ROSS FELLER CASEY, LLP
By: Robert Ross, Esquire (ID No. 28351986)
Joel J. Feller, Esquire (ID No. 030791993)
Brian J. McCormick, Jr., Esquire (ID No. 023981997)
Dena R. Young, Esquire (ID No. 033022010)
One Liberty Place
1650 Market Street, 34th Floor
Philadelphia, PA 19103
Telephone: 215.574.2000
Fax: 215.574.3080

Attorneys for Plaintiffs

MICHELE REA and CARL REA, h/w 9890 Oxcrest Drive Fairfax, Virginia 22039, Plaintiffs v. Allergan plc Clonshaugh Business and Technology Park Coolock, Dublin, Ireland D17 E400 Allergan, Inc. 5 Giralda Farms Madison, NJ 07940 Allergan USA, Inc. 5 Giralda Farms Madison, NJ 07940 Defendants.	:	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: MIDDLESEX COUNTY** **DOCKET NO.: _____** **CIVIL ACTION** **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs MICHELE AND CARL REA, h/w, based on information and belief, and for causes of action against the Defendants ALLERGAN plc, ALLERGAN, INC., and ALLERGAN USA, INC., and each of them, hereby allege as follows:

INTRODUCTION

1. Plaintiffs MICHELE AND CARL REA, h/w, bring this action against Defendants ALLERGAN plc, ALLERGAN, INC., and ALLERGAN USA, INC. (hereinafter, collectively referred to as "Defendants" or "Allergan"), and each of them, in relation to the design, manufacture, marketing, labeling and distribution of Allergan's Natrelle® Style 410 macrotextured breast implant, the pervasive, reckless and continuous failure to comport with the Premarket Approval Application (''PMA") requirements imposed by the Food & Drug Administration ("FDA"), and failure to warn consumers of the known dangers and known adverse events.

2. Defendant Allergan is a global leader in aesthetic medicine, and a market leader in breast aesthetics.

3. Plaintiffs bring this action against Defendants in relation to the design, manufacture, marketing, and distribution of Allergan's Breast Implants, the repeated failure to follow the requirements imposed by FDA, failure to warn consumers and healthcare providers of known dangers and known adverse events, and reckless violation of state law.

PARTIES

4. Plaintiff Michele Rea is, and at all material times was, a resident of Virginia.

5. Plaintiff Carl Rea is, and at all material times was, the husband of Plaintiff Michele Rea and a resident of Virginia.

6. 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.

7. 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.

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

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

10. The combined acts and/or omissions of each Defendant resulted in injuries to the Plaintiffs. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiffs 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.

11. At all relevant times, Defendants acted in concert with one another in the State of New Jersey to fraudulently convey false and misleading information concerning Allergan's Natrelle® Style 410 macrotextured breast implant and concealed the risks of serious adverse events associated with the implant from Plaintiffs, the public, physicians, and other healthcare providers. But for the Defendants' actions, Plaintiff Michele Rea would not have suffered the severe injuries and harms that resulted from implantation of the Allergan's Natrelle® Style 410 macrotextured breast implant into Plaintiff Michele Rea's body.

12. The Defendant, Allergan plc, is a leading breast implant manufacturer, having collected approximately $400 million in net revenue in 2017 from the sale of breast implants alone.

13. At all relevant times, Defendants acted in concert with one another in the State of New Jersey to fraudulently convey false and misleading information concerning Allergan's Natrelle® Style 410 macrotextured breast implants, and concealed the risks of serious adverse events associated with its breast implants from Plaintiffs, the public, physicians, and other healthcare providers. But for the Defendants' actions, Plaintiff Michele Rea would not have suffered the severe injuries and harms which have resulted from implantation of Allergan's Natrelle® Style 410 macrotextured breast implants into Plaintiff Michele Rea's body.

14. This Court has personal jurisdiction over Defendants. Defendants are, and at all material times were residents of and/or authorized to conduct business in, the State of New Jersey. Defendants conducted such business within the State, as well as Middlesex County, including the acts which caused or contributed to Plaintiffs' injuries.

15. At all material times, Defendants maintained systematic and continuous contacts within this jurisdiction, employed numerous individuals in this district and regularly availed themselves of the benefits of this judicial district. Defendants received substantial financial gain as a result of designing, formulating, testing, packaging, labeling, producing, assembling, advertising, marketing, promoting, distributing, manufacturing, and selling the product within this jurisdiction.

16. The amount in controversy exceeds the prevailing local arbitration limits.

FACTS REGARDING ALLERGAN AND NATRELLE® STYLE 410 MACROTEXTURED BBREAST IMPLANTS

17. 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 silicone-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).

18. In 1988, in response to growing safety concerns, the FDA re-classified breast implants as Class III devices requiring premarket approval ("PMA"). Upon final publication of the FDA's new regulations in 1991, manufacturers were required to obtain premarket approval for new silicone gel-filled breast implants.

19. 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.

20. 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.

21. 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.

22. In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that the manufacturers stop supplying them and that surgeons stop implanting them while the FDA engaged in a further review of the products' safety and effectiveness.

23. In April 1992, the FDA determined that insufficient data existed to support PMA for silicone breast implants. From that time, implantation of the products in the United States was limited to reconstruction and revision patients.

24. Allergan Natrelle® Silicone-Filled breast implants are Class III medical devices receiving pre-market approval by the FDA in November of 2006, marking the first time in fourteen years that the products were available for elective augmentation in addition to reconstruction and revision.

25. Allergan Natrelle® Silicone-Filled breast implants have a silicone outer shell that is fined 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.

26. As conditions of the 2006 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:

a. *Core Post-Approval Studies (Core Studies)* – 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.

b. *Large Post-Approval Studies (Large Studies)* – 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.

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

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

e. *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.

f. *Adjunct Studies* – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

27. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as Allergan's Natrelle® Silicone-Filled breast implants, rests with the manufacturer.

28. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

29. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

30. When monitoring and reporting adverse events, especially those indicating an association between their product and breast cancer, ALCL and/or BIA-ALCL, as required by both federal regulations and New Jersey law, time is of the essence.

31. Delayed reporting prevents the healthcare community and the public from timely learning of risks which must inevitably play a part in their decision-making, by both physicians and consumers, regarding treatments and procedures, and thereby expose countless additional women to potential harm.

32. Specifically, Allergan's obligations after the PMA included, but are not limited to:

a. 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 and would be likely to cause death or serious injury if the malfunction were to recur [21 CFR §§803.50];

b. Monitoring the product and reporting to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 CFR §814];

c. Submitting a PMA supplement for any listed or material changes to the product [21 CFR §814.39];

d. Establishing and implementing a quality policy which all aspects of the manufacturer's operations must meet [21 CFR §820.20];

e. Establishing and maintaining procedures for validating the device design, including testing of production units under actual or stimulated use conditions, and creation of a risk plan and conduction of risk analyses [21 CFR §820.30];

f. Documenting all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues [21 CFR §820.100];

g. Establishing internal procedures for reviewing complaints and event reports [21 CFR §§820.198, 820.100, 820.20];

h. Establishing Quality Management System (QMS) procedures to assess potential causes of quality problems, including non-conforming products [21 CFR §§820.70 and 820.90];

i. Reporting on Post-Approval Studies in a timely fashion [21 CFR §814.80]; and

j. Advertising the device accurately and truthfully [21 CPR §801].

33. The overall follow-up rate was 65% at 10 years. The final report as submitted in year 5 of the study, in 2011.

34. 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, such as Plaintiff's.

35. Had Defendants' not intentionally failed to comply with their clearly-established post-market surveillance obligations, Mrs. Rea would have decided against implantation and her injuries would not have occurred.

36. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to exercise reasonable care in adequately warning Plaintiff and/or Plaintiff's treating and implanting medical

professionals about the dangers of Allergan's Natrelle® Silicone-Filled breast implants, and about all adverse events of which Allergan became aware, and had a post-market duty to identify, monitor and report all adverse events and all risks associated with the product.

37. Despite having knowledge and possession of evidence showing that the use of Allergan's Natrelle® Silicone-Filled breast implants was dangerous and likely to place consumers' health at serious risk, as will be detailed further below, Allergan 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 Allergan.

38. Instead, Defendant marketed, advertised and promoted the product while at the same time consciously refusing and/or recklessly failing to monitor, warn, or otherwise ensure the safety and efficacy for users of the Allergan's Natrelle® Silicone-Filled breast implants.

39. At relevant times, Defendants advertised and marketed their Natrelle® Silicone-Filled breast implants as safe for use by women and are "designed TO PROTECT" and that the "gel in *Natrelle*® gummy implants is surrounded by a state-of-the-art breast implant shell that is designed to keep the gel inside."

See https://www.natrelle.com/gel-technology (all capitals in original).

40. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle® Silicone-Filled breast implants products. Allergan refused or recklessly failed to do so.

41. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan was required at all material times

to promptly report any information suggesting that one of its products may have contributed to a serious injury, or had malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

42. The PMA provided as follows:

> Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

43. Allergan's insufficient follow-up rates and inadequate data, as detailed above, establish and confirm Allergan's reckless and intentional disregard for the safety of hundreds of thousands of women.

44. Each of the above-cited deficiencies in Allergan's post-market compliance, including those described above, was a "failure to comply with any post-approval requirement" and each constituted a ground for withdrawal of the PMA. Defendants' conduct separately violated their duties under the law.

45. Notwithstanding Allergan's failures to comply with post-approval requirements, including the failures described above, Allergan continued to commercially distribute its Allergan's Natrelle® Silicone-Filled breast implants. As expressly provided in the PMA, such distribution was a violation of federal law.

46. Had Allergan substantially complied with the PMA, rather than flagrantly under-performing the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Plaintiff, and medical providers including Plaintiff's physicians, would not in ignorance

have purchased or implanted Allergan's products, including, but not limited to, the causative association to Breast Implant Associated – Anaplastic Large Cell Lymphoma.

47. Specifically, Defendants knew or should have known that the new breast implants, specifically the textured design models, were associated with Anaplastic Large Cell Lymphoma.

48. To protect the Allergan's Natrelle® Silicone-Filled breast implant brand, the Defendants intentionally failed in their post-market surveillance obligations, and thereby consciously and deliberately concealed its knowledge of known safety risks from the FDA, the medical community, and the public at large. Additionally, the Defendants ignored the available scientific studies and publications indicating an association between textured breast implants and Anaplastic Large Cell Lymphoma.

49. Defendant also has a duty to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of the product after it was approved for sale by the FDA in 2006, which does not impose duties or requirements materially different from those imposed by federal law. Defendants failed or refused to do so.

50. At material times, Defendants routinely maintained manufacturing facilities that failed to comply with applicable law and regulations in relation to:

a. The lack of approved software and systems;

b. The use of nonconforming products;

c. Documents which failed to include data or statistical rationale to support sampling plans used to test saline and gel-filled products;

d. The failure to initiate or take corrective action to reassess the results and adjust the values of product bioburden samples;

e. The omission of any reference in Allergan's reporting to its manufacturing

processes as a potential cause of product failures relating to the inability to sterilize the product;

f. The omission of any reference in Allergan's reporting to its manufacturing processes as a potential cause of product failures relating to finished products which showed an "absence of material" or a "fail[ure] to contain gel";

g. The failure to adhere to an appropriate Environmental Monitoring Program;

h. Deficiencies in Allergan's sampling methods for finished product testing;

i. Deficiencies in Allergan's risk analyses and its investigation of non-conformances;

j. Deficiencies in Allergan's environmental monitoring control procedures; and

k. Citations to incomplete data and missing statistical or technical rationales to justify the performance of finished product testing.

51. These deviations contributed to faulty manufacture of Allergan's Natrelle® Silicone-Filled breast implant products which were prone to rupture and which were thus defective and adulterated.

52. Allergan failed to warn consumers, healthcare providers, and the FDA that ALCL or BIA-ALCL, and symptomatology attenuated thereto, was a potential risk of Allergan's Natrelle® Silicone-Filled breast implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk.

53. The risk of ALCL or BIA-ALCL was not disclosed or discussed in the product's consumer labeling, despite the availability of substantial evidence that an association existed and was established by at least 2008 as further detailed below.

54. Allergan knew of the manufacturing failures, and multiple risks associated with implants design, and consciously responded by terminating the studies required within post market

surveillance, in favor of self-serving research that it could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

55. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, but also caused a massive failure of information that has to be present in the medical and scientific community to protect a patient's interest. Because Defendants failed to timely, completely, or accurately report their knowledge of the risks and complications associated with their Natrelle® Silicone-Filled breast implants, the public's knowledge of the risks associated with Natrelle® Silicone-Filled breast implants were seriously hampered and delayed. This endangered patient safety, including Plaintiff Michelle Rea's safety.

BREAST IMPLANT–ASSOCIATED ANAPLASTIC LARGE-CELL LYMPHOMA

56. Breast Implant-Associated Anaplastic Large-Cell Lymphoma ("BIA-ALCL") 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.

57. 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 breast capsule.

58. Upon information and belief, the first case of anaplastic large cell lymphoma (ALCL) in association with silicone breast implants was diagnosed in 1994 and reported in 1996.

59. In November 2008, 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.

60. In 2011, a summary of published studies, evidence and reports was published that identified 27 cases of ALCL, and concluded that there was an association between breast implants and ALCL.

61. In March 2015, an analysis identified 173 cases of ALCL.

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

63. Soon thereafter on May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and it was a few months after the National Comprehensive Cancer Network ("NCCN") released the first worldwide oncology standard for the disease.

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

65. A recent update reported that the FDA has been made aware of 414 medical device reports (MDRs) related to breast implants and ALCL, including 9 deaths.

66. Upon information and belief, all confirmed cases of BIA-ALCL are associated with textured breast implants.

67. 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.

FACTS SPECIFIC TO MICHELE REA

68. In 2010, Michele Rea contracted breast cancer in her right breast. As a result of this diagnosis, Rea underwent a partial mastectomy in which her right breast was surgically removed.

69. On January 3, 2011, Michele Rea's reconstructive surgeon offered her the opportunity to participate in Allergan's "Continued Access Reconstruction/Revision Expansion (CARE) Clinical Study." The purpose of this study was to continue to evaluate the safety and effectiveness of the Allergan Natrelle® Style 410 macrotextured breast implant, which did not then possess FDA premarket approval.

70. As a part of the study, Allergan provided to Rea's surgeon (who, in turn, provided to Rea) a document entitled "Informed Consent for A Research Study Permission for Participation in Research."

71. The Informed Consent form listed "risks, complications, and discomforts of the breast implants." BIA-ALCL was not listed.

72. The Allergan Informed Consent form went on to describe "unknown risks." One of these was cancer.

> ***Cancer: At this time there is no scientific evidence that silicone-filled breast implants can increase the risk of cancer in women.*** However, this possibility cannot be completely ruled out. Average follow-up time of completed studies in women has been too short to be fully conclusive.

73. As shown above, this was a false statement.

74. On January 21, 2011, Michele Rea underwent reconstructive surgery, receiving a Style 410MM implant to her right breast.

75. Five days later—January 26, 2011— unbeknownst to Mrs. Rea, the FDA released a monumental report on BIA-ALCL, 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***."

76. 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."

77. On February 20, 2013, the FDA granted premarket approval to the Allergan Natrelle® Style 410 breast implant. Prior to this date, the Allergan Natrelle® Style 410 breast implant enjoyed no FDA premarket approval.

78. On May 2, 2016, Michele Rea presented to Fairfax Hospital with pain and swelling in her reconstructed right breast. Surgeons removed the previously implanted Allergan Natrelle® Style 410 breast implant along with the tissue capsule and fluid that surrounded the implant.

79. On May 9, 2016, a preliminary pathology analysis of the tissue and fluid suggested that Rea contracted Breast Implant-Associated Anaplastic Large Cell Lymphoma.

80. Mrs. Rea's BIA-ALCL diagnosis was confirmed by M.D. Anderson Cancer Center on June 13, 2016.

81. Subsequent to the FDA's 2011 announcement pertaining to BIA-ALCL, additional medical studies have continued to confirm the causal relationship between breast implants and Anaplastic Large Cell Lymphoma. A Dutch epidemiological study published in the January 2018 edition of JAMA Oncology 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%...".

82. At the time the Allergan implants were placed into Mrs. Rea'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.

83. If Mrs. Rea 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.

84. Had the medical community been made aware of the existence of the true frequency, severity and significance BIA-ALCL in Allergan's Natrelle® Style 410 breast implants 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 Allergan's products.

85. Due to the Defendants' failures to comply with their post-approval surveillance obligation, Mrs. Rea did not suspect, nor did she have reason to suspect, that her injuries were caused by the Allergan Natrelle® Style 410 breast implant, or by Allergan's tortious conduct.

86. 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 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 Products.

87. All conditions precedent to filing this action have occurred, or have been satisfied or waived.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

88. Plaintiffs hereby incorporate by reference all other paragraphs in this Complaint as if set forth fully herein.

89. 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 Natrelle® Style 410 breast implant.

90. 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.

91. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth regarding the safety of the Natrelle® Style 410 breast implant.

92. Defendants were under a duty to disclose the true character, quality and nature of the Natrelle® Style 410 breast implant because this was non-public information over which they continue to have exclusive control. Defendants knew that this information was not available to Plaintiff Mrs. Rea, her medical providers and/or her health facilities, yet they failed to disclose the information to the public.

93. 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.

94. 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

COUNT 1 - NEGLIGENCE AND NEGLIGENCE *PER SE*
(Against All Defendants)

95. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

96. At all material times, Defendants owed to Plaintiff Michele Rea a duty to use reasonable care, pursuant to the federal post-approval requirements, in conducting and reporting on post-approval studies, monitoring, testing, and adequately warning of the dangers, including the development of BIA-ALCL, related to Defendant Allergan's Natrelle® Style 410 breast implants.

97. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Allergan's Natrelle® Style 410 breast implants, including the devices which were implanted into Plaintiff Michele Rea.

98. Plaintiff was implanted with Allergan's Natrelle® Style 410 breast implant which was defective, dangerous and adulterated upon manufacture, and without adequate warnings, in violation of state law, 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.

99. 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 Allergan's Natrelle® Style 410 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.

100. Defendants breached their duty, pursuant to federal post-approval requirements, by failing to adequately warn Plaintiff Michele Rea 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.

101. Defendants' specific actions which constitute breaches of these duties to Plaintiff include: failing to timely and accurately report adverse events regarding the Allergan's Natrelle® Style 410 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 complaints and specific events about Natrelle® Style 410 breast implants causing BIA-ALCL, and additional injuries including:

a. Adverse events requiring removal;

b. Persistent and/or chronic inflammation or autoimmune impacts;

c. suspected cancer linked to breast implants;

d. ALCL diagnoses linked to breast implants; and,

e. BIA-ALCL diagnoses linked to breast implants.

102. Defendants disseminated false information by deliberately engaging in false and misleading sales and marketing tactics touting the aesthetic beauty of breast augmentation while minimizing and/or avoiding the risks, which only later, after causing avoidable injury, reached physicians, the medical community, and the public.

103. At all material times, Defendants knew and intended that the medical community and/or patients would rely upon Defendants' disseminated information in deciding whether to purchase and/or implant the Allergan's Natrelle® Style 410 breast implants.

104. At all material times, Defendants knew and intended that patients who were implanted with Allergan's Natrelle® Style 410 breast implants would, in reliance on false information, be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Allergan's Natrelle® Style 410 breast implants, causing them to develop cancer requiring future removal surgeries and to suffer debilitating injuries and conditions, and emotional turmoil attenuated thereto.

105. 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.

106. 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.

107. For each of the statutes and regulations cited in this Complaint, Plaintiff Michele Rea is within the class of persons the statutes and regulations are intended to protect, and Plaintiff's injuries are of the type of harm these statutes and regulations are designed to prevent. Defendants were negligent in their development, promotion, marketing, manufacture, distribution, sale and/or post-market surveillance of Allergan's Natrelle® Style 410 breast implants in one or more of the following ways:

a. Failing to identify the risk of BIA-ALCL in a timely manner;

b. Failing to warn of the risk of BIA-ALCL;

c. Designing, manufacturing, distributing and selling Allergan's Natrelle® Style 410 breast implants that are dangerous to the consuming public;

d. Designing, manufacturing, distributing and selling Allergan's Natrelle® Style 410 breast implants which differ from the specifications set forth in the PMA, its Supplements, and the Conditions of Approval;

e. Failing to conduct regular risk analyses of Allergan's Natrelle® Style 410 breast implants; and,

f. Failing to exercise reasonable care in the manufacturing, inspection, testing, and quality control processes.

108. As a proximate and legal result of Defendants' failure to exercise reasonable care in the warning, design, manufacture, distribution and sale of the Allergan's Natrelle® Style 410 breast implants implanted into Plaintiff, Plaintiff has suffered and will continue to suffer severe from BIA-ALCL and its accompanying symptoms including physical injuries, pain and suffering, severe emotional distress, mental anguish, economic loss, future medical care and treatment, lost

wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 2 – STRICT PRODUCTS LIABILITY: FAILURE TO WARN
(Against All Defendants)

109. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

110. 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 Allergan's Natrelle® Style 410 breast implants

111. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Allergan's Natrelle® Style 410 breast implants, including those which were implanted into Plaintiff Michele Rea.

112. Plaintiff was implanted with Allergan's Natrelle® Style 410 breast implants which were defective, dangerous and adulterated upon manufacture, and which were manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements,

resulting in product failure and serious injury to Plaintiff.

113. At all material times, Defendants intended for the Allergan's Natrelle® Style 410 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.

114. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects, adulterations and life-altering complications faced by patients, including patients who had reported adverse, hazardous ailments and conditions, rendering the product defective and unreasonably dangerous.

115. Defendants also failed to revise its labeling to give warnings consistent with adverse event information which was known or available to Allergan at the time of distribution, and failed to warn Plaintiff of information which became known or available to Allergan after implantation into Plaintiff.

116. Plaintiff's Allergan's Natrelle® Style 410 breast implant was defective and adulterated 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 was vulnerable to degradation, deterioration, ruptures, and leakage, and that the product was susceptible to causing ALCL and/or BIA-ALCL as suffered by Plaintiff Michele Rea.

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

118. Despite the fact that Defendants knew or should have known that implantation of Allergan's Natrelle® Style 410 breast implants was unreasonably dangerous and was likely to

seriously jeopardize the health of consuming patients, Defendants failed to identify, monitor and warn of the defects, adulterations, health hazards and increased risks associated with the product.

119. The defects, adulterations and increased risks inherent in Allergan's Natrelle® Style 410 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.

120. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendants when she consented to the implantation of Allergan's Natrelle® Style 410 breast implants.

121. At all relevant times, Plaintiff's Natrelle® Style 410 breast implant was used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

122. The Natrelle® Style 410 breast implants 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.

123. Defendants knew that Natrelle® Style 410 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.

124. Natrelle® Style 410 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 Natrelle® Style 410 breast implants.

125. 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 Allergan's Natrelle® Style 410 breast implants.

126. As a proximate result and/or substantial factor of Allergan's Natrelle® Style 410 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, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 3 – STRICT PRODUCTS LIABILITY
(Against All Defendants)

127. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

128. 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 Allergan's Natrelle® Style 410 breast implants.

129. Defendants formulated, designed, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted

Allergan's Natrelle® Style 410 breast implants, including those which were implanted into Plaintiff Michele Rea.

130. Plaintiff was implanted with Allergan's Natrelle® Style 410 breast implant which was defective, dangerous and adulterated upon manufacture, and which was manufactured with nonconforming materials and uncertified components, or with appropriate components in inappropriate quantities, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

131. At all material times, Defendants intended for the Allergan's Natrelle® Style 410 breast implant 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.

132. Defendants failed to warn Plaintiff and her physicians of the risk of serious defects, adulterations and life-altering complications such as the development of BIA-ALCL described in this Complaint, rendering the device defective and unreasonably dangerous.

133. Defendants also failed to revise the Product's labeling to give warnings consistent with adverse event information which was known or available to Defendants at the time of distribution, and failed to warn Plaintiff of information which became known or available to Defendants after implantation into Plaintiff.

134. Plaintiff's Allergan Natrelle® Style 410 breast implant was defective and adulterated at the time of sale and distribution, and at the time they left Defendants' possession, and Defendants failed to adequately warn of the risks that the product was vulnerable to degradation, deterioration, ruptures, and leakage, and that the product was susceptible to causing

BIA-ALCL as suffered by Plaintiff Michele Rea.

135. Defendants knew or should have known that there was a significant risk that its Natrelle® Style 410 breast implant caused, and did in fact increase the risk of contracting, BIA-ALCL. Defendants deliberately refused to disclose this information to FDA, the medical community and the public.

136. Despite the fact that Defendants knew or should have known that implantation of Allergan's Natrelle® Style 410 breast implant was unreasonably dangerous and was associated with an increased risk of serious injury to consuming patients, Defendants failed to monitor and warn of the defects, adulterations, health hazards and increased risks associated with the product.

137. The defects, adulterations and increased risks inherent in Allergan's Natrelle® Style 410 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.

138. Plaintiff's physician reasonably relied upon the skill, superior knowledge, and judgment of Defendant Allergan when she consented to the implantation of Allergan's Natrelle® Style 410 breast implants.

139. At all relevant times, Plaintiff's Natrelle® Style 410 breast implant was used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants.

140. The Allergan Natrelle® Style 410 breast implant was manufactured, designed, promoted, marketed, distributed, and sold by Defendant were expected to, and did, reach Plaintiff and/or Plaintiff's physician without substantial change in the condition in which they were sold.

141. Defendants knew that the Natrelle® Style 410 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.

142. Allergan's Natrelle® Style 410 breast implants, which were defectively manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented by Defendants, were a substantial contributing factor in bringing about Plaintiff's injuries, which would not have occurred but for the use of Allergan's Natrelle® Style 410 breast implants.

143. The defective and adulterated product was a substantial contributing factor in bringing about or did in fact cause the injuries to Plaintiff that would not have occurred but for the use of Allergan's Natrelle® Style 410 breast implant.

144. 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 Allergan's Natrelle® Style 410 breast implant.

145. As a proximate result and/or substantial factor of Allergan's Natrelle® Style 410 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, lost wages, lost future earning capacity, and other damages for which she is entitled to compensatory and other damages in an amount to be proven at trial.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 4 - BREACH OF EXPRESS WARRANTY
(Against All Defendants)

146. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

147. Defendants in their manufacturing, design, distribution, marketing and promotion of Natrelle® Style 410 breast implants expressly warranted same to be safe and effective for Plaintiff and members of the public generally.

148. At the time of making of these express warranties, Defendants had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective, fit and proper for such purpose and use.

149. Defendants further expressly warranted that their Natrelle® Style 410 breast implants were safer and more effective than other breast implants.

150. Allergan's Natrelle® Style 410 breast implants do not conform to these express warranties and representations because Allergan's Natrelle® Style 410 breast implants are not safe or effective, nor are they safer or more effective than other breast implants available, and they may produce serious side effects, including among other things BIA-ALCL.

151. As a direct and proximate result of the breach of express warranties by Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience

mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 5 - BREACH OF IMPLIED WARRANTY
(Against All Defendants)

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

153. Defendants marketed, manufactured, promoted, distributed and/or sold Natrelle® Style 410 breast implants for use by the public at large and including the Plaintiff herein. Defendants knew the use for which their product was intended and impliedly warranted said product to be of merchantable quality, safe and fit for use.

154. Plaintiff reasonably relied on the skill and judgment of Defendants, and as such their implied warranty, in using Natrelle® Style 410 breast implants. Contrary to same, Natrelle® Style 410 breast implants were not of merchantable quality or safe or fit for its intended use, because said product is unreasonably dangerous and unfit for the ordinary purpose for which it was intended and used.

155. As a direct and proximate result of the breach of implied warranties by Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become

and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff 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.

COUNT 6 - NEGLIGENT MISREPRESENTATION
(Against All Defendants)

156. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

157. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of Natrelle® Style 410 breast implants described herein, owed a duty to provide accurate and complete information regarding their product.

158. Defendants falsely represented that the aforesaid product was safe and. These representations by Defendants were in fact false and the product was not safe for said purpose and was in fact dangerous to the health of Plaintiff. Defendants concealed, omitted, or minimized the side effects of Natrelle® Style 410 breast implants or provided misinformation about adverse reactions, risks and potential harms from Natrelle® Style 410 breast implants and succeeded in persuading consumers and Plaintiff to purchase and implant Natrelle® Style 410 breast implants

despite the product's lack of safety and the risk of adverse effects, including ALCL and/or BIA-ALCL.

159. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and healthcare providers information about the propensity of their product to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of said product despite the lack of information regarding same.

160. Defendants' misrepresentations in promoting and marketing Natrelle® Style 410 breast implants created and reinforced a false impression as to the safety of Natrelle® Style 410 breast implants, thereby placing consumers at risk of serious and potentially lethal effects.

161. The aforesaid misrepresentations were made by Defendants with the intent to induce Plaintiff to use the product, to the detriment of Plaintiff.

162. At the time of Defendants' misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

163. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Natrelle® Style 410 breast implants.

164. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have

and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 7 - FRAUDULENT MISREPRESENTATION
(Against All Defendants)

165. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

166. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Natrelle® Style 410 breast implants described herein, owed a duty to provide accurate and complete information regarding their product.

167. Defendants' fraudulently misrepresented information regarding their product including, but not limited to, its propensity to cause serious physical harm.

168. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

169. Defendants breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product.

170. Defendants acted with deliberate intent to deceive and mislead Plaintiff.

171. Plaintiff reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

172. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 8 – FRAUDULENT CONCEALMENT
(Against All Defendants)

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

174. Prior to Plaintiff's use of the Natrelle® Style 410 breast implant and during the period in which Plaintiffs actually used the Natrelle® Style 410 breast implant, Defendants fraudulently suppressed material information regarding the safety and efficacy of the Natrelle® Style 410 breast implants and the availability of an alternative feasible safer design.

175. Further, Defendants fraudulently concealed the safety information about the use of Natrelle® Style 410 breast implants, generally, and textured implants, specifically. Plaintiffs believe the fraudulent misrepresentations and fraudulent concealment described throughout this

Complaint were intentional so as to maintain the sales volume of the Natrelle® Style 410 breast implants.

176. Defendants intentionally concealed safety issues with the Natrelle® Style 410 breast implants in order to induce consumers, including Plaintiffs, to purchase Natrelle® Style 410 breast implants, and to induce healthcare providers to utilize Natrelle® Style 410 breast implants.

177. At the time Defendants concealed the fact that Natrelle® Style 410 breast implants were not safe as designed and marketed, Defendants were under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with Natrelle® Style 410 breast implants, generally.

178. Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of Natrelle® Style 410 breast implants.

179. As a direct and proximate result of Defendants' malicious and intentional concealment of material and information, Defendants caused or significantly contributed to Plaintiff's injuries.

180. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff and the public.

181. Defendants' acts before, during and/or after the act causing Plaintiff's injuries prevented Plaintiff from discovering the injury or cause thereof.

182. Defendants' conduct, as described in the preceding paragraphs and in the Complaint, amounts to conduct purposely committed, which Defendants must have realized was

dangerous, needless and reckless, without regard to the consequences or the rights and safety of Plaintiff and the public.

183. As a direct and proximate result of Defendants' fraudulent concealment concerning Natrelle® Style 410 breast implants, as described herein, Plaintiff suffered and continues to suffer from the damages for which she is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

WHEREFORE, Plaintiff Michele Rea 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.

COUNT 9 – LOSS OF CONSORTIUM
(Against All Defendants)

184. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

185. As a result of the injuries and damages caused to Plaintiff Michele Rea by Defendants' tortious conduct in violation of federal law and the post-approval requirements, Michele Rea was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support. Consequently, Plaintiff Carl Rea was required to:

a. Perform all activities and upkeep around the house;

b. Support Michele Rea by performing activities she previously performed for her own needs and maintenance;

c. Take over many of the activities which Michele Rea previously commonly performed as a parent to Michele Rea and Carl Rea's children.

186. As a result of Defendants' defective and adulterated Natrelle® Style 410 breast implants and the development of Michele Rea's BIA-ALCL, Plaintiff Carl Rea effectively lost the companionship and accompaniment of his wife.

187. As a further result of Defendants' defective and adulterated Natrelle® Style 410 breast implants and the injuries they caused to Michele Rea and the resulting demands placed upon Carl Rea has suffered lost wages and income.

188. As a direct and proximate result of the injuries caused to Plaintiff Michele Rea by Defendants' tortious conduct, Spouse Plaintiff Carl Rea suffered and will continue to suffer the loss of his wife's consortium, companionship, society, intimacy, affection, services and support, and suffered and will continue to suffer economic damages, including lost wages and income.

WHEREFORE, Plaintiff Carl Rea 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.

COUNT 10 - PUNITIVE DAMAGES
(Against All Defendants)

188. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

189. Defendants' manufacture, marketing, promotion, distribution and sale of a defective product and their failure to provide adequate warnings and instructions concerning its hazards was willful, wanton, reckless and without regard for the public's safety and welfare.

190. Defendants misled both the medical community and the public at large, including Plaintiff herein, by making false representations about the safety of Natrelle® Style 410 breast implants.

191. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Natrelle® Style 410 breast implants despite available information demonstrating that Natrelle® Style 410 breast implants was likely to cause serious and potentially fatal side effects to users.

192. At all times relevant hereto, Defendants knew of the defective nature of their Natrelle® Style 410 breast implants, and continued to design, manufacture, market, label, and sell Natrelle® Style 410 breast implants so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by Natrelle® Style 410 breast implants, including Plaintiff who did suffer such harm.

193. Defendants misled regulators, the medical community and the public at large, including Plaintiff, by making false and misleading representations about the safety of Natrelle® Style 410 breast implants. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiff.

194. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Plaintiff in particular, Plaintiff suffered profound injuries which are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiffs Michele and Carl Rea demand 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.

DEMAND FOR JURY TRIAL

The Plaintiffs demand trial by a jury on all of the triable issues of this complaint, pursuant to New Jersey Court Rules 1:8-2(b) and 4:35-1(a).

Dated: May 8, 2018

Respectfully submitted,

ROSS FELLER CASEY, LLP

/s/ Brian J. McCormick, Jr.
Robert Ross, Esquire
Joel J. Feller, Esquire
Brian J. McCormick, Jr., Esquire
Dena R. Young, Esquire
1650 Market Street, 34th floor
Philadelphia, PA 19103
Tel.: (215) 574-2000
Fax: (215) 574-3080
bmccormick@rossfellercasey.com
dyoung@rossfellercasey.com

CHAPPELL, SMITH & ARDEN, P.A.

Graham L. Newman, Esquire (to be admitted *pro hac vice*)
2801 Devine Street, Suite 300
Columbia, South Carolina 29205
Telephone: 803.929.3600
Fax: 215.545.8805

McELDREW YOUNG
James J. McEldrew, III, Esquire
Daniel Purtell, Esquire
123 S. Broad Street, Suite 2250
Philadelphia, PA 19109
Tel.: (215) 545-8800
Fax.: (215) 545-8805
jim@mceldrewyoung.com
dpurtell@mceldrewyoung.com

CERTIFICATION PURSUANT TO RULE 4:5-1

I certify that this dispute is not the subject of any other action pending in any other court or a pending arbitration proceeding to the best of my knowledge and belief. Also, to the best of my knowledge and belief no other action or arbitration proceeding is contemplated. Further, other than the parties set forth in this complaint, Plaintiff knows of no other parties that should be made a part of this lawsuit. In addition, Plaintiffs recognize the continuing obligation to file and serve on all parties and the court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 8, 2018

ROSS FELLER CASEY, LLP
Attorneys for Plaintiffs

/s/ Brian J. McCormick, Jr.
BRIAN J. MCCORMICK, JR.

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-002694-18

Case Caption: REA MICHELE VS ALLERGAN PLC
Case Initiation Date: 05/08/2018
Attorney Name: BRIAN J MC CORMICK JR
Firm Name: ROSS FELLER CASEY LLP
Address: ONE LIBERTY PLACE, 34TH FL 1650 MARKET ST
PHILADELPHIA PA 19103
Phone:
Name of Party: PLAINTIFF : Rea, Michele
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PERSONAL INJURY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: NO
If yes, list docket numbers:
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

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

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

If yes, is that relationship:

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

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

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

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

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

05/08/2018
Dated

/s/ BRIAN J MC CORMICK JR
Signed

Done

Please print out and include as the final page of your last final complaint sent each day