Mark P. Robinson, Jr., CA Bar No. 054426
Shannon Lukei, CA Bar No. 202868
Lila Razmara, CA Bar No. 269779
ROBINSON CALCAGNIE, INC.
19 Corporate Plaza Drive
Newport Beach, California 92660
Telephone: (949) 720-1288
Facsimile: (949) 720-1292
mrobinson@robinsonfirm.com

Jennifer A. Lenze
Amanda D. McGee
LENZE LAWYERS, PLC
1300 Highland Ave, Suite 207
Manhattan Beach, CA 90266
Telephone (310) 322-8800
Facsimile (310) 322-8811
jlenze@lenzelawyers.com
mcgee@lenzelawyers.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SOUTHERN DIVISION

ANGELA SCHARF, Plaintiff, v. ALLERGAN INC. f/k/a/ INAMED CORPORATION f/k/a MCGHAN MEDICAL CORPORATION; ALLERGAN USA, INC.; ALLERGAN PLC, Defendants.	CASE NO. **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff Angela Scharf, an individual, based on information and belief, and for causes of action against the Defendants ALLERGAN INC. f/k/a/ INAMED CORPORATION f/k/a MCGHAN MEDICAL CORPORATION, a Delaware Corporation with its principal place of business in Irvine, California and administrative headquarters in Madison, New Jersey; ALLERGAN USA, INC., a Delaware Corporation; ALLERGAN PLC, a foreign corporation, and each of them, hereby allege as follows:

INTRODUCTION

1. Plaintiff Angela Scharf was implanted with Allergan BIOCELL implants in approximately April 2016. Her case clearly demonstrates the dangers of a manufacturer's failure to warn the FDA and thus doctors of adverse events and associated risks of significant injury means in terms of a patient being able to obtain an accurate diagnosis.

2. Ms. Scharf recently went to the ER and the doctors felt a pocket of fluid around her breast tissue. The doctors at the ER ordered blood tests. The lab results of her blood tests were positive for Breast Implant Associated–Anaplastic Large Cell Lymphoma (BIA-ALCL). Following her diagnosis, Ms. Scharf is planning on having her Allergan BIOCELL implants removed.

3. BIA-ALCL is *not* a breast cancer but a subtype of non-Hodgkin's lymphoma, a cancer of the immune system. It presents as a late-onset seroma in the breast (accumulation of fluid between the capsule and the implant, resulting in swelling of the breast) with high CD30 expression and an absence of anaplastic lymphoma kinase (ALK).

4. By way of background, attempts to augment women's breasts date back to the 1880s, however, implants as we know them today hit the market in the 1960s. Early versions of implants had thick shells to help keep rupture rates low but, ultimately led to a complication called capsular contracture. This results from the growth of scar tissue around the implant (due to a foreign body reaction) causing it to become thick and constrict the implant. This causes pain and can lead to severe aesthetic problems.

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5. The 1970s brought about the first type of "texturing" in the form of a polyurethane foam coating on the implant shell in an attempt to reduce capsular contracture. These were removed from the market in 1991 due to reporting of an association between polyurethane and cancer concerns. The texturing process evolved in the 1980s with different technologies, yet, the theory remained the same – the growth of tissue into the irregular spaces of the shell would prevent collagen and fibrous tissue from forming in excess – and uniform- around the implant capsule.

6. Allergan's texturing process is trademarked BIOCELL®. The textured surface is created by dipping a silicone capsule into salt crystals before it is dry. The surface is washed and cured, leaving behind a pitted surface with randomly sized pores.

7. The first case of BIA-ALCL was reported in the literature in 1997. Reports in the literature continued into the 2000s.

8. In November 2008, the Journal of the American Medical Association ("JAMA") published a retroactive analysis of 11 cases of ALCL between 1994 and 2006, and based upon preliminary findings, concluded that the evidence indicated an association between silicone breast prosthesis and ALCL. De Jong, Daphne (2008). Anaplastic Large-Cell Lymphoma in Women with Breast Implants, *JAMA: Journal of the American Medical Association*, 300(17), 2030-35.

9. On January 26, 2011, unbeknownst to Ms. Scharf, the FDA released a report on BIA-ALCL, identifying 27 cases and listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, ***the FDA believes that there is a possible association between breast implants and ALCL***."

10. The FDA further noted that, while it was not prepared to associate a particular type of breast implant with BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a *textured* outer shell rather than a *smooth* outer shell."

11. In July 2014, the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("MHRA") issued a Medical Device Alert "to further encourage

healthcare professionals to report cases of ALCL in women who have breast implants or who have had them removed."

12. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

13. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, *separate from other categories of ALCL*.

14. It was a few months after the National Comprehensive Cancer Network ("NCCN") released the first worldwide oncology standard for the disease.

15. In November 2016, Australia's Therapeutic Goods Administration ("TGA") convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

16. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL.

17. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after receiving breast implants and stated that "[a]t this, time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.

18. In May 2017, a global analysis of forty governmental databases identified 363 cases of BIA-ALCL with 258 being reported to the FDA.

19. A July 2017 article stated that "[e]xperts have called for a common type of breast implant to be banned after it was revealed two people died and 23 developed the same type of cancer in the UK following breast enlargement surgery." Katie Forster, *Calls to ban textured breast implants after two die and 23 develop same type of cancer*, The Independent Online, July 10, 2017, available at https://www.independent.co.uk/news/health/breast-implants-cancer-ban-two-die-23-develop-same-type-textured-common-women-enlargement-cosmetic-a7832996.html.

20. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including 9 deaths.

21. A recent JAMA Oncology article concluded that "[b]reast implants are associated with increased risk of breast-ALCL", but the absolute risk has not been determined. Mintsje de Boer, et al., *Breast Implants and the Risk of Anaplastic Large-Cell Lymphoma in the Breast*. JAMA ONCOL. (published January 4, 2018). The Dutch epidemiological study reports the risk of developing BIA-ALCL to be 421.8x higher in women with breast implants than in women with no implants, "implying an attributable risk approaching 100%."

22. On May 9, 2018, Australia's Therapeutic Goods Administration ("TGA") reported 72 cases of ALCL in Australian patients.

23. The natural occurrence of this cancer is 1/300,000. However, FDA recently cited to studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1:3,817 and 1:30,000. This is consistent with risks reported in Europe. A December 2016 update from the TGA reported a risk of 1:1,000 to 1:10,000 for textured implants.

24. In its July 24, 2019 announcement recalling the product, the FDA stated that there are 573 cases of BIA-ALCL worldwide and that 33 people have died, a "significant increase" since the FDA's last update earlier in 2019—reflecting 116 new cases and 24 more deaths. The FDA stated that the risk of developing BIA-ALCL with Allergan BIOCELL textured implants is about six times that of becoming ill with textured implants from other manufacturers available in the U.S. The FDA noted that of the 573 cases of BIA-ALCL, 481, or more than 80%, were attributed to Allergan implants, and of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients for whom the implant manufacturer was known had an Allergan implant when they were diagnosed. Dr. Amy Abernethy, principal FDA deputy commissioner, stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence

indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

25. Despite knowledge on the part of the Defendants of an association between breast implants and anaplastic large cell lymphoma dating back into the mid-1990's, Defendants purposefully failed to comply with their clearly-established post-market surveillance obligation and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer.

26. Plaintiff brings this action against Defendants for their failure to use reasonable care to warn consumers and healthcare providers of known or knowable product dangers and adverse events. This claim is provided for by longstanding California common law failure to warn which parallels Defendants' duty under federal-law and the Code of Federal Regulations 21 C.F.R. §803.50(a) (requiring a manufacturer of class III devices to file adverse event reports whenever the device may have caused or contributed to death or serious injury if it recurred) and 21 C.F.R. §814.84(b)(2) (requiring a manufacturer of a class III device to report new reports of data from any clinical investigations or studies involving the device, reports in the scientific literature concerning the device that are known or that should reasonably be known) and does not impose duties or requirements materially different from those imposed by federal law. The California duties precisely parallel the duties imposed by federal law and do not exist solely by virtue of the federal requirements.

PARTIES

27. Plaintiff Angela Scharf is a resident of Sanford, North Carolina.

28. Allergan PLC is a publicly-traded corporation whose headquarters is in Dublin, Ireland. Allergan's administrative headquarters in the United States are located in the states of New Jersey and California.

29. Allergan, Inc. is a wholly-owned subsidiary of Allergan PLC and is incorporated under the laws of Delaware possessing its principal place of business in Morris County, New Jersey.

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30. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware possessing its principal place of business in Morris County, New Jersey.

31. Inamed Corporation ("Inamed") f/k/a McGhan® Medical Corporation ("McGhan®") is incorporated under the laws of Delaware and its principal place of business is in Orange County, California. Upon information and belief, McGhan® changed its name to Inamed in 1986.

32. Inamed was a global surgical and medical device company engaged in the development, manufacturing and marketing of products for the plastic and reconstructive surgery, aesthetic medicine and obesity markets. Inamed sold a variety of lifestyle products, including breast implants for cosmetic augmentation and breast implants for reconstructive surgery following a mastectomy.

33. McGhan® previously served the North American aesthetic medicine and reconstructive surgery markets. McGhan® developed, manufactured and sold plastic and reconstructive surgery (PRS) products (primarily saline-filled breast implants and tissue expanders). It sold primarily to plastic surgeons, dermatologists, cosmetic surgeons and other medical practitioners in the United States and Canada.

34. In March 2006, Allergan purchased substantially all of Inamed including Inamed's outstanding common stocks, as well as its wholly-owned subsidiary, McGhan®.

35. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

36. The combined acts and/or omissions of each Defendant resulted in injuries to the 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, and/or ratified the conduct of each and every other Defendant.

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JURISDICTION AND VENUE

37. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District. Allergan, Inc. was previously headquartered in Irvine, California and Allergan, PLC continues to maintain a large presence in Irvine, where the U.S. Medical Aesthetics division responsible for breast implants is now based, including thousands of employees, offices, and research and development facilities. Senior Vice President, U.S. Medical Aesthetics, Carrie Strom, signatory of the "Replacement Warranty" letter to Allergan's plastic surgery customers is based in Irvine, California.

FACTS REGARDING ALLERGAN AND MCGHAN® SALINE-FILLED BREAST IMPLANTS

A. General Information Relating to Breast Implants

38. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. §360e(d)(2).

39. In 1988, in response to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices.

40. In 1989, the FDA published a notice of intent to require submissions of a premarket approval application ("PMA") or completion of product development protocols ("PDPs') for these devices.

41. In 1999, the FDA issues a final rule requiring PMAs for these devices to be filed with the FDA, or PDPs to be completed, within ninety (90) days. Thus, an approved PMA or PDP is now required to market a saline-filled breast implant.

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42. Through its PMA process, the FDA engages in scientific evaluations of the safety and effectiveness of Class III medical devices. The FDA considers Class III devices to create the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

43. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk;

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

44. Where Conditional Premarket Approval ("CPMA") is granted, a device marketed by a manufacturer which fails to perform any requirements of the CPMA is considered to be adulterated under §501 of the FDCA and may not be further marketed.

B. <u>Information Specific to McGhan® Breast Implants</u>

45. In 1991, McGhan, a predecessor corporation to Inamed and Allergan, Inc., applied for premarket approval for various styles of implants. The FDA denied approval of

the application for use of such devices for the augmentation of healthy female breasts, but also determined there was a public health need for the devices to be available for reconstruction patients.

46. In April 2002, the FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct clinical trials of the silicon implant devices for use in reconstruction patients. Under the agreement, the FDA required that any clinical trial protocols be approved by the FDA and local Institutional Review Boards. The FDA also required McGhan to take all reasonable steps to ensure that it received informed consent from all patients prior to implantation of any evidence on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all products were labeled consistent with the agreement and the terms of the approved protocols.

47. McGhan was also required to submit data from the trials in accordance with an agreed schedule and take reasonable steps to ensure that participating physicians complied with the protocols. Further, McGhan was required to cooperate with the FDA's review of the application and monitoring of the clinical trials.

48. The FDA also retained the power to terminate the study at any time if the data showed that continuation of the study was not necessary to, or in the interest of, the public health.

49. In March 1998, the FDA approved McGhan's study protocol which was submitted pursuant to the 1992 agreement, subject to the FDA's inspection of McGhan's manufacturing facilities. In the same letter indicating approval, the FDA stated that McGhan's facility in Arklow, Ireland had been inspected and was found to be incompliance with regulations and therefore that facility could export silicone gel-filled mammary prostheses into the United States.

50. McGhan was further informed that it could begin enrolling patients in the study. This study was referred to as the adjunct study.

51. In addition to the adjunct study involving reconstruction patients, McGhan also applied for an investigational device exemption ("IDE") for use of the same devices

for breast augmentation. The breast augmentation clinical trial was referred to as the "core" study and was approved by the FDA in 1998.

52. As the studies progressed, the FDA continued its oversight and considered a large volume of material submitted about the core and adjunct studies submitted by McGhan each year. The submissions in both included detailed manufacturing, chemical, physical, toxicological, and clinical information. McGhan noted that while the adjunct study was not being conducted under an IDE, the submissions it made relative thereto were structured to follow FDA guidelines for IDE clinical study annual reports.

53. Pursuant to FDA action in the second half of 1999, the FDA required any manufacturer wishing to continue to market saline-filled implants in the U.S. to file an application for pre-market approval of such products by November 17, 1999.

54. On November 16, 1999, Inamed filed a PMA for the "McGhan Medical RTV Saline-Filled Breast Implant" which was referred to an FDA Advisory Panel on general plastic surgery for review. This product utilized the BIOCELL® lost-salt technology.

55. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications. On May 10, 2000, the FDA announced that it had approved the application for PMA of four styles of McGhan saline-filled breast implants for augmentation in women age 18 and older and for reconstruction in women of any age. These products were previously available in the U.S. marketplace as 510(k)-cleared devices.

56. As conditions of the 2000 approval, the FDA required McGhan to conduct multiple post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies included:

a. *10-year Post-Approval Studies* – To assess long-term clinical performance of the device. These studies were designed to follow women for 10 years after initial implantation.

b. *Retrieval Study* – To collect visual examination, physical, and histological data on explanted implants to determine the mode of failure of implants.

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c. *Focus Group Studies* – To improve the format and content of the patient labeling.

d. *Mechanical Testing*

57. This approval was three years prior to the 1997 report of ALCL in a patient with a McGhan Medical RTV Saline-Filled Breast Implant (Style 168) -published in the journal of Plastic and Reconstructive Surgery.

58. The Summary of Safety and Effectiveness Data ("SSED") and Directions for Use ("DFU") did not contain any mention of BIA-ALCL or anything related to this particular risk of lymphoma.

59. In December of 2002, Allergan sought (and received in November of 2006) PMA approval for its second generation of BIOCELL® textured breast implants (then known as Inamed). The SSED and DFU for this PMA likewise contained no mention of BIA-ALCL or risk of lymphoma.

OBLIGATIONS OF A MANUFACTURER

60. 21 CFR §§ 814 et seq. sets forth the Federal Postapproval requirements for a manufacturer. This requires a manufacturer to monitor the product after pre-market approval and discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it becomes aware and that are or may be attributable to the product.

61. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, rests with the manufacturer.

62. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, and to fully and promptly report all relevant information, specifically but not limited to foreseeable dangers with the product, to the FDA, the healthcare community, and consumers. An adequate warning mitigates the risk of harm posed by a product by allowing consumers to make informed choices about whether and how to encounter certain risks.

63. Post approval requirements under both federal regulations and state law would have indicated the association between the BIOCELL® product and BIA-ALCL.

64. Not only were the associations present in the literature but Defendants' own adverse events highlighted the association and triggered the obligation under federal law and state law to communicate the risk.

65. Defendants' obligations after the PMA included, but are not limited to: Reporting to the FDA information suggesting that one of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned 21 CFR §803.50.

66. Adverse event reports date back to 1995 when the FDA created its adverse event reporting database, MAUDE (Manufacturer and User Facility Device Experience). MAUDE data is publicly available, but MAUDE searches are limited and do not allow for searches of multiple side effects. MAUDE also only returns 500 reports for any given search, making it difficult to analyze reporting patterns in any meaningful way.

67. "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time under 21 CFR §803.19. The ASRs require less detail—for instance, they do not contain any report narrative describing the event—and were not publicly available through the MAUDE website. They were not available through a FOIA request. This exception was for well understood types of events and failure modes. "Since the program's inception in 1997, the FDA granted 108 such exemptions to individual manufacturers for certain well-known events associated with specific devices, which were often already described in the product labeling available to health care professionals and patients. The ASR Program allowed the FDA to more efficiently review reports of well-known, well-understood adverse events, so we could focus on identifying and taking action on new safety signals and less understood risks," Dr. Jeffrey Shuren, head of the FDA's Center for Devices & Radiological Health, said in prepared remarks. BIA-ALCL was no such "well-known" risk.

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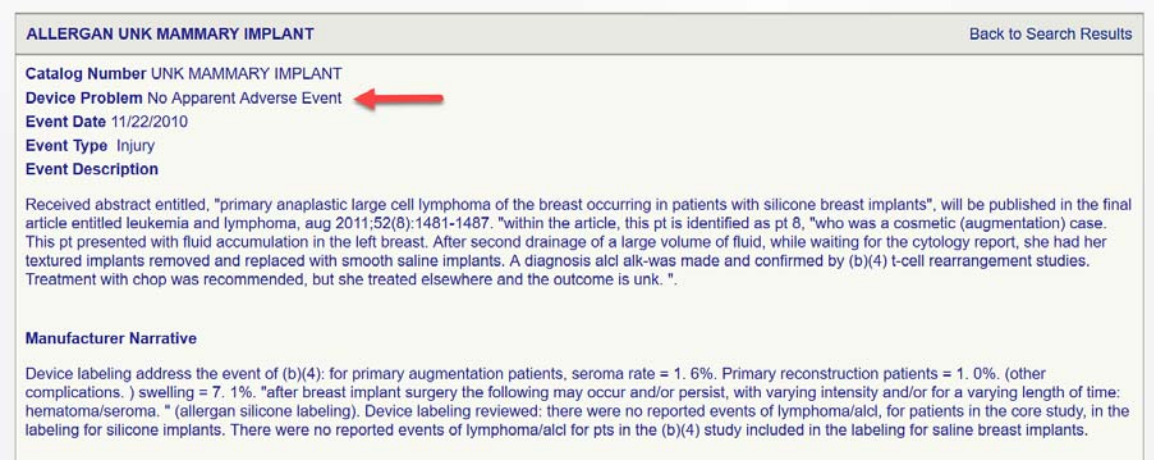
68. In violation of the law requiring Defendants to report adverse events to the FDA, and in order to conceal from doctors and the public the full extent of the risks of BIOCELL® products, Defendants submitted adverse event reports with incorrect manufacturer names, including "Santa Barbara" and "Costa Rica."

69. On information and belief, Plaintiff believes there was a failure to report adverse events and a failure to timely report adverse events.

70. A review of both the MAUDE database and the ASR reports (released by the FDA in June of 2019) as of September 2019 revealed there were 1,298 reports of Allergan textured implants containing the term ALCL, lymphoma, CD30 and ALK testing.

71. Examples are seen of ALCL with "no apparent adverse event" determination by Allergan.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=2210596



ALLERGAN UNK MAMMARY IMPLANT Back to Search Results

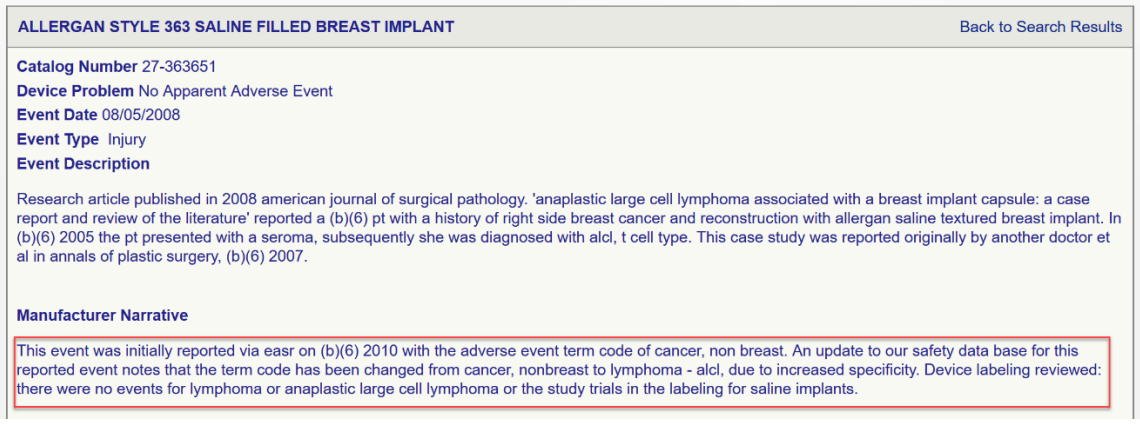
Catalog Number UNK MAMMARY IMPLANT
Device Problem No Apparent Adverse Event
Event Date 11/22/2010
Event Type Injury
Event Description

Received abstract entitled, "primary anaplastic large cell lymphoma of the breast occurring in patients with silicone breast implants", will be published in the final article entitled leukemia and lymphoma, aug 2011;52(8):1481-1487. "within the article, this pt is identified as pt 8, "who was a cosmetic (augmentation) case. This pt presented with fluid accumulation in the left breast. After second drainage of a large volume of fluid, while waiting for the cytology report, she had her textured implants removed and replaced with smooth saline implants. A diagnosis alcl alk-was made and confirmed by (b)(4) t-cell rearrangement studies. Treatment with chop was recommended, but she treated elsewhere and the outcome is unk. ".

Manufacturer Narrative

Device labeling address the event of (b)(4): for primary augmentation patients, seroma rate = 1. 6%. Primary reconstruction patients = 1. 0%. (other complications.) swelling = 7. 1%. "after breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma. " (allergan silicone labeling). Device labeling reviewed: there were no reported events of lymphoma/alcl, for patients in the core study, in the labeling for silicone implants. There were no reported events of lymphoma/alcl for pts in the (b)(4) study included in the labeling for saline breast implants.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=3693305



ALLERGAN STYLE 363 SALINE FILLED BREAST IMPLANT Back to Search Results

Catalog Number 27-363651
Device Problem No Apparent Adverse Event
Event Date 08/05/2008
Event Type Injury
Event Description

Research article published in 2008 american journal of surgical pathology. 'anaplastic large cell lymphoma associated with a breast implant capsule: a case report and review of the literature' reported a (b)(6) pt with a history of right side breast cancer and reconstruction with allergan saline textured breast implant. In (b)(6) 2005 the pt presented with a seroma, subsequently she was diagnosed with alcl, t cell type. This case study was reported originally by another doctor et al in annals of plastic surgery, (b)(6) 2007.

Manufacturer Narrative

This event was initially reported via easr on (b)(6) 2010 with the adverse event term code of cancer, non breast. An update to our safety data base for this reported event notes that the term code has been changed from cancer, nonbreast to lymphoma - alcl, due to increased specificity. Device labeling reviewed: there were no events for lymphoma or anaplastic large cell lymphoma or the study trials in the labeling for saline implants.

72. Due to Defendants' unlawful reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of Allergan devices.

73. Despite having knowledge and possession of evidence showing that the use of the breast implants was dangerous and likely to place consumers' health at serious risk, as will be detailed further below, Defendants refused or recklessly failed to identify, disclose and warn of the health hazards and risks associated with the product, and about all adverse events which were known to them.

74. Instead, Defendants marketed, advertised and promoted the product while at the same time consciously refusing and/or recklessly failing to warn the FDA, health care providers where it would ultimately reach consumers.

75. Had Defendants substantially complied with their requirements under the PMA and controlling CFRs, Defendants' disclosures would have led to much wider knowledge of the risks associated with Defendants' products, including BIA-ALCL. Medical providers including Plaintiff's physicians, would have warned about the risk of Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL") and ultimately Ms. Scharf would have avoided the product.

FACTS SPECIFIC TO PLAINTIFF ANGELA SCHARF

76. In approximately April 2016, Plaintiff Angela Scharf was implanted with textured Allergan BIOCELL implants.

77. At the time the implants were placed into Ms. Scharf's body, she was not advised, nor did she have any independent knowledge, that they were anything other than safe, life-long products. Nor was she advised that the product was associated and/or known to cause BIA-ALCL.

78. Ms. Scharf was not advised, and had no independent knowledge that:

a. A significant risk of ALCL existed; or

b. A significant risk of BIA-ALCL existed; or

c. She might need future surgery to remove the implants in the future based

upon contracting ALCL and/or BIA-ALCL; or

d. She might need future imaging and/or diagnostic procedures to check for, or evaluate ALCL and/or BIA-ALCL; or

79. Recently, Ms. Scharf developed pain and inflammation in her breast tissue.

80. Due to the pain and inflammation, Ms. Scharf went to the ER. The doctors at the ER were able to feel a pocket of fluid around her breast tissue. The doctors at the ER ordered blood tests.

81. The results of Ms. Scharf's blood tests were positive for BIA-ALCL. Ms. Scharf is now planning on proceeding to remove her Allergan implants.

82. As a result of her diagnosis, Ms. Scharf is currently awaiting a decision regarding further treatment and monitoring for the disease.

83. Ms. Scharf suffered debilitating side effects from ALCL and/or BIA-ALCL.

84. At the time the implants were placed into Ms. Scharf's body, she was not advised, nor did she have any independent knowledge, that the Products were anything other than safe, life-long products. Nor was she advised that the product was associated and/or known to cause BIA-ALCL and that she would require future surgery and treatments.

85. If Ms. Scharf had been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation of the Products.

86. Had the medical community been made aware of the existence of the true frequency, severity and significance of BIA-ALCL caused by the products, medical professionals and providers, including those who advised and served Plaintiff, would not have advised patients, including Plaintiff, to proceed with implantation of the products.

87. Due to the Defendants' failures to comply with their post-approval surveillance obligations, Ms. Scharf did not suspect, nor did she have reason to suspect, that her injuries were caused by the breast implants, or by Defendants' tortious conduct.

88. Defendants, through their misrepresentations and omissions including their refusal or reckless failures to disclose or report defects and significant events as required by

federal law, and by state law which is parallel and does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and her healthcare providers the true and significant risks associated with the products.

89. Defendants knew of the implants' defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Ms. Scharf, in conscious and/or negligent disregard of the foreseeable harm caused by the breast implants.

90. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Ms. Scharf, she suffered severe and permanent physical injuries. Ms. Scharf endured substantial pain and suffering and had to undergo extensive medical and surgical procedures. Ms. Scharf was forced to incur significant expenses for medical care and treatment as a direct and proximate result of Ms. Scharf's injuries due to the breast implants. Ms. Scharf suffered substantial economic loss, and have otherwise been physically, emotionally and economically injured.

91. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Ms. Scharf, and was wanton and reckless, thereby entitling Ms. Scharf to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

92. Plaintiff hereby incorporates by reference all other paragraphs in this Complaint as if set forth fully herein.

93. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and other consumers the true risks associated with the breast implants.

94. As a result of Defendants' actions, Plaintiff was unaware, and could not reasonably know or have learned through reasonable diligence, that she had been exposed

to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

95. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of the breast implants.

96. Defendants were under a duty to disclose the true character, quality and nature of the breast implants because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff Ms. Scharf, her medical providers and/or her health facilities, yet they failed to disclose the information to the public.

97. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purposes of marketing and promoting a profitable product, notwithstanding the known or reasonably knowable risks.

98. Plaintiff, consumers, and medical professionals could not have afforded to and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and they were forced to rely on Defendants' representations

CAUSES OF ACTION

FIRST CAUSE OF ACTION - NEGLIGENCE

(Against All Defendants)

99. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

100. At all material times, Defendants owed to Plaintiff Angela Scharf a duty to use reasonable care, pursuant to the federal post-approval requirements, in adequately warning of the dangers, including the development of BIA-ALCL, and any adverse events of BIA-ALCL related to Defendants' Breast Implants.

101. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted the McGhan® Breast Implants, including the devices which were implanted into

Plaintiff Angela Scharf.

102. Plaintiff was implanted with the McGhan® and Allergan Saline-Filled Breast Implants which were defective, dangerous and without adequate warnings, in violation of state law, including but not limited to the common law of the California which provides a duty to warn of known or knowable product danger which does not impose duties or requirements materially different from those imposed by federal law including the PMA post approval specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

103. Defendants had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in providing adequate warnings about the risks and dangers of the McGhan® and Allergan Saline-Filled Breast Implants, including the risk of developing BIA-ALCL, which was known or reasonably knowable to Defendants at the time of distribution, and that Defendants had come to know in light of adverse conditions and events experienced by patients in whom the Defendants' products were implanted.

104. Defendants breached their duty, pursuant to federal post-approval requirements, by failing to adequately warn Plaintiff Angela Scharf and her physicians, either directly or by not timely and accurately reporting to regulatory authorities the risks of serious defects, adulterations and life-altering complications, including the development of BIA-ALCL, experienced by patients in whom the products were previously implanted.

105. Defendants' specific actions which constitute breaches of these duties to Plaintiff include: failing to timely and accurately report adverse events regarding the McGhan® and Allergan Breast Implants; failing to report the products' failure to meet performance specifications and expectations under the PMA and FDA requirements; failing to revise and update product labeling to reflect Allergan's current knowledge of BIA-ALCL; receiving but failing to warn or report to the FDA and the medical community Allergan's knowledge and information regarding the risk of BIA-ALCL.

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106. Plaintiff and/or Plaintiff's physicians reasonably relied on Defendants' negligent misrepresentations and omissions, as Defendants intended, and would not have made the same decision(s) if provided the required information.

107. As a proximate and foreseeable result of the foregoing misrepresentations by Defendant, Plaintiff has suffered and will continue to suffer from BIA-ALCL and its accompanying symptoms including, but not limited to, 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.

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

SECOND CAUSE OF ACTION – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

(Against All Defendants)

108. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

109. At all material times, Defendants were engaged in the business of formulating, designing, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting McGhan® and Allergan Saline-Filled Breast Implants.

110. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted McGhan® and Allergan Saline-Filled Breast Implants, including those which were implanted into Plaintiff Angela Scharf.

111. Plaintiff was implanted with McGhan® and Allergan Saline-Filled Breast Implants which were dangerous in their risk to cause ALL and did cause serious injury to Plaintiff.

112. At all material times, Defendants intended for the McGhan® and Allergan Saline-Filled Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew the product would be surgically implanted into members of the general public, including Plaintiff.

113. Defendants failed to warn Plaintiff and her physicians of the risk of serious life-altering complications faced by patients, including BIA-ALCL. As a result the product was defective and unreasonably dangerous.

114. Defendants also failed to revise its labeling and directions for use to give warnings consistent with the BIA-ALCL risk which was known or available to them at the time of distribution and failed to warn the FDA, Plaintiffs health care providers, and as a result Plaintiff, of information which became known or available to them after implantation into Plaintiff.

115. Plaintiff's McGhan® and Allergan Saline-Filled Breast Implants were defective in their warning at the time of sale and distribution, and at the time they left Defendant Allergan's possession, and Defendants failed to adequately warn of the risks that the product that the product was susceptible to causing ALCL and/or BIA-ALCL as suffered by Plaintiff Angela Scharf.

116. Defendants knew or should have known that the breast implants were associated with or did actually in fact cause ALCL and/or BIA-ALCL.

117. Despite the fact that Defendants knew or should have known that implantation of the McGhan® and Allergan Saline-Filled Breast Implants was unreasonably dangerous and was likely to seriously jeopardize the health of consuming patients, Defendants failed to warn of the risks associated with the product.

118. The defects, adulterations and increased risks inherent in McGhan® and Allergan Saline-Filled Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiff and/or Plaintiff's physician. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the defects.

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119. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

120. At all relevant times, Plaintiff's McGhan® and Allergan Saline-Filled Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

121. The McGhan® and Allergan Saline-Filled Breast Implants were manufactured, designed, promoted, marketed, distributed, and sold by Defendants were expected to, and did, reach Plaintiff's physician without substantial change in the condition in which they were sold.

122. Defendants knew that the McGhan® and Allergan Saline-Filled Breast Implants would be used by the ordinary purchaser or user without inspection for defects and adulterations and without knowledge of the hazards involved in such use.

123. The McGhan® and Allergan Saline-Filled Breast Implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, and caused Plaintiff's injury of BIA-ALCL, which would not have occurred but for the use of McGhan® and Allergan Saline-Filled Breast Implants.

124. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiff that would not have occurred but for the use of McGhan® and Allergan Saline-Filled Breast Implants.

125. As a proximate result and/or substantial factor of McGhan® and Allergan Saline-Filled Breast Implants' defective and adulterated condition at the time they were sold, Plaintiff suffered and will continue to suffer severe physical injuries, pain and suffering, emotional distress, mental anguish, economic loss, future medical care and treatment, , and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Angela Scharf demands judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys'

fees and all such other relief as the Court deems proper and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the *Federal Rules of Civil Procedure*, Plaintiff demands a trial by a jury on all of the triable issues of this Complaint.

Dated: November 6, 2019

Respectfully submitted,

/s/ Mark P. Robinson, Jr.

Mark P. Robinson, Jr.
Shannon Lukei
Lila Razmara
ROBINSON CALCAGNIE
19 Corporate Plaza Drive
Newport Beach, CA 92660
Telephone (949) 720-1288
Facsimile (949) 720-1292
mrobinson@robinsonfirm.com

Attorneys for Plaintiff

Jennifer A. Lenze
Amanda D. McGee
LENZE LAWYERS, PLC
1300 Highland Ave, Suite 207
Manhattan Beach, CA 90266
Telephone (310) 322-8800
Facsimile (310) 322-8811
jlenze@lenzelawyers.com
mcgee@lenzelawyers.com

Attorneys for Plaintiff