Civil Case Information Statement
(CIS)

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

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

Attorney/Pro Se Name	Telephone Number	County of Venue
Gregory S. Spizer	(215) 960-0402	Bergen

Firm Name (if applicable)	Docket Number (when available)
VSCP LAW	

Office Address	Document Type
2001 Market Street Suite 3700 Philadelphia, PA 19103	Complaint
	Jury Demand ■ Yes ☐ No

Name of Party (e.g., John Doe, Plaintiff)	Caption
Dorenda Willmore	DORENDA WILLMORE v. EISAI, INC. and ARENA PHARMACEUTICALS, INC.

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

Related Cases Pending?	If "Yes," list docket numbers
■ Yes ☐ No	BER-L-1208-21; BER-L-3052-21; BER-L-3557-21; BER-L-5757-21; BER-L-3555-21, et al.

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

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

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

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

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

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

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

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

Attorney Signature: Greg S. Spizer

Side 2

Civil Case Information Statement
(CIS)

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

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

Track I - 150 days discovery

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

Track II - 300 days discovery

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

Track III - 450 days discovery

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

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

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

Multicounty Litigation (Track IV)

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

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

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

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Attorneys for Plaintiff

	: SUPERIOR COURT OF NEW JERSEY BERGEN COUNTY: LAW DIVISION
DORENDA WILLMORE, :	
Plaintiff, :	Docket No.: BER- L-
v. :	
EISAI, INC., and ARENA PHARMACEUTICALS, INC. :	COMPLAINT AND JURY DEMAND
:	
Defendants. :	

COMPLAINT

Plaintiff Dorenda Willmore, by and through her undersigned counsel, hereby files this Complaint and alleges against Defendants Eisai, Inc., ("Eisai") and Arena Pharmaceuticals, Inc., ("Arena") as follows:

PARTIES, JURISDICTION, AND VENUE

1. Dorenda Willmore is an adult resident and citizen of Colorado Springs, Colorado.

2. Upon information and belief, Defendant Eisai, Inc., is a Delaware corporation, having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677. As part of its business, Eisai, Inc., is involved in the research, development, sales, and marketing of pharmaceutical products, including Belviq and lorcaserin hydrochloride.

3. Upon information and belief, Defendant Eisai is a subsidiary of Eisai Co., Ltd., which is a Japanese pharmaceutical company headquartered in Tokyo, Japan.

4. Defendant Eisai, Inc. is subject to general jurisdiction in the State of New Jersey because it has continuous and systematic contacts that render it essentially at home in New Jersey. Defendant Eisai is also subject to specific jurisdiction in New Jersey because it transacted substantial Belviq-related business in New Jersey and has its principal place of business in New Jersey.

5. Defendant Arena Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 6154 Nancy Ridge Drive, San Diego, California 92121.

6. Defendant Arena is subject to personal jurisdiction in the State of New Jersey under New Jersey's Long-Arm Statute because:

(a) Arena regularly transacts, solicits, and conducts business in New Jersey, including manufacturing, testing, advertising, promoting, marketing, selling, and distributing Belviq for use in which its primary purpose is chronic weight management; and

(b) Arena engages in substantial and not isolated activity with New Jersey directly and through agents, subsidiaries, or business affiliates.

7. Arena is subject to specific jurisdiction in the State of New Jersey because it has sufficient minimum contacts that arise out of or relate to Plaintiff's claims so that it could reasonably anticipate being subject to suit in the State of New Jersey:

(a) Arena has derived substantial revenue from Belviq-related activities and business with Eisai within the State of New Jersey.

(b) Arena and Eisai collectively launched Belviq in the United States in 2012 and named Defendant Eisai in New Jersey as the exclusive distributor.

(c) Arena collaborated with Eisai in New Jersey to communicate with the United States Food & Drug Administration regarding Belviq.

(d) Arena worked closely and collaborated with Eisai in New Jersey regarding marketing of Belviq.

(e) Arena worked closely and collaborated with Eisai in New Jersey regarding the instructions and labeling for Belviq.

(f) Arena worked closely and collaborated with Eisai in New Jersey to provide guidance and instructions for packaging the final product for Belviq in New Jersey.

(g) Arena worked closely and collaborated with Eisai in New Jersey in planning and conducting the CAMELLIA-TIMI 61 trial involving Belviq.

(h) Arena worked closely and collaborated with Eisai in New Jersey to review the data from the CAMELLIA-TIMI 61 trial.

(i) Arena worked closely and collaborated with Eisai in New Jersey to publish the findings of the CAMELLIA-TIMI 61 trial.

(j) Arena worked closely and in collaboration with Eisai in New Jersey on the development of Belviq and Belviq XR.

(k) Arena worked closely and in collaboration with Eisai in New Jersey on the research, development, sales, and marketing of Belviq XR and lorcaserin hydrochloride in New Jersey.

(l) These contacts arise out of or relate to the Plaintiff's products liability claims for Belviq causing Plaintiff's cancer.

(m) New Jersey has an interest in adjudicating this dispute since Belviq was distributed and sold from New Jersey, and ultimately consumed by the Plaintiff.

8. At all relevant times, Defendants Eisai and Arena were responsible for collective efforts in the design, research, manufacture, testing, advertisement, labeling, promotion, marketing, sale, and/or distribution of Belviq.

9. At all relevant times, Defendants Eisai and Arena were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter

egos of the other Defendants Eisai and Arena and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

10. Defendants Eisai and Arena 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 products, including Belviq or lorcaserin hydrochloride, as well as monitoring and reporting adverse events.

11. Venue is in this action properly lies in the Superior Court of New Jersey, Bergen County, in that the Defendant Eisai, Inc., maintains its principal place of business in Bergen County. In addition, Defendant Arena did regular business with Defendant Eisai in Bergen County arising out of the product at issue, Belviq and/or lorcaserin hydrochloride, as well as distributed Belviq that Plaintiff consumed.

12. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.* ("Products Liability Act"), the New Jersey Punitive Damages Act, N.J.S.A 2A:15-5.9, *et seq.* ("Punitive Damages Act"), and the common law of the State of New Jersey to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries the Plaintiff has sustained as a result of the Defendants Eisai's and Arena's negligent and wrongful conduct in connection with the design, development, manufacturer, testing, packing, promoting, marketing, distributing, labeling and/or sale of the product at issue, Belviq.

BACKGROUND

13. At all relevant times, Defendants Eisai and Arena 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.

14. 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.

15. 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").

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

17. Arena and Eisai jointly launched Belviq in the United States in 2012, with Arena manufacturing Belviq and Eisai as the exclusive distributor.

18. In 2017, Eisai purchased the global rights to develop and market Belviq from Arena.

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

20. During the preclinical trial program, Defendants Eisai and Arena 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, the 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.

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

22. During the preclinical trial program, Arena 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.

23. From September 2006 through February 2009, Arena 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 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.

24. From December 2007 to July 2009, Arena 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.

25. 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.

26. On December 18, 2009, Arena and Eisai submitted its first New Drug Application for Belviq.

27. 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.

28. 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.

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

30. The CRL also requested that Arena submit the final report from the third Phase 3 trial in overweight and obese patients with Type 2 Diabetes Mellitus.

31. From December 2007 to August 2010, Arena 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.

32. On December 27, 2011, in response to the CRL, Arena submitted to the FDA the final report of the BLOOM-DM study and data from the PWG readjudication, 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.

33. 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 readjudication data.

34. 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 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 Eisai and Arena conduct six (6) post-marketing studies, including a cardiovascular outcomes trial.

35. On June 26, 2012, in her Summary Review of Defendants Eisai's and Arena's 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.

36. In contrast, on May 3, 2013, Arena withdrew the application for marketing authorization for Belviq with the European Medicines Agency (hereinafter referred to as "EMA"). 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 readjudication, the risk of carcinogenicity in humans needed further consideration and the overall clinical risk/benefit balance was negative in that the modest efficacy results did not outweigh safety concerns. The CHMP further 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.

37. From January 2014 to June 2018, Arena 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). 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.

38. 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.

39. In January of 2017, Eisai announced that it acquired all global development and marketing rights to Belviq from Arena.

40. Under the 2017 agreement between Eisai and Arena, Eisai became "solely responsible for all decision-making and implementation related to global development and submissions for regulatory approvals," as well as global marketing rights.

41. Pursuant to the agreement between Eisai and Arena, all post-2017 regulatory approvals sought from the FDA were submitted by Eisai.

42. 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.

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

44. 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.

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

46. Defendant possessed pre-clinical scientific studies, which evidence Eisai and Arena knew or should have known was the signal that the cancer risk needed further testing and studies prior to its introduction to the market.

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

48. Upon information and belief, from the date Defendants Eisai and Arena received FDA approval to market Belviq, Eisai and Arena 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 Eisai and Arena had not adequately conducted complete and proper testing and studies of Belviq with regard to carcinogenicity.

49. Eisai and Arena's 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

50. In or around January 2015, Plaintiff Dorenda Willmore was prescribed Belviq for weight loss and diet control by Dr. Deborah Sullivan and Dr. Carol Lee Zielomski in Colorado Springs, Colorado.

51. Plaintiff's physicians continued to prescribe her Belviq until February of 2020.

52. From January 2015 to February 2020, Plaintiff continued to take Belviq for her weight loss without knowing of the significant increased risk that Belviq could cause her to develop cancer.

53. In October 2020, Plaintiff was diagnosed with anaplastic astrocytoma, a form of brain cancer.

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

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

56. Plaintiff could not have reasonably discovered that Belviq was the cause of her brain cancer until at least January 2020, when the FDA announced it was reviewing clinical trial data and alerted the public about a possible risk of cancer associated with Belviq based on its preliminary analysis of the clinical trial data.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT (N.J.S.A. 2A:58C-1 *et seq.*)
(Defendants Eisai and Arena)

57. 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.

58. At all times herein mentioned, Defendants Eisai and Arena collectively researched, designed, manufactured, tested, advertised, promoted, marketed, packaged, labeled, sold and/or distributed Belviq, which is defective and unreasonably dangerous.

59. 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.

60. 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 Eisai and Arena. 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.

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

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

63. At or before the time Belviq was released on the market and/or sold to Plaintiff, Defendant Eisai 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.

64. At or before the time Belviq was released on the market and/or sold to Plaintiff, Defendant Arena 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.

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

66. Belviq is and was being used in the Defendants Eisai's and Arena's intended manner at the time it was prescribed to Plaintiff.

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

68. As Belviq's exclusive distributor who collectively launched Belviq with Arena, Defendant Eisai knew or should have known that Belviq would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendant Eisai 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.

69. Defendant Arena knew or should have known that Belviq would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable product. Further, Defendant Arena 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.

70. Defendants Eisai and Arena collectively 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 both Defendants Eisai and Arena are therefore strictly liable for the injuries sustained by Plaintiff.

71. As a direct and proximate result of Defendants Eisai's and Arena's collectice 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 Eisai and Arena, 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 Eisai and Arena, 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 II
STRICT PRODUCTS LIABILITY- FAILURE TO WARN (N.J.S.A. 2A:58C-1 *et seq.*)
(Defendants Eisai and Arena)

72. 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.

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

74. 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 Eisai and Arena.

75. Defendants Eisai's and Arena's duty to provide adequate warnings extends not only to consumers of its own product, but also to those persons whose doctors foreseeably rely on Defendant Eisai's and Arena's product information when prescribing a medication, even if the prescription is filled with a generic version of that prescribed drug. Defendants Eisai and Arena also had a continuing duty to warn Plaintiff and her physicians of the dangers associated with the subject product.

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

77. Defendants Eisai and Arena knew or should have known that the product created a risk of serious and dangerous side effects including cancer, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendant Eisai and Arena failed to adequately warn of said risk.

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

79. Information provided by Defendants Eisai and Arena to the medical community, consumers, and ultimately Plaintiff concerning the safety and efficacy of Belviq did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

80. At all times relevant hereto, Belviq was dangerous and presented a substantial danger to consumers like Plaintiff who were prescribed with Belviq, and these risks and dangers were known or knowable at the times of distribution and/or prescription to Plaintiff. Ordinary consumers like Plaintiff would not have recognized the potential risks and dangers that Belviq posed to patients, because its use was specifically promoted to improve the health of such patients, including Plaintiff.

81. Had adequate warnings and instructions been provided, Plaintiff would not have been prescribed Belviq, and would not have been at risk of the harmful injuries, including but not limited to cancers described herein. Defendants Eisai and Arena failed to provide warnings of such risks and dangers to the Plaintiff and her medical providers as described herein.

82. Neither Plaintiff nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Belviq.

83. Defendant Eisai, as the exclusive distributor that collectively launched Belviq and collaborated with Arena in its regulatory submissions to the FDA, knew or should have known that the warnings given failed to properly warn both medical professionals and consumers of the increased risks of serious injury and/or death associated with and/or death associated with and/or caused by Belviq.

84. Defendant Arena, as the manufacturer of Belviq with direct access and control over product testing studies, knew or should have known that the warnings given failed to properly warn both medical professionals and consumers of the increased risks of serious injury and/or death associated with and/or caused by Belviq.

85. Defendant Eisai, while working in close collaboration with Arena, deliberately concealed and did not disclose knowledge acquired after Belviq's 510(k) clearance that Belviq caused serious health issues and side effects, including cancers.

86. Defendant Arena also deliberately concealed and did not disclose knowledge acquired after Belviq's 510(k) clearance that Belviq caused serious health issues and side effects, including cancers. Defendants Eisai and Arena knew or should have known that the warnings given failed to properly warn both medical professionals and consumers of the increased risks of serious injury and/or death associated with and/or caused by Belviq.

87. Defendants Eisai and Arena also engaged in an economically driven manipulation of the post-market regulatory process involving Belviq.

88. Plaintiff, individually and through her treating physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants Eisai and Arena.

89. As a direct and proximate result of Belviq's defects as described herein, Plaintiff 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. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to care because of Belviq's defects.

90. Based on the foregoing, Defendants Eisai and Arena are liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn or instruct the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by Belviq.

WHEREFORE, Plaintiff demands judgment against Defendants Eisai and Arena, 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.

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

91. 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.

92. The acts and omissions of Defendants Eisai and Arena 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 Defendants Eisai's and Arena's officers, directors, and/or managing agents.

93. In 2012, the FDA approved Belviq but required that Defendants conduct a post-market clinical trial to evaluate risk of cardiovascular problems. Defendants Eisai and Arena were then required to submit the results to the FDA. The clinical trial became known as the "CEMELLIA-TIMI 61" trial.

94. After Defendants Eisai and Arena received FDA approval for Belviq, they later came into possession of knowledge linking Belviq to substantial and unreasonably dangerous side effects, including a link to cancer.

95. Despite this knowledge, Defendants Eisai and Arena knowingly withheld materials information from the FDA relating to Belviq's significant increased risk of cancer. If Defendants Eisai and Arena would have communicated this material information to the FDA sooner, the FDA would have taken earlier steps to withdraw Belviq.

96. Despite this knowledge, Defendants Eisai and Arena remained silent until their required submission to the FDA regarding the post-market clinical trial results. During these

required submissions to the FDA, Defendants Eisai and Arena withheld critical information and downplayed Belviq's link to cancer.

97. Once the FDA conducted their own evaluation of Defendants' required submissions, in January 2020, the FDA made an announcement alerting the public of Belviq's possible increased risk of cancer.

98. Less than one month later, on February 13, 2020, the FDA announced that Defendants Eisai and Arena agreed to withdraw Belviq from the market.

99. Despite this knowledge, Defendants Eisai and Arena, for financial reasons, sought to create and market a weight loss and diet control drug, and Defendants did in fact create such drug, Belviq, that had substantial and unreasonable risks and side effects of Belviq, including brain cancer.

100. Yet, despite having substantial information about the serious and unreasonable side effects of Belviq, Defendants Eisai and Arena intentionally and recklessly failed to adequately instruct physicians, including Plaintiff's physicians, of the serious and unreasonable side effects of Belviq, and failed to warn physicians, including Plaintiff's physician, and consumers, including Plaintiff, of the significant risks of cancers from Belviq.

101. Defendants Eisai and Arena failed to pull Belviq from the market after indications of serious, unreasonable side effects such as cancers were prevalent among Belviq consumers, and instead unjustifiably delayed its inevitable removal until the FDA forced such in February of 2020.

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

103. Defendants Eisai and Arena undertook a marketing campaign to globally market Belviq despite conducting proper testing.

104. Additionally, Defendants Eisai and Arena undertook this marketing campaign despite its own preclinical trial results showing an increased risk of tumors and cancers in rats.

105. Defendants Eisai and Arena intentionally and recklessly omitted information in the warnings and instructions to physicians on Belviq's significant increased risk of cancers.

106. Defendants Eisai and Arena downplayed, understated, and disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Belviq.

107. Finally, Defendants Eisai and Arena were aware during marketing Belviq that there was a potential increase and significant risk of cancers.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dorenda Willmore prays for judgment against Defendants Eisai and Arena, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against all Defendants for all compensatory allowable to Plaintiff;

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

(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: January 11, 2022.

Respectfully Submitted,

/s/ Gregory Spizer
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*Pending *Pro Hac Vice* Admission

Counsel for Plaintiff Dorenda Willmore

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-000172-22

Case Caption: WILLMORE DORENDA VS EISAI, INC.
Case Initiation Date: 01/11/2022
Attorney Name: GREGORY STEVEN SPIZER
Firm Name: VSCP LAW
Address: TWO COMMERCE SQUARE 2001 MARKET ST., STE 3700
PHILADELPHIA PA 19104
Phone: 2159600000
Name of Party: PLAINTIFF : Willmore, Dorenda
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: BER-L-1208-21
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Are sexual abuse claims alleged by: Dorenda Willmore? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

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

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

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

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

01/11/2022
Dated

/s/ GREGORY STEVEN SPIZER
Signed