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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES - UNLIMITED JURISDICTION

VIVIAN SKELTON, an individual;

Plaintiff,

v.

ALLERGAN INC., ALLERGAN USA, INC; and DOES 1-100, inclusive,

Defendants.

Case No. BC 6 9 6 4 0 0

COMPLAINT FOR DAMAGES
(1) NEGLIGENT AND NEGLIGENCE PER SE
(2) STRICT PRODUCTS LIABILITY-FAILURE TO WARN
(3) BREACH OF IMPLIED WARRANTY

DEMAND FOR JURY TRIAL

By Fax

Plaintiff Vivian Skelton, an individual (hereinafter "Plaintiff"), by and through her attorneys, based on information and belief, and for causes of action against the Defendants, ALLERGEN, INC., ALLERGEN USA, INC. (hereinafter collectively referred to as "ALLERGEN"), and DOES 1 through 100, inclusive (hereinafter collectively referred to as "Defendants"), and each of them, hereby allege

as follows:

I. INTRODUCTION

1. Plaintiff brings this action against Defendants, and each of them, as a result of her Allergan Natrelle® Silicone breast implants product that was manufactured, designed, formulated, tested, packaged, produced, created, made, labeled, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

2. Plaintiff was injured severely and permanently when she developed and was diagnosed with breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL" or "ALCL") after being implanted with Defendants' defective and unreasonably dangerous breast implants.

3. This action arises out of the physical injuries and damages suffered by Plaintiff as a result of Defendants' actions and/or omissions. Plaintiff maintains that Defendants' breast implants lacked proper warnings as to the dangers associated with their use.

II. PARTIES, JURISDICTION AND VENUE

4. At all times relevant hereto, Plaintiff VIVIAN SKELTON is and was a citizen and resident of Denver, Colorado.

5. ALLERGAN INC., is a Delaware Corporation with its principal place of business in California.

6. ALLERGAN USA, INC. is a Delaware Corporation with its principal place of business in California. Upon information and belief it is a wholly owned subsidiary and controlled by Allergan, Inc.

7. The true names and/or capacities, whether individual, corporate, associate or otherwise of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiff at this time, who therefore sue said Defendants by such fictitious names. Plaintiff is informed and believes, and thereupon alleges, that each of the Defendants fictitiously named herein as a DOE is legally responsible, negligently or in some other actionable manner, for the events and happenings hereinafter referred to, and thereby proximately caused the injuries and damages to Plaintiff as hereinafter alleged. Plaintiff will seek

leave of court to amend this Complaint to insert the true names and/or capacities of such fictitiously named Defendants when the same have been ascertained.

8. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

9. At all relevant times, Defendants acted in concert with one another in the State of California to fraudulently convey false and misleading information concerning the breast implants they manufacture and to conceal the risks of serious adverse events associated with their breast implants from the public, Plaintiff, physicians, and other healthcare providers. These concerted efforts resulted in significant harm to Plaintiff. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiff would not have been implanted with Allergan Natrelle® Silicone breast implants and would not have suffered severe injuries.

10. This Court has personal jurisdiction over Defendants. Defendants are and were at all relevant times residents of and/or authorized to conduct business in the State of California and Defendants conducted such business within the State including the performance of acts that caused or contributed to the harm giving rise to this action.

11. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial benefit and profits as a result of the designing, formulating, testing, packaging, labeling, producing, creating, constructing, making, assembling, advertising, clinical testing, marketing, promoting, distributing, manufacturing, and selling the product in this

district and throughout the United States.

12. At all times material hereto, the action arises from obligations that arise out of, or are connected with, Defendants' activities within the State of California.

13. Plaintiff's claims arise out of and/or are related to Defendants' California-related forum activities. Plaintiff is informed and believes and on that basis alleges that Defendants have purposefully directed their activities at this forum State, and the exercise of jurisdiction is reasonable and would not offend the traditional notions of fair play and substantial justice. Plaintiffs is informed and believes and on that basis alleges that Defendants have purposefully availed themselves of the privileges and benefits of conducting activities with the forum State, and have invoked the benefits and protections of its laws.

14. Venue is proper in the county where plaintiff's injuries occurred, or where the defendants, or some of them, reside under California Code of Civil Procedure section 395. Venue is proper in Los Angeles County in accordance with Code of Civil Procedure section 395, because Defendant Allergan has its principle place of business in Irvine, California, and a substantial part of the events giving rise to this action occurred in this District.

III. DESCRIPTION OFALLERGAN NATRELLE® SILICONE BREAST IMPLANTS

15. Allergan Natrelle® Silicone breast implants are Class III medical devices receiving pre-market approval by the FDA in November of 2006.

16. Allergan Natrelle® Silicone breast implants have a silicone outer shell that is filled with silicone gel. They come in different sizes and have either smooth or textured shells and are approved for revision surgery, breast augmentation in women age 22 or older, and for breast reconstruction in women of any age.

17. As conditions of approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Allergan's Natrelle® silicone filled breast implants included:

1. Core Post-Approval Study (Core Study) – To assess long-term clinical performance of

breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

2. Large Post-Approval Study (Large Study) – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10-years.

3. Device Failure Study (Failure Study) – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

4. Focus Group Study – To improve the format and content of the patient labeling.

5. Annual Physician Informed Decision Survey (Informed Decision Study) – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

6. Adjunct Study – To provide performance and safety information about silicone gel-filled breast implants provided to U.S. women from 1992-2006, prior to approval, when implants could only be used for reconstruction and replacement of existing implants.

18. The overall follow-up rate was 65% at 10 years. The Final Report was submitted in year 5 of the study in 2011.

19. Allergan failed to report adverse events from the post market approval studies commissioned as part of the implant's PMA approval, which would have led to reports suggesting the device's contribution to serious injury.

20. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post market complaints and data.

21. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the U.S. Food and Drug Administration ("FDA"), the healthcare community and to consumers. The manufacturer also must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer's approved design, as well as its representations and warranties and with specifications of approval.

22. When monitoring and reporting adverse events as required by both federal regulations

and California law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could mean that researchers, regulatory bodies, and the medical community are years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experience, but it must also report the data as soon as it is received.

23. This action arises from Defendants' failures of their post-market responsibilities to monitor and warn about serious health risks that emerged after their Allergan Natrelle® Silicone breast implants were marketed in the United States.

IV. BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA

24. Breast Implant-Associated Anaplastic Large Cell Lymphoma is a rare T-cell Lymphoma that can develop following breast implants. It is a type of non-Hodgkin's lymphoma, a cancer of the cells of the immune system.

25. The most common presenting symptom for BIA-ALCL is a swollen breast caused by the formation of a delayed unilateral idiopathic seroma occurring between the implant surface and the capsule.

26. The World Health Organization gave the disease a designation in 2016 and it was a few months after that the National Comprehensive Cancer Network (NCCN) released the first worldwide oncology standard for the disease.

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27. On March 21, 2017, the U.S. Food and Drug Administration (FDA) released a safety communication updating the current understanding of BIA-ALCL.

28. The recent BIA-ALCL update reported that the FDA has been made aware of 359 medical device reports (MDRs) related to breast implants and ALCL, including 9 deaths.

V. SPECIFIC ALLEGATIONS

29. Plaintiff Vivian Skelton underwent a bilateral breast augmentation procedure on May 6, 2014 wherein Allergan Natrelle® Silicone breast implants (the "product") were implanted.

30. Subsequently Plaintiff began to experience discomfort, pain, and fatigue, as well as swelling in the left breast.

31. In January 2015, Plaintiff underwent a left breast implant revision at Kaiser. Pathology was negative for malignancy at that time.

32. Due to ongoing discomfort and fluid recurrence, a mammogram and ultrasound were obtained in June 2015, which revealed the persistence of fluid collection.

33. A second revision occurred in September 2015, and a biopsy of the surrounding tissue showed fat necrosis.

34. A medial left breast ultrasound in early 2016 revealed thickening, subcutaneous edema, and an ill-defined fluid collection 9 cm from the nipple and measuring 5.6 x 4.7 x 2.9 cm extending to the implant.

35. In February 2016, an MRI of the left breast showed skin thickening and edema with a fluid collection measuring 6.2 x 5.3 x 5.9 cm and a second complex cystic collection measuring 3.4 x 3.3 x 3.1 cm in size, both abutting the implant.

36. Plaintiff Vivian Skelton was thereafter diagnosed with BIA-ALCL on March 3, 2016 at Rock Creek Oncology, Kaiser Permanente.

37. Plaintiff began CHOP chemotherapy on March 24, 2016 and interim staging scans after two cycles showed decreased metabolic activity and size of the left breast masses.

38. Plaintiff received three additional cycles and restaging imaging in June 2016 showed that the lobulated mass of the left breast had not changed in size from the interim staging, with the

median lesion measuring 4.9 x 5.4 cm with an SUV of 3.1 and an inferior lesion measuring 2.7 x 4.0 cm with an SUV of 3.7.

39. Plaintiff underwent a left mastectomy and implant removal on or about July 28, 2016, and a sentinel lymph node biopsy was obtained. The lesions returned positive for a CD30+ large cell lymphoma.

40. Soon after explantation, Plaintiff developed left axillary lymphadenopathy.

41. In September 2016, Plaintiff was initiated on brentuximab monotherapy and a restaging scan after three cycles in November 2016 showed the inferior left chest wall mass measuring 4.8 x 0.9 cm with an SUV of 2.6.

42. Plaintiff was thereafter admitted to Presbyterian/St. Luke's Hospital on February 1, 2017 to undergo chemotherapy with BEAM followed by autologous stem cell rescue. Her post-transplant course was complicated by significant abdominal pain and suspected typhlitis, as well as febrile neutropenia and transaminitis. Plaintiff was observed to have increasing cognitive dysfunction prior to her discharge, and was therefore discharged to Spalding Rehabilitation Facility where she completed a two-week stay of rehabilitation.

43. Plaintiff continues to receive treatment to date for the adverse effects caused by the product.

VI. CAUSES OF ACTION
FIRST CAUSE OF ACTION

NEGLIGENCE & NEGLIGENCE PER SE
(Against All Defendants)

44. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

45. At all relevant times, Defendants had a duty to Plaintiff to use reasonable care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting Allergan Natrelle® Silicone breast implants.

46. Defendants formulated, made, created, labeled, packaged, tested, constructed,

assembled, advertised, manufactured, sold, distributed, marketed, and promoted Allergan Natrelle® Silicone breast implants, including the product that was implanted into Plaintiff Vivian Skelton.

47. Defendants had a duty under parallel state law, including California law, to exercise reasonable care to provide adequate warning about the risks and dangers of Allergan Natrelle® Silicone breast implants that were known or knowable to Defendants at the time of distribution.

48. Defendants breached their duty in that they failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Allergan Natrelle® Silicone breast implants prior to the time of Plaintiff's implantation, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiff.

49. Specifically, upon information and belief, Defendants breached these duties and violated federal and state law by, inter alia: receiving and failing to warn of or report adverse events to the FDA or the public; failing to warn of or report Allergan Natrelle® Silicone breast implant failure to meet its performance specifications or perform as intended under the PMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Allergan Natrelle® Silicone breast implants.

50. Despite the fact that evidence existed that Allergan Natrelle® Silicone breast implants were dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Allergan Natrelle® Silicone breast implants. Instead, Defendants manufactured, marketed, sold, advertised, and promoted Allergan Natrelle® Silicone breast implants while failing to warn or otherwise ensure the safety of its users in violation of state law, including California law, the Allergan Natrelle® Silicone breast implants PMA, and FDA regulations.

51. In addition, the Allergan Natrelle® Silicone breast implants PMA set forth six specific studies and reporting requirements—as described above—that obligated Defendants to report their results.

52. Defendants negligently failed to comply with the above requirements and failed to take

necessary actions - such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs - to advise users of Allergan Natrelle® Silicone breast implants of the defects and risks described above.

53. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. Health & Saf. Code, §§ 111440 ("it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded"), 111445 ("it is unlawful for any person to misbrand any drug or device.").

54. Under parallel federal law, Defendants had the ability to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded. 21 U.S.C. § 331 ("the following acts and the causing thereof are prohibited: (a) the introduction . . . of any device that is . . . misbranded, (b) the . . . misbranding of any . . . device . . . .).

55. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiff's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiff's physician, regarding the dangers of Allergan Natrelle® Silicone breast implants that were known or knowable to Defendants at the time of distribution.

56. If Plaintiff and Plaintiff's physician been adequately warned of the serious risks and adverse events, they would not have agreed to or used Allergan Natrelle® Silicone breast implants. As a proximate and legal result of Defendants' failure to comply with its PMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiff under parallel state law and caused Plaintiff past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

57. Defendants owed a duty in all of their several undertakings, including the communication of information concerning Allergan Natrelle® Silicone breast implants, and to

exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others.

58. Defendants, in the course of their business and profession, knowingly and negligently disseminated inaccurate and misleading information to physicians concerning the properties and effects of Allergan Natrelle® Silicone breast implants, with the intent and expectation that physicians would rely on that information in their decisions in recommending and surgically implanting Allergan Natrelle® Silicone breast implants in their patients.

59. When Defendants disseminated information to physicians and/or patients concerning the properties and effects of Allergan Natrelle® Silicone breast implants, they knew or should have known that physicians and/or patients would reasonably rely on that information in their decisions concerning the use of Allergan Natrelle® Silicone breast implants.

60. Defendants disseminated false information, in that they engaged in false and misleading sales and marketing tactics, touting the aesthetic beauty of breast augmentation and minimizing the risks, which reached physicians, the medical community, and the public with knowledge that the information was, in fact, false and misleading.

61. Defendants produced false and misleading sales and marketing tactics and concealed adverse information at a time when Defendants knew, or should have known, that Allergan Natrelle® Silicone breast implants had defects, dangers, and characteristics that were other than what Defendants had represented to consumers and the healthcare industry generally.

62. Defendants had no reasonable grounds for believing these representations were true when they were made; in fact, Defendants knew the representations to be false.

63. Defendants' breach of their duties under state law parallel to their violations of federal law; the Allergan Natrelle® Silicone breast implants PMA specifically mandates, and state law independently requires, that any representations regarding the device must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

64. Defendants disseminated the false information, as referenced above, to physicians, the

medical community, and the public with the intention to deceive physicians and their patients and to induce physicians to surgically implant Allergan Natrelle® Silicone breast implants.

65. In willfully supplying the false and misleading information, Defendants negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Allergan Natrelle® Silicone breast implants was accurate and not misleading.

66. By failing to ensure representations regarding Allergan Natrelle® Silicone breast implants were truthful, accurate, and not misleading, Defendants have violated the Allergan Natrelle® Silicone breast implants PMA, FDA regulations, and parallel state law.

67. Defendants expected or should have expected that patients, in reliance on false information, who were implanted with Allergan Natrelle® Silicone breast implants would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Allergan Natrelle® Silicone breast implants, causing them to undergo future removal surgeries.

68. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended.

69. As a proximate and foreseeable result of the foregoing misrepresentations by Defendants, Plaintiff has suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

70. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their PMA and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, testing, and sale of Allergan Natrelle® Silicone breast implants. 21 U.S.C. §§ 301, *et seq.*; 21 U.S.C. § 360l (postmarket surveillance).

71. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence per se: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21

C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.1; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R. 820.70; 21 § 820.90; and 21 C.F.R. § 820.160.

72. Defendants' conduct also violates their duties under the Sherman Food, Drug, and Cosmetic laws and gives rise to negligence per se. West's Ann. Cal. Health & Safety Code §§ 109875, et. seq.; 111260; 111295; 111300; 111305; 111440; 111445; and 111450.

73. Plaintiff is within the class of persons the statutes and regulations protect, and Plaintiff's injuries are of the type of harm these statutes and regulations are designed to prevent.

74. Defendants' violations of these statutes and regulations proximately caused Plaintiff's injuries alleged herein.

75. The conditions of the Allergan Natrelle® Silicone breast implants PMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the PMA. See 21 C.F.R. § 814.82(c).

76. Defendants had a parallel duty under state law, including California law, to exercise reasonable care in testing and inspecting their product, in monitoring conformity with the design of Allergan Natrelle® Silicone breast implants placed into Plaintiff, in performing continuing risk-analysis and risk assessments of Allergan Natrelle® Silicone breast implants, in manufacturing Allergan Natrelle® Silicone breast implants, and in marketing Allergan Natrelle® Silicone breast implants.

77. As a proximate and legal result of Defendants' failure to exercise reasonable care in Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future follow-up medical care, medical treatment, and procedures, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

78. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

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SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

79. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

80. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Allergan Natrelle® Silicone breast implants.

81. At all times relevant herein, Defendants intended for the Allergan Natrelle® Silicone breast implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiff.

82. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

83. Defendants also failed to revise their labeling to warn of the accurate rate of occurrence of adverse events based upon the post-market adverse event information available to them.

84. Defendants knew or should have known there was an association between the use of Allergan Natrelle® Silicone breast implants and BIA-ALCL. Defendants failed to adequately warn users, including Plaintiff, of Defendants' products and of these potential serious and harmful risks.

85. Defendants failed to provide follow-through post-approval studies required by the FDA's granting of the PMA necessary in order to market and sell their product, and thus failed to report to, and warn, the FDA of the risks described above.

86. Allergan Natrelle® Silicone breast implants unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of BIA-ALCL that could, and did, harm consumers, including Plaintiff, and Defendants failed to adequately warn consumers of said risks - including Plaintiff and/or her physician- in accordance with state law, including California law.

87. At all relevant times, Plaintiff's Allergan Natrelle® Silicone breast implants were used and implanted into Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

88. Allergan Natrelle® Silicone breast implants manufactured, marketed, promoted, distributed, and sold by Defendants were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

89. Despite the fact that Defendants knew or should have known that the use of Allergan Natrelle® Silicone breast implants were unreasonably dangerous and likely to place users at serious risks to their health, Defendants failed to monitor and warn of the defects, health hazards, and risks associated with Allergan Natrelle® Silicone breast implants.

90. The wrongful acts, representations and/or omissions of Defendants, hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or ratified by Defendants' officers, directors, or managing agents, and were done maliciously, oppressively, fraudulently and/or with a willful and knowing disregard of the probably dangerous consequences for the health and safety of its products users, including Plaintiff. In making, adopting, approving, authorizing, endorsing and/or ratifying such conduct hereinabove set forth, the officers, directors and/or managing agents of Defendants acted with a willful and/or knowing disregard of the probably dangerous consequences, and/or acted with an awareness of the probably dangerous consequences of their conduct and deliberately dialed to avoid those consequences, thereby creating a substantial risk of injury to Plaintiff and other users of their products. Plaintiffs are entitled to punitive and exemplary damages in an amount to be ascertained, which is appropriate to punish to set an example of Defendants and deter such behavior by them in the future.

91. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

92. Plaintiff incorporates by reference all previous and subsequent paragraphs of this

93. Complaint as if fully set forth herein and further allege as follows:

94. At all relevant times, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, marketed, advertised, and sold Allergan Natrelle® Silicone breast implants.

95. Prior to Plaintiff's implantation of Allergan Natrelle® Silicone breast implants, Defendants impliedly warranted to Plaintiff and Plaintiff's health care providers that Allergan Natrelle® Silicone breast implants were of merchantable quality, reasonably fit for its intended purpose, and safe for the use for which it was intended.

96. At all relevant times, Plaintiff and Plaintiff's physician used and implanted Allergan Natrelle® Silicone breast implants for the purpose and in the manner intended by Defendants.

97. At all relevant times, Allergan Natrelle® Silicone breast implants were not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold and/or used and it did not meet the expectations for the performance of the product when used in a customary, usual and reasonably foreseeable manner.

98. Plaintiff and/or her healthcare provider reasonably relied upon the skill and judgment of Defendants and upon said warranties in using Allergan Natrelle® Silicone breast implants.

99. Defendants' breaches of their implied warranties under state law parallel their violations of federal law; the Allergan Natrelle® Silicone breast implants PMA specifically mandates, and state law, including California law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

100. As a direct result of the unsafe nature of Allergan Natrelle® Silicone breast implants Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

101. By reason of the foregoing, Plaintiff has been damaged by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of

punitive damages.

102. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

RELIEF REQUESTED

WHEREFORE Plaintiffs pray for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1) Economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;
2) For compensatory damages according to proof;
3) For an award of attorneys' fees and costs;
4) For prejudgment interest and the costs of suit;
5) Punitive or exemplary damages according to proof; and
6) For such other and further relief as this Court may deem just and proper.

Dated: March 3, 2018

By: _____
Jennifer A. Lenze
LENZE LAWYERS, PLC
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand individual trials by jury as to all claims so triable in this action.

Dated: March 3, 2018

By: _____
Jennifer A. Lenze
LENZE LAWYERS, PLC
Attorneys for Plaintiffs