UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE-OPELOUSAS DIVISION

PAIGE VERON	**CIVIL ACTION NO.: 6:20-cv-00932**
VERSUS	**JUDGE:**
ALLERGAN USA, INC.	**MAG. JUDGE:**

ORIGINAL COMPLAINT FOR DAMAGES

NOW INTO COURT, through undersigned counsel, comes the Plaintiff, PAIGE VERON, who is a competent major domiciled and residing in the Parish of Lafayette, State of Louisiana and who respectfully represents:

I. PARTIES

1. **PAIGE VERON**, (hereinafter referred to as "Plaintiff" and/or "VERON"), a competent major domiciled and residing in the Parish of Lafayette, State of Louisiana.

2. **ALLERGAN USA, INC**., (hereinafter referred to as "Defendant" and/or "ALLERGAN"), a foreign business corporation authorized to do and doing business in the State of Louisiana, who is domiciled in Wilmington, Delaware, with its principal place of business in New Jersey and who can be served through its registered agent for service of process, CT Corporation System, located at 3867 Plaza Tower Drive, Baton Rouge, LA, 70816.

II. SUBJECT MATTER JURISDICTION AND VENUE

3. This Court has diversity jurisdiction over this lawsuit under 28 USC §1332(a) because Plaintiff and Defendant are citizens of different states and the amount in controversy exceeds the requisite $75,000.00, exclusive of interest and costs.

4. Venue is proper in this Court pursuant to 28 U.S. §1391, as a substantial part of the events and/or omissions giving rise to this claim occurred within this District, and because the Defendant conducts substantial business in this District sufficient to make them subject to the personal jurisdiction of this Court.

III. PERSONAL JURISDICTION

5. ALLERGAN USA marketed, advertised and sold medical devices, including its "Natrelle Style TRF-240 macrotextured breast implant product within the Western District of Louisiana.

IV. FACTS

6. At all times pertinent herein, ALLERGAN was the manufacturer of the ALLERGAN Natrelle Inspira silicone-filled breast implant, style TRF-240, bearing serial number 20965383 on the left side; and an ALLERGAN Natrelle Inspira silicone-filled breast implant, style TRF-240, bearing serial number 20965381 on the right side which were implanted in the plaintiff, VERON [hereinafter referred to as "SUBJECT DEVICES"].

7. At all times pertinent hereto, ALLERGAN acted individually and/or through its agents, servants, or employees, as specified below, for which ALLERGAN is independently and vicariously liable.

8. At all times pertinent hereto, ALLERGAN is in the business of manufacturing, selling, marketing and otherwise labeling as their own the ALLERGAN silicone-filled breast implants for placement into trade or commerce in Louisiana.

9. At all times pertinent hereto, ALLERGAN produced, made, fabricated, constructed, and designed the ALLERGAN breast implants [SUBJECT DEVICES] for placement into trade or

commerce in Louisiana.

10. At all times pertinent hereto, ALLERGAN labeled as its own, the SUBJECT DEVICES for placement into trade or commerce in Louisiana.

11. At all times pertinent hereto, ALLERGAN sold the SUBJECT DEVICES in Louisiana and exercised control over or influenced characteristics of the design, construction, or quality of the SUBJECT DEVICES as well as quality and process control.

12. ALLERGAN owed a duty to consumers, including VERON to accurately report any and all risks associated with the SUBJECT DEVICES to the FDA in order for the FDA to accurately assess and determine if the SUBJECT DEVICES were safe for consumer use.

13. ALLERGAN breached its duties to consumers, including VERON by knowingly and willfully failing to report accurately any and all risks associated with the SUBJECT DEVICES to the FDA in order for the FDA to accurately assess and determine if the SUBJECT DEVICES were safe for consumer use.

14. ALLERGAN owed a duty to VERON to provide her with an implant free from defect and to act in a reasonable and prudent manner in assessing, investigating and reporting the effectiveness and safety of the SUBJECT DEVICES.

15. ALLERGAN breached the duties it owed to VERON, as described herein, resulting in injuries and damages to VERON, for which they are liable.

16. ALLERGAN is required to seek Premarket Approval Applications ["PMAs"] process, which allows the FDA to evaluate the safety and effectiveness of medical devices, including the SUBJECT DEVICES. This process includes known investigations showing whether or not the device is safe and effective, and other data relevant for evaluating the safety and effectiveness of the

device that is known or should reasonably be known to the manufacturer.

17. Upon information and belief therein, ALLERGAN did not provide the FDA with accurate information known by them with regards to the data required by the FDA to evaluate the safety and effectiveness of the SUBJECT DEVICES. Specifically the information and data concerning its textured breast implants, including the SUBJECT DEVICES, that breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), that demonstrates that the risk of BIA-ALCL with ALLERGAN's BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers that can cause and/or lead to serious adverse health consequences and potentially death.

18. ALLERGAN is required to file an adverse event reports with the FDA, and has the responsibility for timely communicating complete and accurate information. It is further obligated to monitor all reasonably available information and clinical experiences.

19. Upon information and belief therein, and as more fully set forth herein, ALLERGAN failed to file all adverse event reports with the FDA in a transparent fashion and failed to communicate complete and accurate information. Further, they failed to properly monitor all reasonably available information and clinical experiences.

20. On March 5, 2018, VERON underwent a bilateral breast augmentation, which involved the insertion and placement of an ALLERGAN Natrelle Inspira silicone-filled breast implant, style TRF-240, bearing serial number 20965383 on the left side; and an ALLERGAN Natrelle Inspira silicone-filled breast implant, style TRF-240, bearing serial number 20965381 on the right side [hereinafter referred to as "SUBJECT DEVICES"].

21. The surgery, insertion and placement of the SUBJECT DEVICES was performed by

Kenneth Odinet, D.D.S., M.D. located at 200 Beaullieu Drive, Building #6, Lafayette, LA, 70508.

22. On July 24, 2019, the United States Food & Drug Administration (hereinafter referred to as "FDA") issued a news release, announcing its initiated recall of the Biocell textured breast implants and Biocell tissue expanders manufactured by the Defendant due to the FDA's finding that the Biocell textured breast implant appeared to be directly linked to significant patient harm, including death.

23. The FDA published an explanation of the July 24, 2019 recall of the Defendant's Biocell breast implants, stating this was a Class I recall and that the "use of these devices may cause serious injuries or death".

24. On or about July 24, 2019, ALLERGAN, announced a voluntary worldwide withdrawal of unused stock of Biocell textured breast implants and tissue expanders from doctors' offices and hospitals, and a suspension of any future sales, including the SUBJECT DEVICES.

25. On or about August 9, 2019, VERON received a product safety alert from Allergan notifying that their records indicated that the SUBJECT DEVICES were subject to a safety recall requested by the U.S. Food and Drug Administration (FDA).

26. The FDA reported on its site 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. Specifically, the FDA stated "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 textured breast implants would likely cause serious, adverse health consequences and potentially death from BIA-ALCL."[1]

27. On or about September 5, 2019, VERON consulted with Dr. Kenneth Odinet with regards to the implant recall and voiced her concerns with regards to her health and her well being since the surgery and placement of the SUBJECT DEVICES on March 5, 2018.

28. On or about September 24, 2019, VERON underwent an additional surgery, which included a bilateral breast implant [SUBJECT DEVICES] removal and a bilateral mastopexy. The removed implants [SUBJECT DEVICES] were properly packaged and returned to ALLERGAN, for preservation.

29. Upon information and belief therein, ALLERGAN has not accurately reported adverse events as required by the FDA. Specifically, ALLERGAN does not report adverse events individually each time an injury occurred. Rather than accurately reporting these events in a public, searchable database called the Manufacturer and End User Facility Device Experience ["MAUDE"], ALLERGAN filed Alternative Summary Reports ["ASR"}.

30. Accurate reporting of adverse events is critical to ensure that the public is adequately and timely notified of potential problems with a medical device. This includes the SUBJECT devices manufactured and sold by ALLERGAN.

31. The general public, including physicians and patients, receive information from databases like the MAUDE. Researchers, including those studying connections between breast implants and cancer and other health issues, also use the MAUDE database in their studies of

[1]https://www.fda.gov/medical-devices/safety-communications/fda-requests-ALLERGAN-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue

defective medical devices.

32. The FDA had allowed in the past [prior to June 21, 2019] manufacturers, including ALLERGAN, to submit quarterly spreadsheets through ASR, summarizing reports of common problems of approved devices. However, ASRs should not include severe or unexpected events or injuries necessitating remedial action. Reports of such events are to be reported through MAUDE.

33. On June 21, 2019 the FDA formally ended the ASR program. This move was motivated by a dramatic increase in the number of adverse events related to breast implant injuries from 2017 to 2018.

34. Upon information and belief, ALLERGAN used the Alternative Summary Reporting Program instead of MAUDE, and as a result, failed to disclose the risks of its medical devices, including those at issue in this litigation.

35. Upon information and belief, Allergan did not report adverse events from its required post-market approval studies that would have suggested the recalled BIOCELL products have caused or contributed to deaths or serious bodily injury.

36. ALLERGAN continually received new information showing the connection between its textured breast implants and BIA-ALCL and that the risk associated with its BIOCELL breast implants was significantly greater than its competitors. Yet, it failed to properly disclose this information.

37. ALLERGAN failed to comply with the conditions of the PMAs by failing to fulfill its obligations to accurately and promptly report adverse events and continuing to sell the recalled BIOCELL products, including the SUBJECT DEVICES.

38. Had ALLERGAN complied with its obligations under federal law, the disclosure of

the connection between BIOCELL breast implants, including the SUBJECT DEVICES, and BIA-ALCL would have allowed patients, including VERON, and her treating physician to make an informed decision regarding whether to use other implants.

LSA-C.C. ART. 1953 FRAUD

39. Upon information and belief, ALLEGRAN misrepresented the safety of the BIOCELL implants, including the SUBJECT DEVICES, and/or suppressed the truth and/or was silent with respect to the safety of the BIOCELL implants, including the SUBJECT DEVICES to the FDA with the intent to deceive in order to obtain an unjust advantage that resulted in loss and damages to end users, including VERON.

40. Upon information and belief, ALLEGRAN misrepresented the safety of the BIOCELL implants, including the SUBJECT DEVICES, and/or suppressed the truth and/or was silent with respect to the safety of the BIOCELL implants, including the SUBJECT DEVICES to the end users, including VERON, with the intent to deceive in order to obtain an unjust advantage or to cause a loss or inconvenience to VERON that resulted in loss and damages to VERON.

41. Had VERON known the truth about the SUBJECT DEVICES, namely that 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 that the SUBJECT DEVICES would likely cause serious, adverse health consequences and potentially death from BIA-ALCL, she would not have purchased the SUBJECT DEVICES.

42. VERON suffered damages as a result of ALLERGAN's misrepresentation and/or suppression of the truth and/or silence or inaction, including but not limited to:

a) The cost of the SUBJECT DEVICES;

b) The costs associated of and with the surgery to implant the SUBJECT DEVICES;

c) The costs associated of and with the surgery to remove the SUBJECT DEVICES; and

43. VERON seeks and is entitled to attorney fees for ALLERGAN's misrepresentation or suppression of the truth and/or silence or inaction, made with the intention either to obtain an unjust advantage or to cause a loss or inconvenience to VERON.

REDHIBITION

44. The ALLERGAN silicone-filled breast implants that were implanted into VERON possessed a redhibitory defect as defined by La.C.C.Art. 2520. Namely, the SUBJECT DEVICES, possess a characteristic that render them useless and/or so inconvenient that had VERON known of the defect, she would not have purchased the SUBJECT DEVICES.

45. The defects in the ALLERGAN silicone-filled breast implants that were implanted into VERON were not known to VERON at the time of sale and could not have been discovered by a reasonable prudent buyer of such things.

46. ALLERGAN is the manufacturer of the SUBJECT DEVICES that were implanted into VERON and thus VERON is not required to give ALLERGAN notice of the existence of a redhibitory defect in the SUBJECT DEVICES and ALLERGAN is presumed to have knowledge of the defect such that they are deemed a "Bad Faith" seller pursuant to La.C.C.Art. 2545.

47. For those reasons stated herein, the SUBJECT DEVICES were useless or so inconvenient that VERON would not have bought the SUBJECT DEVICES.

DAMAGES

48. ALLERGAN knew or should have known that their misrepresentation and failure to inform VERON of the defect in the SUBJECT DEVICES, and because of the nature of the SUBJECT DEVICES and their function and purpose, namely aesthetic, would cause a non-pecuniary loss to VERON.

49. VERON seeks all damages allowed by law based upon the allegation set forth herein to include:

a) Return of purchase price paid for the SUBJECT DEVICES;

b) All damages occasioned by the sale to include those expenses incurred to implant the SUBJECT DEVICE, to remove the SUBJECT DEVICE;

c) Non pecuniary damages; and

d) Attorney Fees, costs and interest from the date of judicial demand until paid.

Prayer

WHEREFORE, Plaintiff, PAIGE VERON prays that the defendant, ALLERGAN USA, INC., be duly cited and served and that after a lapse of all legal delays and proceedings that there be a judgment in favor of Plaintiff, PAIGE VERON, and against the Defendant, ALLERGAN USA, INC., severally, jointly and in solido, for all damages, including all general damages and special damages, attorney fees for which this Honorable Court finds reasonable, together with legal interest thereon from date of judicial demand until paid, for all costs of these proceedings and for other general, equitable and specific relief, to which plaintiff is entitled.

Respectfully submitted by,

DUCK LAW FIRM, LLC

/s/ Kevin R. Duck
KEVIN R. DUCK (#23043)
5040AMBASSADOR CAFFERY PKWY.
SUITE 200
LAFAYETTE, LA 70508
TEL: (337) 406-1144
FAX: (337) 406-1050
EMAIL: krd@ducklawfirm.com

COUNSEL FOR PLAINTIFF, PAIGE VERON