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IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES - UNLIMITED JURISDICTION

JENNIFER ANN COOK and DAVID CHRISTOPHER COOK, wife and husband,

Plaintiffs,

v.

ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., ALLERGAN plc, NUSIL, LLC; NUSIL TECHNOLOGY, LLC, and DOES 1-100, inclusive,

Defendants.

Case No.

COMPLAINT FOR DAMAGES

(1) NEGLIGENT AND NEGLIGENCE PER SE
(2) STRICT PRODUCTS LIABILITY-FAILURE TO WARN
(3) STRICT PRODUCTS LIABILITY-MANUFACTURING DEFECT
(4) FRAUDULENT MISREPRESENTATION
(5) FRAUDULENT CONCEALMENT
(6) NEGLIGENT MISREPRESENTATION
(7) BREACH OF EXPRESS WARRANTY
(8) BREACH OF IMPLIED WARRANTY
(9) LOSS OF CONSORTIUM

DEMAND FOR JURY TRIAL

Plaintiffs Jennifer Ann Cook ("Plaintiff") and David Christopher Cook (collectively, "Plaintiffs"), by and through their attorneys, based on information and belief, and for causes of action against the Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC. and ALLERGAN plc (hereinafter, collectively referred to as "Allergan"), NUSIL, LLC, NUSIL TECHNOLOGY, LLC, and DOES 1 through 100, inclusive, (hereinafter collectively referred to as "Defendants"), and each of them, hereby allege as follows:

I. INTRODUCTION

1. Plaintiffs bring this action against Defendants, and each of them, in relation to the design, manufacture, testing, marketing, packaging, labeling, advertising, promotion, and/or distribution of Allergan's *NATRELLE*® Style 115 BIOCELL® textured breast implants (the "Natrelle Breast Implants" or the "Product"), 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. Plaintiff was injured severely and permanently when she developed and was diagnosed with anaplastic large cell lymphoma ("ALCL") after being implanted with Defendants' defective and unreasonably dangerous breast implants.

3. This action arises out of the physical injuries and damages suffered by Plaintiff as a result of Defendants' actions and/or omissions.

4. Plaintiffs maintain that Defendants' breast implants lacked proper warnings as to the dangers associated with their use.

5. On July 24, 2019. Allergan announced a voluntary worldwide recall of BIOCELL® textured breast implants and tissue expanders.

6. Allergan stated that it took "this action as a precaution following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) provided by the FDA."

7. FDA updated its "safety information" the same day and broadcast:

> To protect individuals from the increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), associated with Allergan BIOCELL textured breast implants, the Food and Drug Administration (FDA) requested that Allergan recall its BIOCELL textured breast implants and tissue expanders. Allergan agreed and is removing these products from the global market. The FDA requested that Allergan recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. based on newly submitted Medical Device Reports (MDRs) reporting worldwide cases of BIA-ALCL and BIA-ALCL-related deaths associated with these devices. Allergan has notified the FDA that it will recall its BIOCELL textured breast implants and tissue expanders from the global market.
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> Based on the currently available information, including the newly submitted data, our analysis demonstrates that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's Biocell BIOCELL textured breast implants would likely cause serious, adverse health consequences and potentially death from BIA-ALCL market.

The FDA Takes Action to Protect Patients from Risk of Certain Textured Breast Implants; Requests Allergan Voluntarily Recall Certain Breast Implants and Tissue Expanders from the Market: FDA Safety Communication, available at https://www.fda.gov/medical-devices/safety-communications/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan?utm_campaign=2019-07-24%20Safety%20Comm-Allergan%20BI%20recall&utm_medium=email&utm_source=Eloqua.

8. The FDA specifically included Allergan's Natrelle Style 115 "BIOCELL Textured Round Midrange Projection Gel Filled Breast Implants" in the FDA's "Affected Products" list. *See id.*

9. In December 21018, Allergan "suspended sales of textured breast implants and tissue expanders" and withdrew the company's remaining supply of textured implants in European markets.

10. Allergan stated that the "withdrawal decision follows a compulsory recall request from Agence Nationale de Sécurité du Médicament (ANSM), the French regulatory authority."

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II. PARTIES, JURISDICTION AND VENUE

11. Plaintiff JENNIFER ANN COOK is a citizen of the State of Georgia. Plaintiff was a citizen and resident of Los Angeles County, California for much of the relevant time period at issue here.

12. Plaintiff DAVID CHRISTOPHER COOK ("Plaintiff Husband") is a citizen of the State of Georgia. Plaintiff Husband was a citizen and resident of Los Angeles County, California for much of the relevant time period at issue here

13. Defendant ALLERGAN plc is a publicly-traded corporation whose headquarters is in Dublin, Ireland.

14. Allergan's administrative headquarters in the United States are located in the states of New Jersey and California.

15. ALLERGAN, INC., formerly known as INAMED CORPORATION ("Inamed"), and prior that known as McGhan Medical Corporation ("McGhan"), is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware possessing its principal place of business in New Jersey.

16. At the time of Ms. Cook's implants, Allergan's headquarters were listed as follows in its own documents:

a. April 2009 Directions for Use – 71 South Los Cameros, Santa Barbara, CA 93117;

b. March 2011 Patient Information - 540 Ekwill Street, Santa Barbara, CA 93111; and

c. 2011 Directions for Use – 5540 Ekwill Street, Santa Barbara, CA 93111.

17. 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 New Jersey.

18. McGhan Medical Corporation ("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.

19. Upon information and belief, McGhan changed its name to Inamed Corporation ("Inamed") in 1986.

20. Inamed Corporation is incorporated under the laws of Delaware and its principal place of business is in Orange County, California.

21. 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.

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

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

24. Defendant NUSIL, LLC is a limited liability company incorporated under the laws of the State of California, with its principal place of business located at 1050 Cindy Lane, Carpinteria, California, 93013.

25. Defendant NUSIL TECHNOLOGY, LLC is a limited liability company incorporated under the laws of the State of Delaware, with its principal place of business located at 1050 Cindy Lane, Carpinteria, California, 93013.

26. Defendant NUSIL, LLC and NUSIL TECHNOLOGY, LLC are hereinafter collectively referred to as "NUSIL DEFENDANTS."

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27. The Nusil Defendants are silicone raw material suppliers that manufactured, produced, supplied and shipped to Allergan the silicone used in the Natrelle Breast Implants.

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

29. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

30. These concerted efforts resulted in significant harm to Plaintiffs. But for the actions of Defendants, individually, jointly, and in concert with one another, Plaintiffs would not have been implanted with Defendants' Breast Implant and would not have suffered severe injuries.

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

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

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

34. Plaintiff's claims arise out of and/or are related to Defendants' California-related forum activities.

35. Plaintiff is informed and believes and, on that basis, alleges that Defendants have purposefully directed their activities at this forum State, and the exercise of jurisdiction is reasonable and would not offend the traditional notions of fair play and substantial justice.

36. Plaintiffs is informed and believes and, on that basis, alleges that Defendants have purposefully availed themselves of the privileges and benefits of conducting activities with the forum State, and have invoked the benefits and protections of its laws.

37. Defendants are citizens of and/or do business in the State of California. Further, a substantial part of the events giving rise to Plaintiffs' claims occurred in California, including the design, formulation, testing, packaging, labeling, production, creation, construction, making, assembly, advertising, clinical testing, marketing, promotion, distribution, manufacturing, and selling of the Product, as well as the implantation of the Product.

38. Venue is proper in this county in accordance with Section 395 of the California Code of Civil Procedure because the injuries alleged herein arose from conduct that occurred in this county.

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III. FACTS RELEVANT TO ALL COUNTS

A. FDA Regulation of Silicone Breast Implants

39. "Silicone" refers to a group of polymers based on the element silicon. Silicone polymers may be produced in a variety of forms, including oil, gels, or elastomers (rubber). Being purely synthetic, silicones do not exist in nature.

40. A breast implant is a prosthetic product used to change the size, shape, and contour of a woman's breast. There are three general types of breast implant products, defined by their filler material: saline solution, silicone gel, and composite filler.

41. Breast implants are available in various sizes and can have either a smooth or textured shell.

42. During the 1950s and 1960s many different materials were used for the purpose of augmenting the female breast which included direct injection of silicone oil, vegetable oil, bee's wax, rubber and Terylene wool. These all led to critical health problems in patients and were rejected as appropriate augmentation materials.

43. In 1961 the first silicone gel prosthesis was developed by American plastic surgeons Thomas Cronin and Frank Gerow and manufactured by the Dow Corning Corporation with the first augmentation mammoplasty being performed in 1962.

44. Upon information and belief, Defendants manufactured, supplied and specially designed silicone raw materials which were used in the Natrelle Breast Implants for both the elastomer shell and silicone gel, including those implanted in Plaintiffs.

45. They are a leading manufacturer of silicone compounds for the medical implants, healthcare, aerospace & defense, electronics and engineering and skin care markets for applications requiring precise, predictable materials performance.

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46. On information and belief, the NUSIL Defendants produced kits containing a variety of chemicals to be mixed and cured by Allergan according to instructions the NUSIL Defendants provided. The process of mixing and curing creates both the silicone elastomer shell and silicone gel that fills the implant.

47. When a kit is improperly mixed or improperly cured it impacts the cohesiveness of the shell elastomer (causing it to degrade) and gel (turning it liquid). This can cause an early failure (rupture), degradation of the shell and failure in biocompatibility of the shell and/or gel to the user. All silicone gels are cohesive, but the degree of cohesiveness has clinical importance.

48. On information and belief, the chemicals provided by the NUSIL Defendants contained other chemicals then what is represented and/or disclosed. The presence of these additional and/or different chemicals can impact the biocompatibility of the shell and/or gel to the user as well as an impact the mixing and curing process.

49. When an elastomer shell is not properly filled it can cause the implant to fold or crease in a woman's body which can also lead to degradation and ultimate rupture of the implant.

50. 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).

51. 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 requiring premarket approval ("PMA").

52. In April 1991, upon final publication of new regulations, FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants.

53. 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.

54. 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.

55. 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.

56. In November 1991, the FDA held an Advisory Panel meeting to discuss several PMAs for silicone gel-filled breast implants. While the Advisory Panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.

57. 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.

58. In April 1992, the FDA determined that none of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support premarket approval for silicone breast implants. From that time, implantation of the products in the United States was limited to reconstruction and revision patients.

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

60. The Style 115 "BIOCELL® Textured shell surface" implants implanted in Ms. Cook's body were

> constructed with barrier shell technology resulting in a low diffusion silicone elastomer shell and are filled with a soft, cohesive silicone gel. All styles are single "lumen" round design and consist of a shell, a patch, and silicone gel fill. *NATRELLE*® Silicone-Filled Breast Implants are dry heat sterilized and are available in both smooth and BIOCELL® surface texture.

NATRELLE® Silicone-Filled Breast Implants Directions for Use (rev. 4/6/09).

B. <u>Information Specific to Allergan's Gel-Filled and Saline-Filled Breast Implants</u>

61. 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.

62. In April 1992, the FDA entered into an agreement with McGhan setting forth the requirements for McGhan to conduct clinical trials of the silicone 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 device 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.

63. 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.

64. 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.

65. 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 in compliance with regulations and therefore that facility could export silicone gel-filled mammary prostheses into the United States.

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

67. 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.

68. 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.

69. 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. McGhan was among the three manufacturers of saline-filled breast implants whose PMA applications were accepted for filing and, in accordance with FDA regulations, each of the three applications was referred to an FDA Advisory Panel on general and plastic surgery.

70. The Advisory Panel met in open session on March 1-3, 2000 to consider the applications.

71. On May 10, 2000, the FDA announced that it had approved McGhan's application for PMA of four styles of 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) devices.

72. Allergan Natrelle Breast Implants are Class III medical devices.

73. Inamed's "Silicone-Filled Breast Implants", including Style 115, received pre-market approval from the FDA in November 2006, marking the first time in fourteen years that the products were available for elective augmentation in addition to reconstruction and revision.

74. The FDA's Approval Letter was sent to Patricia S. Walker, M.D., Ph.D., Executive Vice President and Chief Scientific Officer for Allergan, located in its Santa Barbara, California offices.

75. 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 Breast Implants included:

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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.

76. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as the Natrelle Breast Implants, rests with the manufacturer.

77. 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.

78. 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.

79. 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 federal regulations and California law, time is of the essence.

80. 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.

81. Defendants' specific obligations after the PMA include, 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 [21 C.F.R. § 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 C.F.R. § 814];

c. Submitting an adverse event report within 10 days of receiving knowledge of an adverse reaction, side effect, injury . . . that is attributable to the device [21 C.F.R. § 814.82(a)(9) and PMA];

d. Submitting a PMA supplement for the following:

- When unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification [PMA Conditions of Approval and 21 C.F.R. § 814.39]
- Labeling changes except for those that add to or strengthen a contraindication, warning, precaution or information about an adverse reaction for which there is reasonable evidence of a causal association [21 C.F.R. § 814.39(a)(2) and §814.39(d)(2)(i)];
- for any listed or material changes to the Product [21 C.F.R. § 814.39];

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

f. 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 C.F.R. § 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 C.F.R. § 820.100];

g. Establishing internal procedures for reviewing complaints and event reports [21 C.F.R. §§ 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 C.F.R. §§ 820.70 and

820.90];

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

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

82. Defendants violated other federal requirements including the requirements to:

a. establish and maintain a quality system. [21 C.F.R. § 820.5];

b. provide for management responsibility [21 C.F.R. § 820.20];

c. provide for quality audits [21 C.F.R. § 820.22];

d. establish and maintain procedures to control the design of the device in ordered to ensure that specified design requirements are met [21 C.F.R. § 820.30];

e. establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonable be anticipated to have an adverse effect on product quality [21 C.F.R. § 820.70(e)];

f. establish and maintain procedures for acceptance activities, including inspections, tests, or other verification activities [21 C.F.R § 820.80];

g. identify the "conformance or nonconformance of product with acceptance criteria ... throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed" [21 C.F.R § 820.86];

h. establish and maintain procedures to control product that fails to conform with specified requirements, including the evaluation of non-conforming products [21 C.F.R. § 820.90(a)];

i. establish and maintain procedures for implementing corrective and preventive action including:

i. identifying the cause of product nonconformities,
ii. identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems,
iii. ensuring that information related to quality problems or nonconforming product is disseminated to hose directly responsible for assuring. [21 C.F.R. § 820.100(a)(1)-(7)].

83. Defendants 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 those suffered by Plaintiff Ms. Cook.

84. Had Defendants not intentionally failed to comply with their clearly-established post-

market surveillance obligations, Ms. Cook would have decided against implantation and her injuries would not have occurred.

85. 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 and timely warning Plaintiff and Plaintiff's implanting surgeon about the dangers of the Natrelle Breast Implants, and about all adverse events of which Defendants became aware, and had a post-market duty to identify, monitor and report all adverse events and all risks associated with the Product.

86. Despite having knowledge and possession of evidence showing that the use of the Natrelle 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 Defendants.

87. Instead, Defendants 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 Natrelle Breast Implants.

88. 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.)

89. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Defendants had a duty to revise its Product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle Breast Implants. Defendants refused or recklessly failed to do so.

90. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Defendants were 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.

91. The PMA provided as follows:

> Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

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

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

94. Notwithstanding Defendants' failures to comply with post-approval requirements, including the failures described above, Defendants continued to commercially distribute the Natrelle Breast Implants. As expressly provided in the PMA, such distribution was a violation of federal law.

95. Had Defendants substantially complied with the PMA, rather than flagrantly under-performing the post-approval requirements as alleged above, Defendants' disclosures would have led to much wider knowledge of the risks associated with Defendants' products. In addition, Defendants' 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 Defendants' products, including, but not limited to, the causative association to Breast

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

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

97. To protect the Natrelle and Allergan brands, the Defendants intentionally failed in their post-approval study and conditions of approval, and thereby consciously and deliberately concealed its knowledge of known safety risks from the FDA, the medical community, including Plaintiff's surgeon, and the public at large. Additionally, the Defendants ignored the available scientific studies and publications indicating an association between textured breast implants and ALCL.

98. Defendants also have 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 2000, which does not impose duties or requirements materially different from those imposed by federal law. Defendants failed or refused to do so.

99. 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 Defendants' 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 Defendants' 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 Defendants' sampling methods for finished product testing;

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

j. Deficiencies in Defendants' environmental monitoring control procedures; and

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

100. These deviations contributed to faulty manufacture of Natrelle Breast Implants which were textured, prone to rupture and which were thus defective and adulterated.

101. Allergan failed to warn consumers, healthcare providers, including Plaintiff's surgeon, and the FDA that ALCL or BIA-ALCL, and symptomatology attenuated thereto, was a potential risk of Natrelle Breast Implants, and that hundreds, if not thousands, of patients had suffered negative experiences and events as a result of such known risk.

102. 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, but probably much earlier, as further detailed below.

103. Defendants 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.

104. 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 the Natrelle Breast Implants, the public's knowledge of the risks associated with the Natrelle Breast Implants were seriously hampered and delayed. This endangered patient safety, including the safety of Plaintiff Jennifer Cook.

C. <u>Breast Implant-Associated Anaplastic Large-Cell Lymphoma</u>

105. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000

to 2016, the number of breast augmentations in the United States rose 37%, and reconstructions after mastectomy rose 39%.

106. 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.

107. 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.

108. Upon information and belief, the first case of anaplastic large cell lymphoma (ALCL) in association with silicone breast implants was diagnosed in the early 1990's.

109. 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.

110. 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.

111. In January 2011, unbeknownst to Ms. Cook, the FDA released a 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***." (emphasis added).

112. 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." (italics in original).

113. On February 20, 2013, the FDA granted premarket approval to the Allergan Natrelle®

Style 115 breast implant. Prior to this date, the Allergan Natrelle® Style 115 breast implant enjoyed no FDA premarket approval

114. 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."

115. 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*.

116. 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.

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

118. 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."

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

120. 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. 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."

121. 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 nine deaths.

122. 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).

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

124. 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.

125. Despite Defendants' knowledge of an association between their textured breast implants and ALCL dating back to the 1990's, Defendants purposefully failed to comply with their clearly-established post-market surveillance obligations and in doing so have exposed many hundreds of thousands of women to life-altering and avoidable cancer.

126. On March 19, 2019, the FDA issued warning letters to two breast implant manufacturers for failure to comply with their requirements, under their premarket approval orders, to conduct post-approval studies to assess the long-term safety and risks of their silicone gel-filled breast implants.

127. The FDA held hearings in March 2019 related to the issue (CDRH General and Plastic

Surgery Devices Advisory Committee Meeting). The FDA told ICIJ in a statement pertaining to the 2019 hearing, "[t]his will help inform FDA as to whether we should take additional actions to protect patient safety including a black box label warning, a ban on textured implants, a patient safety checklist, or other steps." Available at https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/.

128. Similarly, the French regulatory body ANSM (Agence Nationale de Sécurité du Méedicament et des produits de santé) has stated - "[T]he ANSM recommends that health professionals rather use implants with a smooth surface." Available at https://www.afp.com/en/news/15/france-review-safety-lymphoma-linked-breast-implants-doc-1b06ve1.

129. While ANSM's recommendation against the use of textured implants due to the risk of BIA-ALCL is the first of its kind for a country's regulatory body, it is not new. Many plastic surgeons in the United States have publicly denounced the use of textured implants for this reason.

IV. FACTS SPECIFIC TO JENNIFER ANN COOK

130. At the time the Natrelle Implants were placed into Ms. Cook's body, she was not advised, nor did she have any independent knowledge, that the Product was anything other than a safe, life-long product. Nor was she advised that the Product was associated and/or known to cause BIA-ALCL.

131. Ms. Cook 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 implant in the future based upon contracting ALCL and/or BIA-ALCL; or

d. She might need future surgery in the event of rupture, leakage or seepage, or

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

132. Even after Defendants became aware of defects in the Breast Implants and harm the

Product was causing, they did not respond in accordance with their obligations and inform Ms. Cook of her risk of developing ALCL.

133. If Ms. Cook 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 Natrelle breast implant.

134. Had the medical community been made aware of the existence of the true frequency, severity and significance BIA-ALCL in Allergan's Natrelle breast implant 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 Product.

135. In August 2010, Ms. Cook was implanted with Natrelle Style 115 Breast Implants. The implantation surgery was performed in Marina del Rey, California.

136. The surgeon who performed the implantation, W. Grant Stevens, M.D., F.A.C.S., was, and remains, a Clinical Investigator for McGhan since 1998 according to his own curriculum vitae, as posted on his website. *See* https://www.marinaplasticsurgery.com/plastic-surgery-los-angeles/grant-stevens-md/curriculum-vitae/ (last visited on July 24, 2019).

137. Dr. Stevens also presented on certain subjects at the "Allergan Academy", which occurred during the Brazilian Society of Aesthetic Plastic Surgery Meeting within a year of Ms. Cook's implantation, in June 2011 in Sao Paolo, Brazil. *See id.*

138. Dr. Stevens continues to advertise "Allergan Natrelle® silicone gel-filled breast implants" on his website. *See* https://www.marinaplasticsurgery.com/before-after-gallery-los-angeles/breast-augmentation/6546/ (last visited on July 23, 2019).

139. On September 20, 2017, Mrs. Cook underwent explant surgery to remove the Natrelle textured silicone breast implants from her body. At the time, Ms. Cook was 45 years old.

140. As a result of Plaintiff's diagnosis of BIA-ALCL, Plaintiff Ms. Cook had seven rounds

of brentuximab, a type of systemic immunotherapy, administered to her body to try to eliminate the disease.

141. Ms. Cook was treated for ALCL in Los Angeles, California.

142. Prior to her development of ALCL, Ms. Cook enjoyed an active, full life.

143. Subsequently, she endured pain, swelling, and other injuries from this terrible disease.

144. Ms. Cook exercised reasonable diligence at all times in investigating her injuries, and could not have discovered at any materially earlier time that her injuries were caused by Defendants' Product.

145. Due to the Defendants' failures to comply with their post-approval surveillance obligation, Ms. Cook did not suspect, nor did she have reason to suspect, that her injuries were caused by Allergan's breast implant products and/or by Defendants' tortious conduct.

146. Defendants, through their misrepresentations and omissions including its refusals 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 Product.

147. Plaintiffs exercised reasonable diligence in investigating the cause of Plaintiff's injuries and could not have discovered that her injuries were caused by the Product at an earlier time. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence, should have known of the existence of her claims against all Defendants.

148. 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 Breast Implants.

149. As a result of Defendants' actions, Plaintiffs were unaware, and could not reasonably know or have learned through reasonable diligence, that Ms. Cook had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE AND NEGLIGENCE PER SE

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

151. At all relevant times, Defendants had a duty to Plaintiffs to use reasonable care in formulating, making, creating, labeling, packaging, testing, constructing, assembling, advertising, manufacturing, selling, distributing, marketing, and promoting its Natrelle Breast Implants.

152. Allergan formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted its Natrelle Breast Implants, including the implants that were implanted into Plaintiff.

153. The Nusil Defendants formulated, made, created, labeled, packaged, tested, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted its silicone elastomer for use in the Natrelle Breast Implants, including the products that were implanted into Plaintiffs.

A. Negligent Failure to Warn

154. Defendants had a duty under California law to exercise reasonable care to provide adequate warning about the risks and dangers of Natrelle Breast Implants that were known or knowable to Defendants at the time of distribution.

155. Defendants were negligent by not using reasonable care to warn about the dangers of which it was aware related to its textured saline breast implants, including the Natrelle Breast Implants placed in Ms. Cook's body or facts that this product was likely to become dangerous after being

implanted into her body.

156. Defendants knew or reasonably should have known that the its Natrelle Breast Implants, including the Natrelle Breast Implants placed in Plaintiffs, were dangerous or were likely to be dangerous when used or misused in a reasonably foreseeable manner.

157. The Nusil Defendants knew or reasonably should have known that its kits were dangerous or were likely to be dangerous when used or misused in a reasonably foreseeable manner.

158. Defendants breached their duty under federal law, and the parallel state duty, in that they failed to warn the FDA, Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Natrelle Breast Implants prior to the time of Plaintiffs implantations, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Plaintiffs.

159. Specifically, Defendants had a duty to report unanticipated adverse device effects (with evaluation) to the FDA, all IRBs, and investigators within 10 working days after notification by the investigator. 21 C.F.R. § 812.150(b). This duty is parallel to the state law duty to exercise reasonable care to provide adequate warning about the risks and dangers associated with their product.

160. Under both federal and state law, Defendants also had a continuing duty to monitor and report adverse events and risks associated with the use of their product.

161. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

162. The FDA publishes this information in a public, searchable Internet database called MAUDE (Manufacturer and User Facility Device Experience) and updates the report monthly with "all reports

received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

163. This duty is parallel to the post-sale duty to warn under California law and applies as Defendants gained knowledge, which it was under a duty to communicate to the FDA and physicians.

164. Under both federal and state law, Defendants had a duty to exercise reasonable care in adequately warning Plaintiffs and Plaintiffs' treating physicians about the dangers of Natrelle Breast Implants that were known or knowable to Defendants at the time of distribution or which became known thereafter.

165. Despite having knowledge and possession of information that showed the use of Natrelle Breast Implants were dangerous and likely to place consumers' health at serious risk, Defendants failed to disclose and warn of the health hazards and risks associated with the Product.

166. Instead, Defendants marketed, advertised, and promoted the Product while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of California law and applicable FDA regulations and requirements.

167. Defendants failed to report adverse events from the studies it was required to conduct, which would have led to adverse event reports revealing the Product's contribution to serious injury.

168. Had Defendants complied with their obligation to report this newly acquired information, true information about: instances of silicone toxicity; instances of adverse events; instances of adverse events requiring removal; instances of constellations of adverse symptoms; instances of chronic/persistent autoimmune-like complaints and inflammatory issues; rupture rates; and other relevant information would have been provided to the FDA and would have been available to

Plaintiffs treating physicians, who would have communicated that information to Plaintiffs.

169. Defendants was, at all times, responsible for maintaining the labeling of the Product, and had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by updating the labeling of Natrelle Breast Implants to reflect newly acquired safety information without advance approval by the FDA.

170. With pre-market approval for its Natrelle Breast Implants, Defendants had a responsibility to file a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Defendants could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

171. Defendants breached their duties under federal law and state law, including California law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

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

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

174. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs treating physicians, regarding the dangers of Natrelle Breast Implants that were known or knowable to Defendants at the time of distribution and afterwards.

175. If Plaintiffs had been adequately warned of the serious risks and adverse events by Defendants, they would not have agreed to implantation of Natrelle Breast Implants.

176. Defendants were negligent in their record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action.

177. Defendants also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 C.F.R. § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

178. As a proximate and legal result of Defendants' failure to comply with its obligations under applicable Federal regulations, Defendants breached their duty of care and caused Plaintiffs to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

B. Negligent Manufacturing

179. Defendants had a duty under federal law, and a parallel duty under California law, to exercise reasonable care in developing, manufacturing, testing, inspecting and selling their product to ensure that it was safe and further that it was made in conformity with the manufacturing and design specifications mandated by the FDA as part of Defendants' PMA.

180. Defendants were negligent under California law, in the development, manufacture, testing, inspection and sale of their Natrelle Breast Implants by: (a) manufacturing Natrelle Breast Implants that differed from the specifications agreed to by the FDA; manufacturing Natrelle Breast Implants using materials and components which differed from those approved by the FDA; failing to follow good manufacturing practices during the manufacture of their Natrelle Breast Implants; failing to properly meet the applicable standard of care by not complying with applicable federal regulations and failing to adhere to the manufacturing protocols approved by the FDA; carelessly and negligently selling and distributing its Natrelle Breast Implants in violation of the terms of the IDE and applicable federal law; negligently incorporating components and/or materials into its Natrelle Breast Implants that could not stand up to normal usage and/or which differed from those which were commercially reasonable and/or failing to use the components and/or materials approved by the FDA; failing to exercise reasonable care in inspecting and testing of the Product; and, failing to exercise reasonable care in its manufacturing, quality control and quality assurance processes.

181. Defendants had a duty under California law to exercise ordinary care in the manufacture of its Natrelle Breast Implants consistent with FDA specifications, the Natrelle Breast Implants IDE, and/or conditions of approval.

182. At all relevant times, Allergan was required to comply with the FDA's Quality System Regulations, the requirements under the PMA.

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183. Natrelle Breast Implants contained a manufacturing defect when they left Allergan's possession, in that Allergan's manufacturing process did not conform to FDA's Quality System Regulations and design control requirements under 21 C.F.R. § 820.30.

184. Upon information and belief, prior to the date that the subject implants were manufactured Allergan was aware that its manufacturing process was deficient and that the implants being produced did not comply with applicable federal requirements.

185. Defendants failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of its Natrelle Breast Implants.

186. Defendants failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of its Natrelle Breast Implants.

187. Defendants failed to adequately inspect, test, and validate its Natrelle Breast Implants after completion of assembly.

188. Defendants failed to comply with the requirements imposed by the FDA and other applicable Federal requirements for the manufacture of its Natrelle Breast Implants.

189. Because Defendants failed to follow specifications, regulations, and required by the FDA, Plaintiffs' Natrelle Breast Implants were defective and were further vulnerable to degradation, deterioration, rupture and leakage.

190. Upon information and belief, when the Natrelle Breast Implants placed into Plaintiffs were manufactured, Defendants had the technological capability to manufacture its Natrelle Breast Implants in a reasonably safe manner.

191. Defendants were negligent in their record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements under 21 C.F.R. § 800.100(a)(6)(7).

192. Defendants also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 C.F.R. § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

193. Upon information and belief, Plaintiff was implanted with Natrelle Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the FDA requirements, resulting in product failure and serious injury.

194. The injuries Plaintiffs suffered resulted from the manufacturing defects identified therein. Ms. Cook and her treating physicians were unaware that the Product was defective at the time of implant and for years thereafter.

195. Plaintiffs are within the class of persons the statutes and regulations referred to herein were designed to protect, and Plaintiffs injuries are of the type of harm these statutes and regulations are designed to prevent.

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

197. As a proximate and legal result of Defendants' failure to exercise reasonable care and the resulting defective condition of the Natrelle Breast Implants implanted into Ms. Cook, Plaintiff suffered injuries and will continue to suffer injuries in the future including severe emotional distress, mental anguish, economic loss, medical care, medical treatment, and procedures, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

198. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

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SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

199. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

200. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Natrelle Breast Implants.

201. At all times relevant herein, Defendants intended for the Natrelle Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiffs, and knew/or should have known that the Product would be surgically implanted into members of the general public, including Plaintiff.

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

203. Allergan also failed to revise the product labeling or otherwise communicate the true rate of occurrence of adverse events to the FDA, the IRB or to physicians based upon the adverse event information available to it through, among other things, the studies which it was required to conduct and the reports of adverse events and effects which it received.

204. Ms. Cook's Natrelle Breast Implants were defective at the time of sale and distribution and at the time they left Defendant's possession in that Defendants failed to adequately warn of the risks that the Product was vulnerable to degradation, deterioration, ruptures, and leakage, and other injuries associated with Natrelle Breast Implants.

205. Ms. Cook's Natrelle Breast Implants were defective and unreasonably dangerous when it left Defendant's possession in that they contained warnings insufficient to alert physicians and consumers, including Plaintiffs, of the dangerous risks and complications associated with the Natrell

Breast Implants, including but not limited to, their propensity to cause injury, including the development of ALCL.

206. Defendants knew, or should have known, of the propensity of Natrelle Breast Implants to cause ALCL and/or BIA-ALCL.

207. Defendants failed to adequately warn physicians and patients implanted with the Product, including Plaintiff, of these potential serious and harmful risks.

208. Defendants failed to provide follow-through post-approval studies required by the FDA's necessary in order to market and sell the Product, and thus failed to report to, and warn, the FDA and the IRB of the risks described above.

209. The accurate rate of occurrence for these and other injuries associated with Natrelle Breast Implants were not readily recognizable to the ordinary consumer, including Plaintiffs and Plaintiffs' treating physicians, as a result of Defendants' conduct.

210. Natrelle Breast Implants were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of degradation, deterioration, ruptures, and leakage, likelihood of developing ALCL, and other injuries that could, and did, harm consumers, including Plaintiff, and Defendants failed to adequately warn consumers of said risks - including Ms. Cook and Ms. Cook's treating physicians - in accordance with Federal requirements and California law.

211. Natrelle Breast Implants were defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known that Natrelle Breast Implants created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them, test for them, and update its labeling and the information provided to the FDA and IRB regarding such risks when the information became available.

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212. Defendants failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements under 21 C.F.R. § 800.100(a)(6)(7).

213. Allergan also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty under 21 C.F.R. § 812.5(a) to describe "all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions."

214. At all relevant times, Ms. Cook's Natrelle Breast Implants were used and implanted into her as intended by Allergan and in a manner reasonably foreseeable to Allergan.

215. The Natrelle Breast Implants were expected to, and did, reach Ms. Cook and Ms. Cook's implanting physician without substantial change in the condition in which they were sold.

216. Despite the fact that Allergan knew, or should have known, that the use of Natrelle Breast Implants were unreasonably dangerous and likely to place users at serious risks to their health, Allergan failed to monitor and warn of the defects, health hazards, and risks associated with Natrelle Breast Implants.

217. Ms. Cook's Natrelle Breast Implants were also defective at the time of sale and distribution, and at the time the devices left the possession of Allergan, in that the devices differed from the intended result and design specifications as approved by the FDA.

218. Upon information and belief, Ms. Cook was implanted with Natrelle Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the specifications and requirements approved and mandated by the FDA, resulting in product failure and serious injury to Ms. Cook.

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219. The injuries Plaintiffs suffered are expected to result from the manufacturing defects identified therein and by the FDA. Ms. Cook and Ms. Cook's treating physicians were unaware that the Product was defective at the time of implant.

220. Defendants violated federal regulations and California law, by placing the Natrelle Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

221. Allergan was, at all times, responsible for maintaining the labeling of the Product, and had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by updating the labeling of Natrelle Breast Implants to reflect newly acquired safety information without advance approval by the FDA.

222. During the IDE process, Allergan was under a duty to advise the FDA, IRB and study investigators of all significant new information, including the duty to monitor, evaluate and report all unanticipated adverse device effects and to terminate the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. *See*, 21 C.F.R. §812.46.

223. Allergan was specifically required to report all unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. *See*, 21 C.F.R. § 812.150(b).

224. California imposes a parallel duty to warn and advise product users.

225. Allergan was responsible for filing a "Special PMA Supplement – Changes Being Effected" ("CBE") by which Allergan could unilaterally update the product labeling to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d). These changes include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance

the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

226. Allergan breached its duties under federal law and state law, including California law, to maintain labeling that: (a) added instructions for use that would enhance the safe use of the device; and (b) added descriptions of adverse events to ensure that the labeling was not false or misleading.

227. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a).

228. Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury, or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

229. The FDA publishes this information in a public, searchable Internet database called MAUDE (Manufacturer and User Facility Device Experience) and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices.

230. Despite the fact that evidence existed that Natrelle Breast Implants were dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Natrelle Breast Implants.

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231. Natrelle Breast Implants had a manufacturing defect when they left Allergan's possession in that Allergan's manufacturing process did not comply with the FDA's Quality System Regulations, the requirements under the IDE and design control requirements under 21 C.F.R. § 820.30.

232. The defects inherent in Natrelle Breast Implants were not readily recognizable to the ordinary consumer, including Ms. Cook and Ms. Cook's implanting physician.

233. Plaintiffs could not, in the exercise of reasonable care, have discovered the defects herein mentioned and perceived their true danger.

234. Ms. Cook and Ms. Cook's implanting physician reasonably relied upon the skill, superior knowledge, and judgment of Allergan when they consented to the implantation procedure using Natrelle Breast Implants.

235. At all relevant times, Ms. Cook's Natrelle Breast Implants were used and implanted as intended by Allergan and in a reasonably foreseeable manner.

236. Had Ms. Cook and Ms. Cook's physician received adequate warnings regarding the risks the risks of Natrelle Breast Implants, they would not have used them.

237. Had Allergan complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Ms. Cook's treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Ms. Cook was experiencing were related to the Natrelle Breast Implants. Had that occurred, Ms. Cook would have been able to undergo the explant surgery at an earlier date and/or would have been tested and treated earlier for ALCL.

238. Natrelle Breast Implants were expected to, and did, reach Ms. Cook and Ms. Cook's implanting physician without substantial change in the condition in which they were sold.

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239. Allergan knew that its Natrelle Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

240. At all times relevant to this action, the dangerous propensities of Natrelle Breast Implants were known to Allergan or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to implant Natrelle Breast Implants for their patients.

241. Allergan was required to provide adequate warnings to consumers and the medical community under federal and California law, but failed to do so in a timely, truthful, accurate and responsible manner.

242. Had Allergan timely and adequately reported adverse events to the FDA and IRB, there would have been effective warnings to physicians, including Ms. Cook's treating physicians, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Ms. Cook and Ms. Cook's treating physicians, regarding the dangers of Natrelle Breast Implants that were known or knowable to Allergan at the time of distribution.

243. Had Allergan complied with its continuing duty to report adverse events and effects, to properly and truthfully report the findings from the studies it was required to conduct and to otherwise provide full, complete and accurate information to the FDA and the IRB, that information would have been available to Ms. Cook's treating physicians and they would have been better able to recognize at an earlier date that the symptoms and complications which Ms. Cook was experiencing were related to her Natrelle Breast Implants. Had that occurred, Ms. Cook would have been able to undergo the explantation surgery at an earlier date and/or would have been tested and treated earlier for ALCL.

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244. Because Allergan failed to follow specifications, regulations, and required the FDA and applicable Federal regulations and requirements, the Natrelle Breast Implants implanted in Ms. Cook was vulnerable to degradation, deterioration, ruptures, and/or leakage.

245. Natrelle Breast Implants were manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendants, and this was a substantial contributing factor in bringing about Ms. Cook's injuries.

246. The defective warnings and failures to provide truthful, accurate and complete information as required under the IDE and other applicable Federal regulations and requirements were a substantial contributing factor in bringing about the injuries to Ms. Cook that would not have occurred but for the use of the Natrelle Breast Implants.

247. As a proximate result and/or substantial factor of the Natrelle Breast Implants' defective condition at the time they were sold, Plaintiff and Plaintiff Husband have suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

248. WHEREFORE, Plaintiffs pray for judgment against Defendants as set forth herein.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

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

250. At all times relevant herein, Allergan was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Natrelle Breast Implants.

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251. At all times relevant herein, Allergan intended for the Natrelle Breast Implants to be surgically implanted into the bodies of members of the general public, including Ms. Cook, and knew or should have known that the Product would be surgically implanted into members of the general public.

252. Allergan manufactured, tested, marketed, promoted, advertised, distributed, and sold the Natrelle Breast Implants that were implanted into Ms. Cook.

253. At all times relevant, Allergan placed Natrelle Breast Implants into the stream of commerce and did so in a manner in which the Natrelle Breast Implants were defective in their manufacturing process did not comply with the FDA's Quality System Regulations and design control requirements under 21 C.F.R. § 820.30.

254. Allergan violated federal regulations and requirements and California law by placing the Natrelle Breast Implants into the stream of commerce in a defective and unreasonably dangerous condition.

255. Defendants failed to keep required records and did not disclose manufacturing flaws that increased the risk of injury to patients receiving the implant in violation of its duty to establish and maintain procedures for implementing corrective and preventative action. This violated both California law and the requirements the IDE approval process under 21 C.F.R. § 800.100(a)(6)(7).

256. Allergan also failed to provide proper warnings concerning defects in the device, including the use of improper and non-conforming component parts and materials, in violation of California law and its duty to describe all relevant contradictions, hazards, adverse effects, interfering substances or devices, warnings and precautions.

257. Natrelle Breast Implants implanted into Ms. Cook contained a manufacturing defect. The contamination of the Natrelle Breast Implants is inconsistent with specifications and conditions of the FDA's Quality System Regulations and design control requirements under 21 C.F.R. § 820.30, and

therefore constitutes a manufacturing defect.

258. Defendants knew that the defects in its product were such that they would not be discovered through reasonable inspection by the users of the Product, including Ms. Cook and Ms. Cook's implanting physician.

259. Defendants knew that Natrelle Breast Implants would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

260. Ms. Cook and her implanting physicians, foreseeable users and ultimate consumers of the Allergan product, were unaware of these defects when Ms. Cook consented to have the Product implanted in her body.

261. As a direct and legal result of the manufacturing defects contained in Ms. Cook's Natrelle Breast Implants, Plaintiff and Plaintiff Husband were injured as described herein.

262. As a proximate result and/or substantial factor of Natrelle Breast Implants defective condition at the time they were sold, Plaintiff and Plaintiff Husband suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, the costs of medical care and treatment, and other injuries for which Plaintiffs are entitled to compensatory and other damages in an amount to be proven at trial.

263. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

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

262. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Natrelle® Style 115 breast implants described herein, owed a duty to provide accurate and complete information regarding the Product.

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263. Defendants' fraudulently misrepresented information regarding the Product including, but not limited to, its propensity to cause serious physical harm.

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

265. Defendants breached their duties to Plaintiffs by providing false, incomplete and misleading information regarding the Product.

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

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

268. 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.

269. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION

FRAUDULENT CONCEALMENT

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

271. Prior to Plaintiff's use of the Natrelle Style 115 breast implants and during the period in which Plaintiff actually used the Natrelle Style 115 breast implants, Defendants fraudulently suppressed material information regarding the safety and efficacy of the Natrelle Style 115 breast

implants and the availability of an alternative feasible safer design.

272. Further, Defendants fraudulently concealed the safety information about the use of Natrelle Style 115 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 115 breast implants.

273. Defendants intentionally concealed safety issues with the Natrelle Style 115 breast implants in order to induce consumers, including Plaintiffs, to purchase Natrelle Style 115 breast implants, and to induce healthcare providers to utilize Natrelle Style 115 breast implants.

274. At the time Defendants concealed the fact that Natrelle Style 115 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 115 breast implants, generally.

275. Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of Natrelle Style 115 breast implants.

276. 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.

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

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

279. 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.

280. As a direct and proximate result of Defendants' fraudulent concealment concerning Natrelle Style 115 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.

281. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

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

283. Prior to Plaintiff's implantation of the Natrelle Breast Implants, Defendants misrepresented the degree to which Natrelle Breast Implants were safe and effective.

284. Defendants failed to disclose material facts regarding the safety and efficacy of Natrelle Breast Implants, including information regarding increased adverse events and harmful side effects.

285. Defendants had a duty to provide Plaintiffs, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the Natrelle Breast Implants they marketed, distributed, and sold.

286. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failure associated with Natrelle Breast Implants that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of Natrelle Breast Implants.

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287. Defendants made the representations and otherwise failed to disclose material facts concerning Natrelle Breast Implants with the intent to induce patients, including Plaintiff Ms. Cook, to act in reliance thereon in using Natrelle Breast Implants.

288. Plaintiffs justifiably relied on Defendants' representations and non-disclosures in choosing to use Natrelle Breast Implants.

289. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiffs sustained the injuries and damages.

290. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

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

292. Defendants expressly represented to Plaintiffs, consumers and the medical community that Natrelle Breast Implants were:

a. safe;

b. efficacious;

c. fit for use in children and adolescents;

d. of merchantable quality;

e. adequately tested;

f. well tolerated in adequate and well-controlled clinical studies; and

g. did not increase the risk of experiencing serious, life threatening side effects.

293. Defendants breached the express warranties as follows:

a. Defendants misrepresented the safety of Natrelle Breast Implants in the

products' labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;

b. Defendants misrepresented the risks associated with using Natrelle Breast Implants;

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that Natrelle Breast Implants were associated with an increased risk of serious injury;

d. Defendants misrepresented that Natrelle Breast Implants were as safe or safer than other available forms of treatment for Plaintiffs' conditions; and

e. Defendants fraudulently concealed information about the safety of Natrelle Breast Implants, including information that the products were not safer than other available forms of treatment for Plaintiffs' conditions.

294. Natrelle Breast Implants did not conform to Defendants' express representations and warranties.

295. At all relevant times, Natrelle Breast Implants did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

296. At all relevant times, Natrelle Breast Implants did not perform in accordance with the Defendants' representations because Natrelle Breast Implants are not safe and cause high levels of serious side effects.

297. In deciding to purchase and use Natrelle Breast Implants, Plaintiffs, other consumers, and the medical community relied upon Defendants' express warranties.

298. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, Plaintiffs sustained injuries and damages.

299. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

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EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

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

301. At all relevant and material times, Defendants manufactured, distributed, advertised, and sold Natrelle Breast Implants.

302. Defendants impliedly warranted to Plaintiffs that Natrelle Breast Implants were safe for use by Plaintiffs and the consuming population.

303. Defendants knew and intended that Natrelle Breast Implants be used as appropriate when the products were placed into the stream of commerce.

304. Plaintiffs and their healthcare providers used Natrelle Breast Implants as intended and directed by the Defendants and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

305. Plaintiff Ms. Cook was a foreseeable user of Defendants' products, Natrelle Breast Implants. Natrelle Breast Implants were expected to reach and did in fact reach Plaintiff, without substantial change in the condition in which the products were manufactured and sold by Defendants.

306. Plaintiff and her healthcare providers reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the Defendants' implied warranty that Natrelle Breast Implants were safe, of merchantable quality, and fit for use.

307. The Natrelle Breast Implants used by Plaintiff were not safe, of merchantable quality, nor fit for use.

308. The Natrelle Breast Implants used by Plaintiff did not perform in accordance with Defendants' representations because Natrelle Breast Implants are not safe and both cause high levels of serious, life-threatening side effects.

309. Defendants breached the implied warranty in that Natrelle Breast Implants did not conform to Defendants' representations.

310. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts described herein, Plaintiffs sustained injuries and damages.

311. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

NINTH CAUSE OF ACTION

LOSS OF CONSORTIUM

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

313. As a result of the injuries and damages caused to Plaintiff Jennifer Cook by Defendants' tortious conduct in violation of federal law and the post-approval requirements, Ms. Cook was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support. Consequently, Plaintiff David Cook was required to, *inter alia*, perform additional activities and upkeep around the house, support Ms. Cook by performing activities she previously performed for her own needs and maintenance and take over many of the activities which Ms. Cook previously commonly performed as a parent to Plaintiffs' son.

314. As a result of Defendants' defective and adulterated Natrelle Style 115 breast implants and the development of Ms. Cook's BIA-ALCL, Plaintiff David Cook effectively lost the companionship and accompaniment of his wife.

315. As a further result of Defendants' defective and adulterated Natrelle Style 115 breast implants and the injuries they caused to Ms. Cook and the resulting demands placed upon David Cook, Plaintiff Husband has suffered lost wages and income.

316. As a direct and proximate result of the injuries caused to Plaintiff Ms. Cook by Defendants' tortious conduct, Plaintiff Husband David Cook 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.

317. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

RELIEF REQUESTED

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

a. Economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

b. For compensatory damages according to proof;

c. Past medical expenses;

d. Past and future lost wages and loss of earning capacity;

e. Past and future emotional distress;

f. Consequential damages;

g. Disgorgement of profits obtained through unjust enrichment;

h. Restitution;

i. Exemplary/Punitive damages according to proof;

j. Reasonable attorneys' fees where recoverable;

k. For prejudgment interest and the costs of suit; and

l. For such other and further relief as this Court may deem just and proper.

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Dated: July 25, 2019

LENZE LAWYERS, PLC

By: 

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DEMAND FOR JURY TRIAL

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

Dated: July 25, 2019

LENZE LAWYERS, PLC.

By: 

JENNIFER A. LENZE

Attorney for Plaintiffs

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