IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

NICOLE WEBER, Plaintiff, v. ALLERGAN, INC., Defendant.	:	CIVIL NO. _____ **COMPLAINT AND JURY DEMAND**

Plaintiff, NICOLE WEBER, by and through her undersigned counsel, sues defendant, ALLERGAN, INC., and states as follows:

THE PARTIES

1. Plaintiff, Nicole Weber ("plaintiff" or "Ms. Weber"), is an individual with an address of 4685 S. Desert Dawn Drive, Gold Canyon, Arizona 85118.

2. Defendant Allergan, Inc. ("Allergan" or "defendant"), is a corporation organized and existing under the laws of the State of Delaware, having its headquarters at 2525 Dupont Drive, Irvine, California 92612.

3. Allergan is the developer and manufacturer of Natrelle silicone-filled breast implants ("Natrelle implants"). At all relevant times, Allergan did business in and distributed Natrelle implants to locations throughout the United States, including Arizona.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction based on diversity of the parties, and the amount in controversy exceeds $75,000.00 as required under 28 U.S.C. § 1332(a)(2).

5. Venue in this Court is proper under 28 U.S.C. § 1391(a) as the injury and transaction giving rise to the claims set forth herein occurred in Maricopa County.

FACTUAL ALLEGATIONS

Silicone Implants - Background

6. At all relevant times, Allergan designed, manufactured and distributed Natrelle implants.

7. Breast implants, and silicone gel-filled implants in particular, have been the subject of much scrutiny in recent years.

8. In 1992, the Food and Drug Administration ("FDA") placed a moratorium on the sale of silicone gel-filled implants.

9. Subsequently, manufacturers, including Allergan, initiated clinical trials to study the safety and efficacy of silicone gel-filled implants.

10. In November 2006, the FDA allowed silicone gel-filled breast implants back on the market.

11. The FDA, however, recognized the need for additional long term and short term safety data; accordingly, as a condition of approval, Allergan was required to conduct additional, post-approval studies to continue monitoring the performance and safety of the implants.

12. Specifically, Allergan was required by the FDA to conduct a large ten-year study to collect data on the implants in order to monitor and validate the implants' long-term safety and effectiveness.

13. In order to comply with the FDA's directive and continue to benefit from the sale of silicone implants, Allergan must enroll thousands of patients through certified surgeons, referred to as investigators, throughout the country.

14. Allergan commenced a ten-year prospective study called the Breast Implant Follow-up Studies program ("BIFS").

15. Upon information and belief, Dr. Bryan W. Gawley was an investigator for BIFS and was acting at all times as an agent for Allergan.

16. Allergan had the goal of enrolling 50,000 patients in BIFS.

Ms. Weber - Background

17. In March 2009, at the age of 53, Ms. Weber was diagnosed with zero staged breast cancer.

18. Ms. Weber's cancer surgeon, Dr. Nedra Harrison, recommended four surgeons specializing in reconstructive surgery, one of whom was Dr. Bryan W. Gawley.

19. On July 8, 2009, Ms. Weber had an appointment with Dr. Gawley to discuss reconstructive surgery following her bilateral mastectomy.

20. Dr. Gawley repeatedly represented to Ms. Weber that silicone implants were very safe.

21. Dr. Gawley advised that the problems previously associated with silicone implants had been remedied before the implants were brought back on the market in 2006.

22. Further, Dr. Gawley stated that silicone implants were natural looking and that Ms. Weber would not be happy with the outcome if she chose saline implants.

23. It was clear that Dr. Gawley's goal was to convince Ms. Weber to choose silicone implants over saline.

24. Dr. Gawley further stated that there was a fringe group of women who were kooks that claimed they experienced problems attributable to silicone implants, but they were just kooks.

25. Dr. Gawley represented that there was absolutely no chance of rupture and that he had no problems with the new silicone implants in his practice.

26. To ease Ms. Weber's concerns about the safety of silicone implants, Dr. Gawley related a well-rehearsed story of his one and only problem case which involved a woman who was a professional dancer who repeatedly banged her breast on the dance pole, causing her implant to explode. He implied that, unless she was planning on taking part in that activity, there was no chance of rupture.

27. Dr. Gawley never discussed the risks associated with a bleed and never disclosed that silicone could bleed into patients' bodies.

28. By information and belief, Dr. Gawley's statements and representations were all based on information and marketing materials he received from Allergan.

29. On July 28, 2009, Ms. Weber underwent a radical mastectomy performed at Piper Surgery Center in Scottsdale, Arizona.

30. Immediately following the mastectomy, Dr. Gawley placed Alloderm tissue expanders to prepare for implant surgery in several months.

31. On or about December 2, 2009, during a pre-operative appointment, Ms. Weber was invited by Dr. Gawley's staff to fill out a questionnaire in order to help cancer patients; Ms. Weber was never advised that the questionnaire was an FDA ordered study to determine whether the implants were safe.

32. The name of the contractor administering the survey was only identified as BIFS and its relation to Allergan was not identified.

33. Ms. Weber agreed to fill out the questionnaire in order to help other cancer patients.

34. On December 2, 2009, Ms. Weber registered with BIFS and was assigned participant registration code no. 974-395.

35. On December 21, 2009, Ms. Weber underwent surgery to substitute the tissue expanders for the Natrelle implants (REF 20-500 and SN 1420687 on the right and REP 20-550 and SN 14578758 on the left).

36. Prior to the surgery and other than the breast cancer, Ms. Weber was a healthy individual and lived a healthy lifestyle.

37. Ms. Weber enjoys exercise and outdoor activities; in fact, she organized and played in an employer-sponsored soccer league in 2007 and 2008.

38. On August 10, 2010, Ms. Weber went in for a follow-up appointment with complaints of severe pressure and discomfort from tightening of the implants.

39. Ms. Weber explained to Dr. Gawley that she was concerned about how tight and uncomfortable the implants felt.

40. Dr. Gawley responded that what Ms. Weber was experiencing was due to the fact that she was swimming three times a week and suggested that she stop doing the breaststroke.

41. Dr. Gawley said that there were no issues with the implants and that Ms. Weber should simply face the reality that the implants were going to be tight.

42. Around August 21, 2010, Ms. Weber received the first annual survey from BIFS. At that time, Ms. Weber checked "no" to every symptom on the list; however, breast tightening was conspicuously absent from the list.

43. From December 2010 to October 2011, Ms. Weber experienced the following symptoms: six weeks of daily migraines; severe lung and breathing difficulties; severe anxiety;

tinnitus; severe vertigo; racing heartbeat; large red strawberries on arms and fungal feet; allergic reactions to all medications; severe chest spasms and tremors and vision loss.

44. Ms. Weber's migraines were so severe that she required weekly visits to the emergency room, as well as an urgent care facility.

45. Ms. Weber also required an emergency room visit in connection with her lung and breathing problems.

46. In March 2011, Ms. Weber began to experience significant vision loss. Over the next year, Ms. Weber sought treatment by numerous ophthalmologists and neurologists in effort to discover a diagnosis.

47. At the end of September 2011, Ms. Weber received the second follow-up survey from BIFS. This time, Ms. Weber checked the following symptoms: a change in the shape or size of the breast; anxiety; changes in mood or personality; chest pain; decreased visual acuity or double vision; depression; dizziness; eye inflammation; headaches; hearing and balance disturbances; insomnia; irritable bowel syndrome; ringing in the ears; strange movements in all or part of the body and sun or light sensitivity.

48. A note of the bottom of the survey form cautioned that she should contact her plastic surgeon if more than three items were checked.

49. On or about October 5, 2011, Ms. Weber had an appointment with Dr. Gawley, who advised that other professionals believed that the problems she was experiencing could be caused by the implants and that they needed to be removed.

50. Ms. Weber asked Dr. Gawley if she had a rupture and he replied that she had not.

51. Instead, Dr. Gawley stated that the implants did not have to rupture to cause problems they could bleed into your system.

52. Ms. Weber inquired about the severe neurological jerking that she was experiencing, and Dr. Gawley recommended that she see a neurologist; Ms. Weber mentioned that she knew a neurologist, Shafeq Lada, and he acknowledged that he also knew Dr. Lada well.

53. Dr. Gawley told Ms. Weber to call Dr. Lada to see if the neurological problems could be linked to the implants; Ms. Weber responded that Dr. Gawley should make the call.

54. Notably, the note from the October 5, 2011 visit appears to be missing from her file.

55. Ms. Weber told Dr. Gawley that she wanted to get tested for silicone sensitivity and he wrote her a script for silicone testing.

56. Unfortunately, when Ms. Weber took the script to the lab to get tested for silicone, the lab refused to fulfill the script as it was written for silicon as opposed to silicone.

57. As a result, Ms. Weber searched for an independent testing site.

58. On October 12, 2011, Ms. Weber underwent testing at Arizona Center for Advanced Medicine which demonstrated a severe generalized reaction to silicone.

59. In light of the test results, Ms. Weber was advised that it was medically necessary for her to have the implants removed immediately.

60. On or about October 14, 2011, Ms. Weber had a second visit with Dr. Gawley, again the record of this visit is missing from the medical records.

61. Dr. Gawley said he spoke with Dr. Lada who said the neurological issues could be related to the implants.

62. Ms. Weber scheduled explanation surgery with Dr. Gawley for October 18, 2011.

63. The day before the surgery, Ms. Weber spoke with Dr. Gawley on the phone and this time advised that he did not believe that her health problems had to do with the implants but he would be happy to proceed with the explantation surgery the following day as planned.

64. Given that conversation, Ms. Weber did not feel comfortable proceeding with the surgery with Dr. Gawley.

65. In light of her unease, Ms. Weber cancelled the surgery with Dr. Gawley and rescheduled with Dr. Lu-Jean Feng, who had advised that her health problems were caused by the implants.

66. On October 20, 2011, Ms. Weber underwent explantation surgery with Dr. Feng who attributed all of her problems, including her vision problems, to the implants.

67. The pathology report documented the following: associated foreign body-type multinucleated giant cells surrounding implants.

68. After the implants were removed, Ms. Weber gradually began to regain her health with respect to her tinnitus, chest spasms, migraines, foot funguses and anxiety.

69. Ms. Weber continues to experience the following symptoms: extreme chemical sensitivity to all medications, severe visual problems and immune system problems.

70. In the end of May 2012, Ms. Weber was diagnosed with autoimmune retinopathy at Stanford University.

71. Autoimmune retinopathy is an eye condition associated with autoantibodies that are generated to attack foreign bodies/offending agents and begin to attack the retina. The condition involves color distortion, light problems increasing dimness and blindness.

72. On July 18, 2012, Ms. Weber received the third survey from BIFS.

73. On August 9, 2011, Ms. Weber was examined by Dr. Stephen Foster, Founder and President of Massachusetts Eye Research and Surgery Institute and Clinical Professor of Ophthalmology at Harvard Medical School. Dr. Foster explained that her prognosis was poor and little treatment would prove successful.

COUNT I

NICOLE WEBER v. ALLERGAN, INC.

STRICT PRODUCT LIABILITY

74. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein.

75. At all times relevant hereto, Allergan was in the business of developing, testing, marketing, promoting and utilizing the subject implants.

76. Allergan tested, marketed, promoted and/or sold the implants utilized during plaintiff's surgery and Dr. Gawley sold the implants to plaintiff.

77. Upon information and belief, the implants utilized in surgery were expected to, and did reach the facility in the condition in which it was intended by Allergan.

78. Allergan's implants were deficient in at least the following particulars:

(a) the implants were defective and/or unreasonably dangerous when inserted in plaintiff;

(b) the implants were not accompanied by adequate or explicit labeling;

(c) the implants' advertising and promotional materials contained misrepresentations of material facts and/or failed to contain sufficient material facts necessary for researchers and/or subjects to make informed decisions regarding its selection and use;

(d) the implants' labeling contained misrepresentations of material fact and/or failed to contain sufficient material facts necessary for researchers and/or subjects to make informed decisions regarding its selection and use;

(e) the dangers associated with the use of the implants by plaintiff exceeded the potential benefits;

(f) the defendant failed to adequately test the system in the face of known consequences;

(g) the defendant allowed the implants to be used and inserted in plaintiff while knowing its dangerous propensities;

(h) failing to warn users of the dangers inherent in using the product;

(i) failing to fix the conditions which increased the risk of harm to the users during the times when this product was being distributed to various physicians; and

(j) being otherwise careless and negligent in the design and conduct of the Breast Implant Follow-up Study.

79. By reason of the carelessness and negligence of defendant, as stated above, plaintiff was proximately caused to sustain severe emotional, psychological and personal injuries.

80. As a direct and proximate result of defendant's actions, as set forth above, plaintiff has in the past been and will in the future continue to be compelled to expend monies and incur obligations for medical care and treatment; plaintiff has also incurred and will hereafter continue to incur other financial expenses or losses which do or may exceed amounts which she may otherwise be entitled to recover.

81. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the State of Arizona.

WHEREFORE, plaintiff Nicole Weber claims of defendant Allergan, Inc. compensatory damages, interest, allowable costs of suit, a trial by jury and such other further relief as the Court deems just.

COUNT II

NICOLE WEBER v. ALLERGAN, INC.

NEGLIGENCE

82. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein.

83. Allergan had a duty to plaintiff to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling Natrelle implants.

84. Allergan was negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling packaging and selling Natrelle implants. Allergan breached is aforementioned duty by, among other things:

a) Failing to design Natrelle implants so as to avoid unreasonable risk of harm to women in whom the implants were implanted, including plaintiff;

b) Failing to manufacture Natrelle implants so as to avoid an unreasonable risk of harm to women in whom the implants were implanted, including plaintiff;

c) Failing to use reasonable care in the testing of Natrelle implants so as to avoid an unreasonable risk of harm to women in whom the implants were implanted, including plaintiff;

d) Failing to use reasonable care in inspecting the implants so as to avoid an unreasonable risk of harm to women in whom the implants were implanted;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the products;

f) Failing to use reasonable care in studying Natrelle implants to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g) Otherwise negligently or carelessly designing , manufacturing, marketing, labeling, packaging and/or selling Natrelle implants.

85. Allergan also negligently failed to warn or instruct plaintiff and/or her healthcare providers of the actual risk of rupture; the risk of silicone bleed; the symptoms associated with silicone bleed and the care and treatment related to symptoms of silicone bleeds.

86. Allergan also is responsible for the false and misleading representations by Dr. Gawley, and for his negligent actions and actions, to the extent he was serving as an agent for Allergan.

87. As a direct and proximate result of Allergan's negligence, plaintiff has experience significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income and other damages.

WHEREFORE, plaintiff Nicole Weber claims of defendant Allergan, Inc. compensatory damages, interest, allowable costs of suit, a trial by jury and such other further relief as the Court deems just.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

Date: 11/7/12

By: _____

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Attorney for Plaintiff Nicole Weber

JOHN C. KUBASCH, ATTORNEY AT LAW, PLLC

Date: 11/7/12

By: _____

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Scottsdale, Arizona 85267-5342
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Facsimile: 480-219-8326

Attorneys for Plaintiff Nicole Weber

JURY TRIAL DEMAND

Please take notice that plaintiff demands a trial by jury as to all issues in the above matter.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

Date: 11/7/12 By: _____

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Attorneys for Plaintiff Nicole Weber

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
Nicole Weber

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alan C. Milstein, Esq., Sherman, Silverstein, Kohl, Rose & Podolsky, 308 Harper Dr., Suite 200, Moorestown, NJ 08057

DEFENDANTS
Allergan, Inc.

County of Residence of First Listed Defendant DE Corp., CA headquarter
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☒ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C 1332(a)(2); 28 U.S.C. 1391(a)

Brief description of cause:
Suit against manufacturer re: personal injury arising from silicone breast implants

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

DATE 11/7/12

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____