated and expected that individuals such as the Plaintiff DEBORAH CRAWFORD would use, consume, or be affected by Belviq based upon their express warranties.
- 409. At all relevant times, Defendants reasonably anticipated and expected that physicians, such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, would recommend, dispense or prescribe Belviq based upon their express warranties.
- 410. Defendants had a duty to use reasonable care in the research, development, design, testing, manufacturing, labeling distribution, marketing, promotion and/or sale of Belviq, including duties to ensure that the product did not cause the user to suffer unreasonably dangerous side effects such as cancer, to warn of dangerous side effects and/or complications, such as cancer; and to disclose such adverse material facts when making representations and warranties to consumers and physicians.
- 411. At all relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff DEBORAH CRAWFORD, and physicians such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, without adequately warning them of the increased cancer risk associated with the use of Belviq.
- 412. All relevant times, Defendants placed Belviq into the stream of commerce for sale and recommended its use to consumers, such as the Plaintiff DEBORAH CRAWFORD, and physicians such as the Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, without adequately warning them that Belviq had not been adequately or sufficiently tested for safety risks, including the increased risk of cancer.
- 413. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, 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).

- 414. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, 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.
- 415. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD and her prescribing physician, Dr. Martha Paterson, that the effectiveness of Belviq outweighed any potential dangers and/or risks.
- 416. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physicians and the medical community that any and all side effects Belviq did produce were accurately reflected in the warnings and instructions.
- 417. At all relevant times, Defendants' expressly warranted to Plaintiff DEBORAH CRAWFORD, her prescribing physicians and the medical community that Belviq had been adequately and sufficiently tested.
- 418. The aforementioned express warranties were made to Plaintiff DEBORAH CRAWFORD by way of Belviq's label.
- 419. Upon information and belief, the aforementioned express warranties were made to Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, by way of Belviq's label.
- 420. In or about December 2017, Plaintiff DEBORAH CRAWFORD presented to the office of her prescribing physician, Dr. Martha Paterson, and they discussed her need for weight loss.

- 421. At this visit, in or about December 2017, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, recommended Belviq as a safe and effective drug to use for weight loss and prescribed it to her.
- 422. Upon information and belief, Dr. Martha Paterson, obtained the information regarding the efficacy and side effects of Belviq from the label of Belviq.
- 423. Upon information and belief, Defendants expressly warranted to Dr. Martha Paterson, by way of the product's label, that Belviq was an effective drug to use for weight loss.
- 424. Upon information and belief, Defendants expressly warranted to Dr. Martha Paterson, by way of the product's label, that Belviq was a safe drug to use for weight loss.
- 425. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was an effective drug to use for weight loss.
- 426. In or about December 2017, when Plaintiff DEBORAH CRAWFORD began using Belviq and throughout her use of Belviq, Defendants expressly warranted to her, by way of the product's label, that Belviq was a safe drug to use for weight loss.
- 427. As a result of Defendants' express warranties to her and Dr. Martha Paterson, Dr. Martha Paterson was induced to prescribe Belviq to Plaintiff DEBORAH CRAWFORD, and Plaintiff DEBORAH CRAWFORD was induced to use Belviq from December 2017 through August 2018.
- 428. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD, with the ordinary knowledge common to the community as to the product's characteristics.
- 429. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary physicians, such as Plaintiff DEBORAH CRAWFORD's prescribing

physician, Dr. Martha Paterson, with the ordinary knowledge common to the community as to the product's characteristics.

- 430. Plaintiff DEBORAH CRAWFORD's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff DEBORAH CRAWFORD.
- 431. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq was unreasonably dangerous because of the breach of their express warranties, especially when the drug was used in the form and manner as provided by Defendants.
- 432. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer 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.
- 433. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq was unreasonably dangerous because its warnings and instructions did not accurately reflect any and all side effects caused by Belviq, particularly cancer.
- 434. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq was unreasonably dangerous because they had failed to adequately and sufficiently test Belviq regarding its propensity to cause cancer.
- 435. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq was not an effective pharmaceutical drug to be used as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial body mass indexes (BMI).
- 436. At all relevant times, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that the carcinogenic risks of Belviq far outweighed the benefits, if any, of Belviq.

- 437. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties that Belviq was safe to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI in that it was associated with an increased risk of cancer.
- 438. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties that Belviq was effective to use as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with certain initial BMI.
- 439. At the time Belviq left the Defendants' control, Belviq did not conform to its express warranties that the effectiveness of the pharmaceutical drug outweighed any potential dangers and/or risks.
- 440. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because its warning and instructions did not accurately reflect any and all side effects caused by Belviq, particular cancer.
- 441. At the time Belviq left the Defendants' control, Belviq did not conform to Defendants' express warranties because they had failed to adequately or sufficiently test Belviq regarding its propensity to cause cancer.
- 442. Belviq was unreasonably dangerous because it did not conform to any of the express warranties made by the Defendants about the product.
  - 443. Defendants created a product unreasonably dangerous for its normal, intended use.
- 444. The express warranties made by Defendants regarding the safety and efficacy of Belviq were made with the intent to induce Plaintiff DEBORAH CRAWFORD to use the product and/or her prescribing physician, Dr. Martha Paterson, to prescribe the product.
- 445. Defendants knew and/or should have known that by making the express warranties to Plaintiff DEBORAH CRAWFORD and/or her prescribing physician, Dr. Martha Paterson, it would be the

natural tendency of Plaintiff to use Belviq and/or her prescribing physician, Dr. Martha Paterson, to prescribe Belviq.

- 446. Plaintiff and her prescribing physician, Dr. Martha Paterson, as well as members of the medical community, justifiably and detrimentally relied on the express warranties of the Defendants identified herein.
- 447. The express warranties made by Defendants regarding the safety and efficacy of Belviq induced Plaintiff DEBORAH CRAWFORD to use the product and/or her prescribing physician, Dr. Martha Paterson, to prescribe the product.
- 448. Had Defendants not made these express warranties, Plaintiff DEBORAH CRAWFORD would not have used the product and/or, upon information and belief, her prescribing physician, Dr. Martha Paterson, would not have prescribed the product.
- 449. Plaintiff DEBORAH CRAWFORD had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.
- 450. Upon information and belief, Plaintiff DEBORAH CRAWFORD's prescribing physician, Dr. Martha Paterson, had no knowledge of the falsity or incompleteness of Defendants' statements and representations regarding Belviq, nor could she have reasonably discovered such.
- 451. Plaintiff DEBORAH CRAWFORD's injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.
- 452. Plaintiff DEBORAH CRAWFORD'S injuries and damages arose from a reasonably anticipated use of the product by Plaintiff DEBORAH CRAWFORD.

- 453. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff DEBORAH CRAWFORD relating to the characteristics of Belviq, particularly its efficacy and safety, at the time Belviq left their control.
- 454. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.
- 455. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff DEBORAH CRAWFORD requires and/or will require more health care and services and Plaintiffs did incur medical, health, incidental, and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff DEBORAH CRAWFORD will in the future be required to obtain further medical and/or hospital care, attention, and services.

# COUNT XI DESIGN DEFECT (LOUISIANA PRODUCT LIABILITY ACT)

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

- 458. Plaintiffs' injuries and damages, particularly parotid gland cancer and any and all injuries and damages related thereto, were proximately caused by a characteristic of Belviq that rendered the product unreasonably dangerous design defect.
- 459. Defendants knew or should have known that Belviq was unreasonably dangerous because of its design defects, especially when used in the form and manner as provided by Defendants.
- 460. The unreasonably dangerous characteristics of Belviq were beyond that which would be contemplated by the ordinary user such as Plaintiff DEBORAH CRAWFORD, with the ordinary knowledge common to the community as to the product's characteristics
- 461. Plaintiff DEBORAH CRAWFORD's injuries and damages arose from a reasonably anticipated use of the product by Plaintiff DEBORAH CRAWFORD.
- 462. At the time Belviq left the Defendants' control, Defendants knew and/or should have known had they acted as a reasonably prudent manufacturer that Belviq posed danger, particularly cancer, to humans, and/or that they had not conducted sufficient and/or adequate testing regarding Belviq's carcinogenicity.
- 463. Upon information and belief, at the time Belviq left the Defendants' control, Belviq was unreasonably dangerous in design because there existed an alternative design for the product that was capable of preventing the Plaintiffs' injuries and damages an alternative design that was and is in the exclusive possession, custody and control of Defendants.
- 464. Upon information and belief, the alternative design was a pharmaceutical drug that was not a serotonin receptor agonist, but rather a pharmaceutical drug that did not affect the serotonin pathway.

- 465. Upon information and belief, Belviq was unreasonably dangerous in design because there existed an alternative design for the product that was capable of preventing the Plaintiffs' injuries and damage and the likelihood that Belviq's design would cause the Plaintiffs' injuries and damages and the gravity of those injuries and damages outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.
- 466. At the time Belviq left Defendants' control, Defendants, in light of then existing reasonably available scientific and technological knowledge and testing, knew and/or should have known of the design characteristic that caused the damage and the danger of such characteristic.
- 467. At the time Belviq left the Defendants' control, the Defendants, in light of then existing reasonably available scientific and technological knowledge and testing, knew and/or should have known of the existing technologically and economically safer alternative design characteristic than that which caused the damage and the danger of such characteristic.
  - 468. Belviq was unreasonably dangerous because of its defect in design.
  - 469. Defendants created a product unreasonably dangerous for its normal, intended use.
- 470. Accordingly, Defendants are liable unto the Plaintiffs as a result of the defective design relating to the characteristics of Belviq at the time Belviq left their control.
- 471. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff DEBORAH CRAWFORD was caused to suffer serious and dangerous side effects including parotid gland 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.
- 472. As a direct and proximate cause of the Defendants' aforesaid actions, Plaintiff DEBORAH CRAWFORD requires and/or will require more health care and services and Plaintiffs did incur medical,

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

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

### COUNT XII LOSS OF CONSORTIUM

- 473. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 474. Plaintiff, BRADLEY TREY CRAWFORD was, at all relevant times, and is the lawful spouse of Plaintiff DEBORAH CRAWFORD, and as such, was and is entitled to the comfort, enjoyment, society, and services of his spouse.
- 475. As a direct and proximate result of the foregoing, Plaintiff BRADLEY TREY CRAWFORD was deprived of the comfort and enjoyment of the services and society of his spouse, Plaintiff DEBORAH CRAWFORD, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured.
- 476. Plaintiff BRADLEY TREY CRAWFORD'S injuries and damages are permanent and will continue into the future. Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

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

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

477. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained

in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

478. At all times material hereto, Defendants' design, testing, manufacturing, marketing,

promotion, distribution and sale of a defective product, and their failure to provide adequate warnings and

instructions concerning its hazards were willful, wanton, reckless and without regard for the public's safety

and welfare. Defendants misled both the medical community and the public at large, including Plaintiff

DEBORAH CRAWFORD and her prescribing physicians, by making false representations about the safety

of Belviq. Defendants downplayed, understated and/or disregarded their knowledge of the serious and

permanent side effects and risks associated with the use of Belviq despite available information

demonstrating that Belviq was likely to cause serious and potentially fatal side effects to users.

479. At all times material hereto, Defendants knew of the defective nature of their Belviq

product, and continued to design, manufacture, market, label, and sell Belviq so as to maximize sales and

profits at the expense of public health and safety, with wanton and willful disregard of the safety of product

users, consumers, or others who foreseeably might be harmed by the product, including Plaintiff

DEBORAH CRAWFORD who did suffer such harm.

480. Defendants misled regulators, the medical community and the public at large, including

Plaintiff and her prescribing physicians, by making false and misleading representations about the safety of

Belviq. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA

under the agency's regulations, which information was material and relevant to the harm suffered by

Plaintiff DEBORAH CRAWFORD.

75

- 481. Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff DEBORAH CRAWFORD and her prescribing physicians of necessary information to enable her to weigh the true risks of using Belviq against its benefits.
- 482. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.
- 483. As a result of the foregoing acts and omissions, the Plaintiffs requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiffs will in the future be required to obtain further medical and/or hospital care, attention, and services.
- 484. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered injuries and damages as summarized herein.

#### PRAYER FOR RELIEF

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

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

BER-L-000968-21 02/11/2021 4:27:35 PM Pg 77 of 81 Trans ID: LCV2021336367

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the

Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of

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

conduct;

3. Awarding Plaintiffs reasonable attorneys' fees;

4. Awarding Plaintiffs the costs of these proceedings; and

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

Dated: February 11, 2021

### **DOUGLAS & LONDON, P.C.**

By: /s/ Michael A. London

MICHAEL A. LONDON (ML-7510)

Bar ID #: 048501997 59 Maiden Lane, 6<sup>th</sup> Floor New York, NY 10038 Ph: (212) 566-7500

Fax: (212) 566-7501

Email: mlondon@douglasandlondon.com

### **DEMAND FOR JURY TRIAL**

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

Dated: February 11, 2021

Respectfully submitted,

**DOUGLAS & LONDON, P.C.** 

By: /s/ Michael A. London

Michael A. London Bar ID #: 048501997 59 Maiden Lane, 6<sup>th</sup> Floor New York, New York 10038 Telephone: (212) 566-7500

#### **CERTIFICATION PURSUANT TO R. 4:5-1**

The undersigned attorney for Plaintiffs certifies as follows:

- 1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;
- 2. No other action or arbitration proceeding is contemplated; and
- 3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of this action that should be joined pursuant to  $\underline{R}$ . 4:28.

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

Date: February 11, 2021

Respectfully submitted,

**DOUGLAS & LONDON, P.C.** 

By: <u>/s/ Michael A. London</u>

Michael A. London Bar ID #: 048501997 59 Maiden Lane, 6<sup>th</sup> Floor New York, New York 10038 Telephone: (212) 566-7500

#### **DESIGNATION OF TRIAL COUNSEL**

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

Plaintiffs in this action

Date: February 11, 2021

Respectfully submitted,

**DOUGLAS & LONDON, P.C.** 

By: /s/ Michael A. London

Michael A. London Bar ID #: 048501997 59 Maiden Lane, 6<sup>th</sup> Floor New York, New York 10038 Telephone: (212) 566-7500

#### **CERTIFICATION OF NOTICE**

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

Date: February 11, 2021

Respectfully submitted,

**DOUGLAS & LONDON, P.C.** 

By: /s/ Michael A. London

Michael A. London Bar ID #: 048501997 59 Maiden Lane, 6<sup>th</sup> Floor New York, New York 10038 Telephone: (212) 566-7500

### Civil Case Information Statement

#### Case Details: BERGEN | Civil Part Docket# L-000968-21

Case Caption: CRAWFORD DEBORAH VS EISAI, INC. Cas

Case Initiation Date: 02/11/2021

Attorney Name: MICHAEL ANDREW LONDON

Firm Name: DOUGLAS & LONDON

Address: 59 MAIDEN LANE 6TH FLOOR

NEW YORK NY 10038 Phone: 2125667500

Name of Party: PLAINTIFF : Crawford, Deborah

Name of Defendant's Primary Insurance Company

(if known): None

Case Type: PRODUCT LIABILITY

**Document Type:** Complaint with Jury Demand

Jury Demand: YES - 12 JURORS

Is this a professional malpractice case? NO

Related cases pending: YES
If yes, list docket numbers: 007357

Do you anticipate adding any parties (arising out of same

transaction or occurrence)? NO

Are sexual abuse claims alleged by: Deborah Crawford? NO

Are sexual abuse claims alleged by: Bradley T Crawford? NO

#### THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

n/a

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

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

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

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

02/11/2021 Dated /s/ MICHAEL ANDREW LONDON Signed