UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

AMY DAVIS, Plaintiff, v. EISAI, INC. and ARENA PHARMACEUTICALS, INC., Defendants.	:	**CIVIL ACTION NO.:** **COMPLAINT AND JURY DEMAND**

COMPLAINT

Plaintiff Amy Davis, by and through her undersigned counsel, hereby files this Complaint and alleges against Defendants as follows:

PARTIES, JURISDICTION, AND VENUE

1. Amy Davis is an adult resident and citizen of Kearney, Missouri.

2. Upon information and belief, Defendant Arena Pharmaceuticals, Inc. ("Arena") is a Delaware corporation with its principal place of business located at 6154 Nancy Ridge Drive, San Diego, California 92121.

3. Upon information and belief, Defendant Eisai, Inc. ("Eisai") is a Delaware corporation with its principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

4. Upon information and belief, Arena designed and developed Belviq and Belviq XR.

5. Upon information and belief, Eisai marketed, sold, and distributed Belviq and Belviq XR throughout the United States, including to Plaintiff and others in Missouri, through activities directed at and occurring within Missouri.

6. At all relevant times, Defendants were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

7. Defendants were involved, either directly or as described in the paragraph above, in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including Belviq or Belviq XR, as well as monitoring and reporting adverse events.

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

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Ms. Davis' claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

BACKGROUND

8. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Belviq and lorcaserin hydrochloride for chronic weight management.

9. Arena received FDA approval for Belviq, also known as lorcaserin hydrochloride, on June 27, 2012, as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a body mass index (hereinafter referred to as "BMI") greater than or equal to 30 kg/m2 or adult patients with a BMI greater than or equal to 27 kg/m2 and at least one weight- related comorbid condition.

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

11. Arena and Eisai jointly launched Belviq in the United States in 2012.

12. Up until approximately 2017, Defendants had a joint contractual agreement in which Arena manufactured Belviq and Eisai marketed, distributed, and sold Belviq.

13. In or around January 2017, Eisai purchased the global rights to develop and market Belviq from Arena.

14. Upon information and belief, Arena continued to maintain control over manufacturing responsibilities for a period of time before transitioning those responsibilities to Eisai.

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

16. During the preclinical trial program, Defendants conducted a two-year carcinogenicity study in rats in which lorcaserin was identified as a non-genotoxic carcinogen inducing multiple tumor types, primarily due to an increase in mammary tumors in both sexes near clinical exposure and at all doses in female rats. There was also an increase in astrocytomas,

malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skin squamous carcinoma, and thyroid follicular cell adenoma in male rats. Adenocarcinoma in the lorcaserin groups demonstrated increased tumor onset, multiplicity, and lung metastases. Fibroadenoma in the lorcaserin groups also demonstrated greater incidence and multiplicity. While the study was ongoing, FDA required bi-monthly updates due to the consistently increased incidence of tumors and mortality in the lorcaserin groups. However, in the final report the incidence of adenocarcinoma was lower in the mid- and high-dose groups than that reported at week 96 and had increased in the control group, while the incidence of fibroadenoma increased across all doses from week 96, with notable variations in the mid- and high-dose groups. Due to the apparent increase in fibroadenoma accompanying the decrease in adenocarcinoma after week 96, the FDA suspected reclassification of tumor types.

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

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

19. From September 2006 through February 2009, Defendants Arena and Eisai 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 Belviq in reducing body weight in the U.S.

While weight reduction was seen in the first year, all treatment groups experienced weight regain during the second year. In July 2010, the results of the BLOOM trial were published in the New England Journal of Medicine (hereinafter referred to as "NEJM"). Smith S.R., et al. *Multicenter, Placebo-Controlled Trial of Lorcaserin for Weight Management*. N. Engl. J. Med. 2010;363:245-56.

20. From December 2007 to July 2009, Defendants Arena and Eisai conducted the Behavioral modification and Lorcaserin Second Study for Obesity Management (BLOSSOM) trial, a one-year randomized, placebo- controlled, double-blind, parallel arm trial involving 4,008 patients to examine the effects of lorcaserin on body weight, cardiovascular risk, and safety in the U.S. In July 2011, the results of the BLOSSOM trial were published in the Journal of Clinical Endocrinology and Metabolism. Fidler, M.C., et al. *A One-Year Randomized Trial of Lorcaserin for Weight Loss in Obese and Overweight Adults: the BLOSSOM trial*. J. Clin. Endocrinol. Metab. 2011;96:3067-3077.

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

22. On December 18, 2009, Arena submitted its first New Drug Application ("NDA") for Belviq.

23. On September 16, 2010, the Endocrinologic and Metabolic Drugs Advisory Committee ("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.

24. 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.

25. In response to the CRL, Defendants convened a pathology working group ("PWG") to blindly reevaluate the preclinical mammary tumor data in rats.

26. 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.

27. From December 2007 to August 2010, Defendants Arena and Eisai conducted the Behavioral modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus (BLOOM-DM) trial, a one- year, randomized, placebo-controlled trial involving 604 patients to examine the efficacy and safety of lorcaserin for weight loss in patients with Type 2 Diabetes Mellitus in the U.S. After one year, there was only a 3.1% mean weight loss with lorcaserin over that of the placebo group. In April 2012, the results of the BLOOM-DM trial were published in the journal of The Obesity Society. O'Neil, P.M., et al. *Randomized Placebo-Controlled Clinical Trial of Lorcaserin for Weight Loss in Type 2 Diabetes Mellitus: The BLOOM-DM Study*. Obesity 2012;20:1426-1436.

28. 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 reevaluation, as well as new

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

29. The PWG found a decreased number of adenocarcinoma and an increased number of fibroadenoma in both the control and the lorcaserin groups of the two-year rat study. For adenocarcinoma, the number decreased to a larger extent in the lorcaserin group compared to the control group, but lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma, and the high-dose lorcaserin group maintained a statistically significant increase in adenocarcinomas compared to the control group. Regarding fibroadenoma, there was an increase in the incidence, tumor onset and multiplicity, and lethality across all lorcaserin dose groups compared to the control group, however these results were disregarded as irrelevant to risk of carcinoma in FDA's review of the reevaluation data.

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

31. 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.

32. In contrast, on May 3, 2013, Defendants withdrew the application for marketing authorization for Belviq with the European Medicines Agency ("EMA"). The EMA Committee for Medicinal Products for Human Use ("CHMP") determined that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG reevaluation, the risk of carcinogenicity in humans needed further consideration and the overall clinical risk/benefit balance was negative in that the modest efficacy results did not outweigh safety concerns. The CHMP further stated that the increased occurrence of several tumor types in male rats was particularly concerning due to the lack of any persuasive mechanism of action that would provide assurance of safety in human use, which also undermined any discussion on exposure margins. Thus, the CHMP concluded that the clinical relevance of the tumors found in the rat study must be evaluated as part of the risk-benefit assessment.

33. From January 2014 to June 2018, Defendants conducted a post-marketing trial, the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61).

34. CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving 12,000 patients conducted in the U.S., Canada, Mexico, the Bahamas, Europe, South America, Australia, and New Zealand to evaluate the risk of heart-related issues with Belviq. CAMELLIA-TIMI 61 began in 2014 and concluded in 2018.

35. 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.

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

37. On February 13, 2020, the FDA announced that Eisai had submitted a request to voluntarily withdraw Belviq from the market.

38. 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. FDA further stated that the risks of Belviq outweigh its benefits and recommended that patients stop taking Belviq and dispose of any unused pills. FDA also instructed all health care professionals to stop prescribing Belviq and to contact their patients taking Belviq to inform them of the increased risk of cancer and ask that they stop taking Belviq.

39. Prior to applying for and obtaining approval of Belviq in 2012, Defendants Arena and Eisai knew or should have known that human consumption of Belviq was associated with significant risks of cancer.

40. Defendants Arena and Eisai possessed pre-clinical scientific studies, which evidence Defendants knew or should have known that the cancer implications required further testing and studies prior to its introduction to the market.

41. Upon information and belief, despite Defendants Arena's and Eisai's knowledge of cancer findings in animal carcinogenicity studies, they each failed to adequately conduct complete and proper testing of Belviq prior to seeking FDA approval for Belviq.

42. Upon information and belief, from the date Defendants received FDA approval to market Belviq, Defendants Arena and Eisai devised a plan to manufacture, distribute, market, and sell Belviq without adequate warnings to 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 Arena and Eisai had not adequately conducted complete and proper testing and studies of Belviq with regard to carcinogenicity.

43. Defendants' failure to disclose information that they possessed regarding failure to adequately test and study Belviq for cancer risk further rendered warnings for this medication inadequate.

CASE SPECIFIC FACTUAL ALLEGATIONS

44. In August 2017, Plaintiff Amy Davis was prescribed Belviq for weight loss and diet control by Dr. David Wilson in Kansas City, Missouri.

45. Plaintiff's physician continued to prescribe her Belviq and Plaintiff continued to take Belviq until November of 2019.

46. From August 2017 to November 2019, Plaintiff continued to take Belviq for her weight loss without knowing of the significant increased risk that Belviq could cause her to develop cancer.

47. In November 2019, Plaintiff was diagnosed with breast cancer.

48. Plaintiff's use of Belviq caused or significantly contributed to her development of breast cancer, which has permanently changed her life.

49. By reason of the foregoing, Plaintiff has had to undergo significant treatment and now requires constant and continuous medical monitoring and treatment due to the defective nature of Belviq.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT
(Defendants Arena and Eisai)

81. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

82. At all times herein mentioned, Defendants are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of Belviq, which is defective and unreasonably dangerous.

83. Belviq is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. Belviq is defective in design because it poses an increased risk of cancers, is more dangerous than other available drugs indicated for similar conditions and uses, and the utility of the Belviq drug does not outweigh its risks.

84. The defective condition of Belviq rendered it unreasonably dangerous and/or not reasonably safe, and Belviq was in this defective condition at the time it left the hands of Defendants. Belviq was expected to and did reach Plaintiff and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

85. Belviq was used for its intended purposes and the product was not materially altered or modified prior to its use.

86. Belviq is defective in design because of its likelihood for, among other things, the increase of cancers in its consumers at an unreasonable rate.

87. At or before the time Belviq was released on the market and/or sold to Plaintiff, Defendants could have designed the Belviq to make it less prone to causing cancers, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the drug.

88. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of Belviq. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured Belviq in a way as to make the risk of harm or injury outweigh any benefits.

89. Belviq is and was being used in the Defendants' intended manner at the time it was prescribed to Plaintiff.

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

91. Defendants knew or should have known that Belviq would prescribed to patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendants knew or should have known that patients in whom Belviq would be used, such as Plaintiff, could be and would be affected by the defective design and composition of Belviq.

92. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably

foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

93. As a direct and proximate result of Defendants' placement of Belviq into the stream of commerce and Plaintiff's use of Belviq as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY- FAILURE TO WARN
(Defendants Arena and Eisai)

94. Plaintiff incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

95. At all times herein mentioned, the Defendants Arena and Eisai designed, developed, researched, tested, and knew about significant cancer risks with Belviq.

96. At all times herein mentioned, Defendant Eisai advertised, promoted, marketed, sold, distributed Belviq that was used by the Plaintiff.

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

98. Defendants each had an independent duty and continuing duty to warn the medical community, Plaintiff's physicians, and Plaintiff about the significance of the risks of cancer with Belviq.

99. Belviq was defective due to inadequate warnings because both Defendants Arena and Eisai knew or should have known that the product created a significantly increased risk of cancer and failed to warn the medical community, Plaintiff's physician, and Plaintiff of such of the nature of such a cancer risk.

100. Defendants Arena and Eisai both omitted and downplayed the significantly increased risks of cancer with Belviq that both Defendants knew of should have known from previous testing and research even prior to Belviq's approval.

101. Belviq's labeling and warnings were defective because they omitted and inadequately warned of Belviq's risk of cancer.

102. Defendant Eisai also launched television commercials regarding Belviq which omitted Belviq's risk of cancer.

103. For instance, Defendant Eisai aired television commercials about "willpower" for eating habits, which stated numerous potential side effects, including heart-related issues, depression, suicidal thoughts, low blood sugar, decreased blood cell count, headache, dizziness, fatigue, nausea, dry mouth, constipation, back pain, and coughing. But Defendant Eisai's "willpower" commercial failed to warn or even mention a potential cancer link.

104. Defendant Eisai's "willpower" commercial even warned users to contact their doctors if their breasts begin to make milk or decrease in size. However, Defendant Eisai's commercial never warned about the potential risk of breast cancer.

105. Although physicians are supposed to weigh the risks and benefits before prescribing a drug, Defendants Arena and Eisai knew that their deliberate omissions would cause physicians, including Plaintiff's physician, to prescribe Belviq without being able to adequately weigh the risk of the weight loss drug's risk of cancer.

106. If Defendants Arena and Eisai would have properly warned about Belviq's cancer risk, no reasonable physician, including Plaintiff's physician, would have recommended or decided to prescribed Belviq because the potential benefits of weight loss is significantly outweighed by the risk of cancer.

107. Had Defendants reasonably and proposed provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have used Belviq and no consumer, including Plaintiff Davis, would have purchased and/or used Belviq.

108. As a direct and proximate result of Belviq's defects as described herein, Plaintiff developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished in the future.

WHEREFORE, Plaintiff demands judgment against Defendants Arena and Eisai, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTIBILITY
(Defendant Eisai)

109. Plaintiff incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

110. Defendant Eisai distributed, recommended, merchandized, advertised, promoted, and sold Belviq as treatment for weight loss and chronic weight management.

111. At the time Defendant Eisai marketed, sold, and distributed Belviq for use by Plaintiff, Defendants knew of the use for which Belviq was intended and impliedly warranted the product to be of merchantable quality and safe and fit for the intended use of weight loss.

112. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant Eisai and used Belviq for its intended use of weight loss and weight management.

113. Plaintiff used Belviq for its intended purpose of weight loss and weight management.

114. Belviq was not fit for its ordinary use of weight loss and weight management because it was defective due to it causing an increased risk of cancer, including breast cancer.

115. As a direct cause of Belviq being not fit for its ordinary purpose of weight loss due to its association with cancer, Plaintiff was diagnosed with cancer after taking Belviq.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IV
NEGLIGENCE
(Defendants Arena and Eisai)

116. Plaintiff incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

117. Defendant Arena had a duty to exercise reasonable care in designing, developing, researching, testing, and manufacturing of Belviq.

118. Defendant Eisai had a duty to exercise reasonable care in designing, developing, marketing, supplying, promoting, selling, and distribution of Belviq.

119. Defendants Arena and Eisai in that they knew or should have known that using Belviq created a significantly increased risk of cancer.

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

(a) Arena and Eisai designed and developed Belviq without thorough or adequately testing it;

(b) Eisai sold Belviq without making proper and sufficient tests to determine the dangers to its users;

(c) Arena and Eisai failed to adequately and correctly warn the Plaintiff, the public, and the medical community, of the cancer risks associated with Belviq;

(d) Eisai advertised and recommended the use of Belviq for weight loss without sufficient knowledge as to the significance of cancer risks;

(e) Arena and Eisai failed to exercise reasonable case in designing Belviq in a manner which was dangerous to its users;

(f) Arena negligently manufactured Belviq in a manner which was dangerous to its users;

(g) Arena and Eisai failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks;

121. Additionally, Arena and Eisai under-reported, underestimated, and downplayed the serious dangers of Belviq's association with cancer.

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

123. Arena and Eisai also 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 detection of cancer.

124. Defendant Eisai specifically failed to exercise reasonable care when it failed to accompany Belviq with proper and/or accurate warnings regarding *all* adverse side effects—namely cancer—associated with the use of Belviq;

125. Once Defendant Eisai gained additional information about Belviq's association with cancer, it failed to update its warnings and thereafter accompany Belviq with adequate warnings regarding cancer.

126. Despite the fact that Arena and Eisai knew or should have known that Belviq caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell Belviq to consumers, including the Plaintiff.

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

128. Defendants' negligence was the proximate cause of Plaintiff's cancer-related injuries, which Plaintiff suffered and/or will continue to suffer.

129. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to her breast cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

130. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT V
NEGLIGENT MISREPRESENTATION
(Defendant Eisai)

86. Plaintiff incorporates by reference all the forgoing language of this Complaint as if fully set forth herein and further states as follows.

87. Defendant Eisai had a duty to exercise reasonable care to those whom they provided product information about Belviq and to all those relying on the information provided, including Plaintiff, her healthcare providers, and the public in general that said product, Belviq, had been tested and found to be safe and effective for chronic weight management.

88. Defendant Eisai, in the course of selling Belviq, supplied information about Eisai through television commercials, advertisements, marketing campaigns, sales representatives, labeling, and warnings.

89. Defendant Eisai breached their duty in representing Belviq's serious side effects involving cancer to the medical and healthcare community, to the Plaintiff, and the public in general.

90. For instance, Defendant Eisai aired television commercials about "willpower" for eating habits, which stated numerous potential side effects, including heart-related issues, depression, suicidal thoughts, low blood sugar, decreased blood cell count, headache, dizziness,

fatigue, nausea, dry mouth, constipation, back pain, and coughing. But Defendant Eisai's "willpower" commercial failed to warn or even mention a potential cancer link.

91. Defendant Eisai's "willpower" commercial even warned users to contact their doctors if their breasts begin to make milk or decrease in size. However, Defendant Eisai's commercial never warned about the potential risk of breast cancer.

92. Eisai's Vice President of Specialty Marketing, Michael O'Brien, said in 2014 that: "For many Americans trying to lose weight, diet and exercise alone are not enough. Further, O'Brien added that Eisai's "goal with this new ad is to turn up the volume on the conversation using realistic situations and questions that real people encounter to raise awareness and encourage those who continue to struggle with their weight to speak to their doctor about BELVIQ as part of a weight loss regimen." *Eisai Inc. Launches National Television Advertising Campaign For BELVIQ® (lorcaserin HCl) CIV*, Biospace (April 14, 2014), https://www.biospace.com/article/releases/eisai-inc-launches-national-television-advertising-campaign-for-belviq-and-0174-lorcaserin-hcl-civ-/.

93. However, Eisai failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that Belviq could lead to cancer.

94. Defendant Eisai's representations were made without properly conducting sufficient testing and by providing insufficient warnings about Belviq's defectiveness relating to cancer without any reasonable ground for believing it to be true based on that lack of testing.

95. Defendants' representations that Belviq was safe for consumers and its failure to disclose material past and existing facts of Belviq's risk of cancer were made or omitted with the intent to induce Plaintiff to rely upon those facts or omissions.

96. Plaintiff was unaware and did not know that Belviq was unsafe for the purpose of weight loss because it caused a significant increased risk of cancer until *after* she was diagnosed with cancer.

97. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including breast cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

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

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VI
FRAUDULENT MISREPRESENTATION
(Defendant Eisai)

99. 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.

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

101. Defendant Eisai also falsely and fraudulently omitted the material fact that Belviq was associated with cancer.

102. These representations and omissions were materially fraudulent and false.

103. When said representations and omissions were made by Eisai, it knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations or omissions were true.

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

105. Plaintiff had a right to rely on the representations or omissions of Eisai as the seller of her prescribed medication, Belviq.

106. However, Plaintiff did not know that Belviq was unsafe for the purpose of weight loss because it caused a significant increased risk of cancer until *after* she was diagnosed with cancer.

107. Defendant Eisai's materially false representations and reckless decision to omit the truth about cancer caused Plaintiff to take Belviq without knowing it could cause cancer up until the point that she was in fact diagnosed with cancer.

108. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including breast cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including

diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

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

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

PUNITIVE DAMAGES
(Defendants Arena and Eisai)

157. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

158. Defendants Arena's and Eisai's conduct described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by their officers, directors, and/or managing agents.

159. Despite their knowledge of Belviq's propensity to cause cancer, Defendants Arena and Eisai chose profits over the safety of American citizens suffering with obesity when they sought to create and market a weight loss drug with significant risks of cancer.

160. Despite having substantial information about the Belviq's serious and unreasonable side effects related to cancer, Defendants Arena and Eisai intentionally and recklessly failed to adequately warn the medical community.

161. Further, despite having substantial information about Belviq's serious and unreasonable side effects related to cancer, Defendants Arena and Eisai failed to make the

decision to pull Belviq from the market after indications of serious, unreasonable side effects such as cancers were prevalent among Belviq consumers.

162. Instead, Defendants Arena and Eisai decided to downplay and hide Belviq's link to cancer until the FDA inevitably requested that Defendant Eisai remove Belviq from the market in early 2020.

163. Defendants Arena and Eisai downplayed and recklessly disregarded their knowledge of the defective nature of Belviq's clear and unequivocal indications of cancers.

164. Defendants undertook a marketing campaign to globally market Belviq despite conducting proper testing.

165. Additionally, Defendant Eisai undertook a marketing campaign related to Belviq despite its own preclinical trial results showing an increased risk of tumors and cancers in rats.

166. Defendant Eisai intentionally and recklessly omitted information in the Instructions for Use ("IFU") to warn and instruct physicians on Belviq's increased risks for cancers.

167. Defendant Arena knew that Eisai was intentionally and recklessly omitted information in the IFU about cancer. However, Defendant Arena chose to do nothing to warn the public about this serious and undisclosed side effect with Belviq.

168. Defendants Arena and Eisai were even aware prior to marketing Belviq that there was a potential increase and/or risk of cancers.

169. Defendant Arena and Eisai recklessly failed to warn and adequately instruct physicians, including Plaintiff's physician, regarding this significant increase in cancers among Belviq users.

170. Consequently, Defendants Arena and Eisai are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amy Davis prays for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory and punitive allowable;

(c) Judgment against Defendants for all other relief sought by Plaintiff;

(d) For reasonable attorneys' fees and costs;

(e) For pre-judgment interest; and

(f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: September 23, 2020

Respectfully Submitted,

/s/ David C. DeGreeff

David C. DeGreeff, MO Bar No. 55019
WAGSTAFF CARTMELL, LLP
4740 Grand Avenue
Suite 300
Kansas City , MO 64112
Phone: 816 701-1100
Fax: 816 531-2372
Email: ddegreeff@wcllp.com

and

Wesley Chadwick Cook*
W. Roger Smith, III*
Ryan J. Duplechin*
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
Post Office Box 4160
Montgomery, Alabama 36103
Phone: (334) 269-2343
Fax: (334) 954-7555
Email: Chad.Cook@BeasleyAllen.com
Email: Roger.Smith@BeasleyAllen.com
Email: Ryan.Duplechin@BeasleyAllen.com

**Pro Hac Vice* Admission to be Sought

Counsel for Plaintiff Amy Davis