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SUPERIOR COURT FOR THE STATE OF CALIFORNIA
COUNTY OF ORANGE

ASSIGNED FOR ALL PURPOSES TO: Judge Sheila Fell

SUSAN MROWIEC, individually,

CASE NO. 30-2020-01154383-CU-PL-CJC

Plaintiff,

v.

COMPLAINT AND DEMAND FOR JURY TRIAL

ALLERGAN, INC. f/k/a INAMED CORPORATION f/k/a McGHAN MEDICAL CORPORATION, a Delaware corporation with its principal place of business in California; ALLERGAN HOLDCO U.S. INC., a Delaware corporation with its principal place of business in California; ALLERGAN HOLDINGS, INC., a Delaware corporation with its principal place of business in California; ALLERGAN SALES, LLC, a Delaware corporation with its principal place of business in California; ALLERGAN USA, INC., a Delaware corporation with its principal place of business in California; ALLERGAN plc, a foreign corporation with its principal place of business in California; and DOES 1 through 100, inclusive,

1. Strict Product Liability-Failure to Warn
2. Strict Product Liability-Manufacturing Defect
3. Negligence
4. Intentional Misrepresentation/ Concealment
5. Negligent Misrepresentation/ Concealment

Defendants

Plaintiff SUSAN MROWIEC ("Plaintiff") brings this action against Defendants ALLERGAN, INC., ALLERGAN HOLDCO U.S., INC., ALLERGAN HOLDINGS, INC., ALLERGAN SALES, LLC, ALLERGAN USA, INC., ALLERGAN PLC (all corporations headquartered in California with their principal place of business and key executives

1 located in California; collectively referred to as “Defendants” or “ALLERGAN”), and
2 DOES 1-100 seeking damages arising out of ALLERGAN’s negligence, deceit,
3 concealment, and misrepresentations concerning the deadly and defective condition of
4 its BIOCELL Textured Breast Implants.

5 INTRODUCTION

6 1. ALLERGAN is a global company that has long pushed a portfolio of
7 consumer products in the medical aesthetics, eye care, central nervous system, and
8 gastroenterology fields. Among its portfolio of products is a specific type of breast
9 implant and tissue expander for cosmetic and reconstructive surgery, referred to broadly
10 herein as the BIOCELL Textured Breast Implant suite of products. ALLERGAN
11 developed, sought regulatory approval for, marketed, advertised, manufactured,
12 distributed, and sold those BIOCELL Textured Breast Implants through its primary
13 office in the United States, located in Irvine, California.

14 2. Across multiple generations of the product, ALLERGAN has sold
15 hundreds of thousands of textured breast implants and developed and marketed dozens
16 of additional styles incorporating their BIOCELL technology. Those products have been
17 sold worldwide, and have been implanted into tens, if not hundreds, of thousands of
18 California and United States consumers. This was highly profitable for ALLERGAN,
19 which received tens, if not hundreds, of *millions* of dollars’ worth of revenue through its
20 sale and distribution of the BIOCELL Textured Breast Implants to consumers across the
21 world.

22 3. ALLERGAN has longed claimed that these products are safe for consumer
23 use and based on those promises they have been widely used by women for both
24 reconstructive surgery—particularly after a breast cancer diagnosis, genetic testing, or
25 other concern—as well as for cosmetic uses.

26 4. But those products pose a significant risk—a risk that was *long* hidden and
27 buried by ALLERGAN in advertisements, flyers, reports, and other communications to
28 both the marketplace and the FDA. ALLERGAN’s BIOCELL Textured Breast Implants

1 have a surface roughness significantly *higher* than the industry standard and are capable
2 of embedding silicone surface particles in the fibrous scar tissue that naturally forms
3 around the implant, known as the “capsule.”

4 5. In part because of that flaw, the medical and scientific consensus has
5 determined that the extreme texturing of the implants, when combined with a bacterial
6 accumulation or a genetic predisposition, form a perfect storm for the development of
7 Breast Implant Associated–Anaplastic Large Cell Lymphoma (BIA-ALCL).¹ BIA-ALCL
8 is an uncommon but emerging subtype of non-Hodgkin's lymphoma—a cancer that
9 originates from lymphatic cells, which are part of the immune system. BIA-ALCL is
10 thus a cancer of the immune system, and *not* a type of breast cancer.

11 6. Because of the processes used in their manufacture, ALLERGAN's
12 BIOCELL Textured Breast Implants increase the likelihood of a woman developing BIA-
13 ALCL dramatically from other textured breast implants on the market, with one study
14 finding that the nexus jumps approximately *10 times* from other products on the US
15 marketplace.

16 7. Despite the grave risks posed by its BIOCELL Textured Breast Implants,
17 and the ready possibility of a safer product, ALLERGAN has for decades orchestrated a
18 disinformation campaign aimed at discrediting and concealing the clearly established
19 link between the occurrence of BIA-ALCL and the presence of an ALLERGAN BIOCELL
20 Textured Breast Implant. This was done in the interest of placing ALLERGAN's
21 pecuniary interest and profits over public safety, so that ALLERGAN could continue to
22 sell and distribute a dangerous product into the marketplace at great financial gain to
23 the company.

24 8. For example, Plaintiff is informed and believes and thereon alleges that
25 between 2007 and 2010—following premarket approval for its first generation of

26 ¹Allergan's Vice President of Clinical Development, Stephanie Manson Brown, acknowledged—while still
27 downplaying—that “[h]igher implant surface area may be a risk factor” because “[s]urface area
28 contributes to bacterial accumulation” in her presentation at the FDA Medical Devices Advisory
Committee General and Plastic Surgery Devices Panel on March 25, 2019.

1 silicone-filled breast implants—ALLERGAN received worldwide 22 complaints of BIA-
2 ALCL in women implanted with the silicone brand of the BIOCELL Textured Breast
3 Implants. Despite the public health crisis implicated by such statistics, ALLERGAN
4 unlawfully failed to report these events of BIA-ALCL to the FDA *at all*.

5 9. Thereafter, as events of BIA-ALCL continued to surface, ALLERGAN
6 doubled-down on its unlawful concealment efforts by abusing its unique adverse health
7 event summary reporting privilege for its breast implants, known as Alternative
8 Summary Reporting. *This privilege was available only for specific adverse event types*
9 *associated with breast implants where compliance with some of the reporting*
10 *requirements was not necessary to protect the public health because such events were*
11 *known and well-documented*. Despite its ineligibility for summary reporting, from at
12 least 2009 until 2019 when the Alternative Summary Reporting was discontinued due to
13 misuse, ALLERGAN buried complaints of BIA-ALCL, and symptoms associated
14 therewith, transmitted to the company from health care professionals, user facilities, and
15 patients in the unscrutinized summary reporting spreadsheets which only recently
16 became publicly available.

17 10. Because ALLERGAN failed to perform its duties under federal law to warn
18 the FDA about BIA-ALCL, and because ALLERGAN failed to comply with its reporting
19 duties under federal law with respect to BIA-ALCL, Plaintiff's claims set forth below are
20 not subject to preemption.

21 11. Plaintiff is informed and believes and thereon alleges that at all times
22 ALLERGAN allowed their BIOCELL Textured Breast Implants to remain in the market
23 knowing they suffered from a serious safety defect/risk and failed to disclose, concealed,
24 and misrepresented the important safety risks associated with textured breast implants
25 in representations made to Plaintiff and the FDA, specifically the clear links between
26 ALLERGAN's BIOCELL Textured Breast Implants and BIA-ALCL. ALLERGAN
27 misrepresented the scope of the risk, failed to publicly report the cases of BIA-ALCL that
28 *had* been caused by its products as it was obligated to do under federal law and

1 regulations, and failed to remedy the danger to consumers around the world and across
2 the country.

3 12. Had Plaintiff known the truth about ALLERGAN's BIOCELL Textured
4 Breast Implants, she would not have had them implanted into her body. Instead, she
5 would have, among other things, forwent implantation, or chosen smooth or
6 microtextured implants, thereby avoiding the heightened risk of developing BIA-ALCL.

7 13. Finally, after decades of misrepresenting and hiding the scope of the
8 problem—and the danger posed to women with these implanted products—the
9 cancerous propensities of ALLERGAN's product finally started coming to light. On
10 December 18, 2018, ALLERGAN was banned from selling its BIOCELL textured
11 implants in the European Union based on health and safety concerns. Five months later,
12 Health Canada suspended ALLERGAN's license to sell BIOCELL Textured Breast
13 Implants in Canada following a safety review that brought to light the increased risk of
14 BIA-ALCL amongst those implanted with BIOCELL Textured Breast Implants sold by
15 the Defendants. Yet ALLERGAN continued to sell its textured implants in the United
16 States.

17 14. On July 24, 2019, the FDA announced the world-wide recall of
18 ALLERGAN's BIOCELL Textured Breast Implants in order to "protect individuals from
19 the increased risk of BIA-ALCL, associated with BIOCELL textured breast implants."²

20 15. Following that recall, and with knowledge of the danger *finally* being
21 provided to the public, numerous consumers across the country are left with fear,
22 concern, and worry that their ALLERGAN BIOCELL Textured Breast Implants have
23 now exposed them to the dangers of BIA-ALCL. As is only reasonable, people, like
24 Plaintiff SUSAN MROWIEC, want these dangerous products *out* of their bodies—yet
25

26 ² The FDA's analysis was attributed to a new worldwide reported total of 573 unique BIA-ALCL cases
27 including 33 patient deaths. Of the 573 cases of BIA-ALCL, 481 are reported to have Allergan breast
28 implants at the time of diagnosis. In addition, 12 of 13 deaths occurring in patients with BIA-ALCL where
the manufacturer was known occurred in patients implanted with an Allergan breast implant at the time
of their BIA-ALCL diagnosis.

1 ALLERGAN has refused to assist in providing for the surgical, medical, hospital,
2 facility, and many other expenses that will be incurred by thousands upon thousands of
3 women across the country, not to mention the stress, fear, anxiety, and worry caused by
4 the company's dangerous products. This action is brought to remedy the dangerous,
5 deceptive conduct of ALLERGAN resulting in the implantation of these dangerous,
6 defective products in Plaintiff SUSAN MROWIEC.

7 VENUE AND JURISDICTION

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

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

15 18. Specifically, the applicant addresses for each of the PMAs, *infra*, affected by
16 the recall of BIOCELL Textured Breast Implants lists ALLERGAN's business office in
17 California.³⁻⁴ Thus, the recalled product that caused damage to the Plaintiff was, upon
18 information and belief, researched, distributed, manufactured, managed, sold through,
19 or represented through the PMA process that the products were initiated and approved
20 from and through the Defendants' offices in California.

21 19. Moreover, ALLERGAN's medical aesthetics division responsible for
22 design/development, clinical operation, data analysis and regulatory affairs for its breast

23 ³ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P990074;>
24 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056;>
25 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040046;>
26 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K143354;>
[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K102806.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K102806)

27 ⁴ Per the California Secretary of State's website, Allergan, Inc.'s "Entity Address" —i.e. its primary
28 worldwide business office, or the "nerve center" of the corporation—is located at 2525 Dupont Drive,
Irvine, CA 92612. At minimum, general personal jurisdiction is appropriate over this defendant as it is "at
home" in this forum.

1 implant products, including the BIOCELL Textured Breast Implants Class 1 Device
2 Recall, is based in its Irvine, California headquarters. In fact, the FDA identifies the
3 "Recalling Firm/Manufacturer" for the BIOCELL Textured Breast Implants Class 1
4 Device Recall as Defendant ALLERGAN PLC with a corresponding address of 2525
5 Dupont Dr., Irvine, CA 92612.⁵

6 20. Additionally, the most recent Establishment Inspection Report performed
7 by FDA Supervisory Consumer Safety Officers on October 19, 2016 for the recalled
8 BIOCELL Textured Breast Implants occurred at the Irvine, California headquarters. The
9 name and address of the appropriate ALLERGAN employee for all FDA official
10 correspondence regarding BIOCELL Textured Breast Implants was Defendant
11 ALLERGAN PLC's CEO/President Mr. Brent Saunders with a corresponding address of
12 2525 Dupont Dr., Irvine, CA 92612.

13 21. Finally, ALLERGAN's predecessor corporation, INAMED
14 CORPORATION, *infra*, conducted product development, executive functioning, and
15 legal compliance for all of the recalled BIOCELL Textured Breast Implants in its
16 California headquarters in Santa Barbara County.

17 22. At all times material hereto, Defendants maintained systematic and
18 continuous contacts in this judicial district, regularly transacted business within this
19 judicial district, employed numerous individuals in this district and regularly availed
20 themselves of the benefits of this judicial district. Defendants received substantial
21 financial benefit and profits as a result of the designing, formulating, testing, packaging,
22 labeling, producing, creating, constructing, making, assembling, advertising, clinical
23 testing, marketing, promoting, distributing, manufacturing, and selling BIOCELL
24 Textured Breast Implants in this state and county, and throughout the United States.
25 Defendants promoted, sold, distributed, made, assembled, marketed, advertised, and
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27

28 ⁵ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=175502>.

1 promoted the BIOCELL Textured Breast Implants in California—including to consumers
2 in this judicial district—with those products ultimately causing harm in California.

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

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

9 25. Plaintiff is informed and believes and, on that basis, alleges that
10 Defendants have purposefully availed themselves of the privileges and benefits of
11 conducting activities and business within the forum State, and have invoked the benefits
12 and protections of its laws.

13 26. A substantial part of the events giving rise to Plaintiff's claims occurred in
14 California, including federal and state regulatory compliance, the preparation and
15 submission of the relevant product PMAs, and communication regarding the product,
16 the design, formulation, testing, packaging, labeling, production, creation, construction,
17 making, assembly, advertising, clinical testing, marketing, promotion, distribution,
18 manufacturing, and selling of the BIOCELL Textured Breast Implants, as well as the
19 implantation of the BIOCELL Textured Breast Implants into Plaintiff in this forum.

20 **PARTIES**

21 **A. Plaintiff**

22 27. Plaintiff SUSAN MROWIEC is a resident of the state of Michigan, County
23 of Montcalm and city of Sheridan.

24 28. In or around 2002, SUSAN MROWIEC was implanted with McGhan style
25 468 breast implants, serial numbers 578468 (left) and 5814686 (right), by Dr. Carlos M.
26 Villafane at DMC Huron Valley General Surgery in Commerce Charter Township,
27 Michigan.

1 29. Thereafter, in 2015, SUSAN MROWIEC experienced severe swelling of her
2 breast and the swelling extended into her neck and shoulder. After seeking assistance
3 from a plastic surgeon, Plaintiff was referred to a cancer specialist and was ultimately
4 referred to Dr. Marguerite Aitken for removal of the McGhan implants.

5 30. In or around August of 2015 Plaintiff underwent a removal of her McGhan
6 textured breast implants and placement of Allergan smooth style 68 implants. During
7 the procedure Dr. Aitken noted the left implant was ruptured and Plaintiff had a
8 “periprosthetic late presenting seroma, yellowish-green viscous fluid in nature.” Out of
9 an abundance of caution, Dr. Aitken sent the fluid to cytology to rule out ALCL.
10 Plaintiff had a total capsulectomy performed on the left side, however it is unclear to
11 Plaintiff whether a total capsulectomy was performed on the right side. During the
12 procedure, Plaintiff had two Allergan style 68 smooth implants placed.

13 31. On or about August 26, 2015 Plaintiff met with Dr. Aitken and confirmed
14 that she was diagnosed with malignant lymphoma, specifically ALCL. Plaintiff
15 proceeded to consult with several doctors over the next five months and the doctors at
16 the University of Michigan suggested Plaintiff undergo a complete removal of her
17 implants as part of her ALCL treatment. Dr. Aitken advised against this on January 15,
18 2016.

19 32. In or around June of 2016 Plaintiff again discussed a removal of her
20 implants in accordance with recommendations from her cancer specialists. Again, Dr.
21 Aitken advised her of her options other than complete implant removal and total
22 capsulectomy, as well as quotes for the costs of these out of pocket procedures.

23 33. On June 29, 2016 Plaintiff returned to Dr. Aitken after receiving a second
24 opinion for her ALCL treatment from Cleveland Clinic. Physicians at that facility
25 advised against implant removal and advocated for continued monitoring. Plaintiff
26 elected this route of treatment. However on October 26, 2016, Plaintiff returned to Dr.
27 Aitken requesting a complete removal of her implants and capsulectomy. This was
28

1 recommended to Plaintiff my multiple cancer doctors. A surgery was scheduled for
2 November of 2016.

3 34. On November 26, 2016 Plaintiff underwent a bilateral capsulectomy with
4 implant removal with Dr. Aitken at Zeeland Community Hospital in Zeeland, Michigan.
5 Pathology of the removed capsules and implants was negative for malignancy.

6 35. SUSAN MROWIEC did not receive any update or warning from
7 ALLERGAN any time before or after her surgeries in 2002 or 2015 about the clearly
8 established link between ALLERGAN's BIOCELL Textured Breast Implants and BIA-
9 ALCL.

10 36. Following the worldwide recall and revelations about the dangers of
11 ALLERGAN's products, SUSAN MROWIEC fully understood that her diagnosis of
12 ALCL was directly attributable to her McGhan textured breast implants. Before the
13 recall, Plaintiff had no idea that the breast implants themselves could have caused her
14 cancer as no doctor ever told her of the established link. Plaintiff's ALCL was never
15 referred to as BIA-ALCL, just a rare, malignant lymphoma.

16 37. Plaintiff had to pay out-of-pocket for the removal of her breast implants
17 because ALLERGAN has *refused* to do so.⁶

18 38. Plaintiff has worried about the risks she faces, has also been subject to out-
19 of-pocket expenses in relation to seeking medical advice, evaluating the flawed product
20 implanted into her body, and seeking recommendations for future care and treatment.
21 Plaintiff also continue to suffer from mental stress, anxiety, worry, humiliation, fear,
22 concern and other personal and financial hardship due to the continuous fear of her
23 BIA-ALCL returning and aftermath from the suffering of BIA-ALCL.

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25
26
27 ⁶ On July 30, 2019, following the worldwide recall, Carrie Strom, Senior Vice President, U.S. Medical
28 Aesthetics, Allergan plc, announced to customer that "Allergan will not provide surgical fee assistance to
revision patients."

1 39. Plaintiff has had to take time away from work in order to seek medical
2 treatment, advice, and consultation, and due to the stress and anxiety related to her
3 flawed ALLERGAN implants.

4 40. Plaintiff would not have had BIOCELL Textured Breast Implants
5 implanted in her had the Defendants honestly, fully, and completely disclosed the risks.
6

7 **B. Defendants**

8 41. ALLERGAN does not adhere to the formalities of corporate structure, but
9 rather employs an extremely fluid corporate hierarchy through a series of largely
10 employee-less holding companies whereby the various entities within the corporate
11 structure serve as alter-egos of each other.

12 42. Defendant ALLERGAN PLC (formerly known as Actavis plc) is the
13 principal entity for the ALLERGAN business and was incorporated in Ireland on May
14 16, 2013.

15 43. Defendant ALLERGAN PLC ordinary shares are traded on the NYSE
16 under the ticker symbol "AGN."

17 44. Defendant ALLERGAN PLC represents itself to the public as a global
18 specialty pharmaceutical company engaged in the development, manufacturing,
19 marketing, and distribution of brand name pharmaceutical products, medical aesthetics,
20 biosimilar, and over-the-counter pharmaceutical products. Conversely, when
21 convenient, Defendant ALLERGAN PLC represents that it is simply a holding company
22 that exists for the purpose of holding shares of other companies that manufacture and
23 distribute such products rather than producing or selling its own goods or services.

24 45. Although Defendant ALLERGAN PLC claims its only principal office is
25 located at Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400,
26 Ireland, it maintains headquarters located at Morris Corporate Center III, 400 Interpace
27 Parkway, Parsippany, New Jersey 07054 and 2525 Dupont Drive, Irvine, California
28 92612.

1 46. As a result of its acquisition of Defendant ALLERGAN, INC. on March 17,
2 2015, Defendant ALLERGAN PLC expanded its franchises to include medical aesthetics/
3 dermatology/plastic surgery, which included the BIOCELL Textured Breast Implants.

4 47. Defendant ALLERGAN, INC. represents itself to the public as a multi-
5 specialty health care company focused on developing and commercializing innovative
6 pharmaceuticals, biologics, medical devices and over-the-counter products “that enable
7 people to live life to its full potential – to see more clearly, move more freely and express
8 themselves more fully.” Conversely, when convenient, Defendant ALLERGAN, INC.
9 represents that it is a holding company with no employees.

10 48. Defendant ALLERGAN, INC. was established pursuant to the laws of
11 Delaware with its principal executive office located at 2525 Dupont Drive, Irvine,
12 California 92612. Defendant ALLERGAN, INC. is headquartered in California, with both
13 its principal place of business as well as its executive team located primarily, if not
14 entirely, in California.

15 49. Defendant ALLERGAN PLC utilized Defendant ALLERGAN, INC. in
16 California as its primary agent, appointed subsidiary, and designated entity for the
17 marketing, development, sales, research, distribution, approval, processing, and
18 regulatory approval of products in the medical aesthetics, dermatology, and plastic
19 surgery fields, including the BIOCELL Textured Breast Implants. Defendant
20 ALLERGAN PLC was thus operating through Defendant ALLERGAN, INC. with
21 respect to the BIOCELL Textured Breast Implants, and was doing so through Defendant
22 ALLERGAN, INC.’s primary corporate offices in Irvine, California.

23 50. In fact, while Defendant ALLERGAN, INC. is a wholly owned subsidiary
24 of Defendant ALLERGAN PLC, a Management Service Agreement between Defendant
25 ALLERGAN PLC, on the one hand, and Defendants ALLERGAN, INC. and
26 ALLERGAN SALES, LLC, on the other, puts these California entities in charge of
27 Defendant ALLERGAN PLC’s executive management; its strategic direction in terms of
28 business operations, financial goals and long-term growth; and its general and

1 administrative services. Thus, Defendant ALLERGAN PLC is the shareholder of the
2 very entities that manage it from California.

3 51. On March 23, 2006, Defendant ALLERGAN, INC. completed the
4 acquisition of INAMED CORPORATION, then a global healthcare company that
5 developed, manufactured, and marketed breast implants, a range of facial aesthetics,
6 and obesity intervention products.

7 52. INAMED CORPORATION was the corporate successor to MCGHAN
8 MEDICAL CORPORATION—the original manufacturer of breast implants for plastic
9 and reconstructive surgery—which was incorporated in 1974.

10 53. INAMED CORPORATION and MCGHAN MEDICAL CORPORATION
11 were the entities that sought and received PMAs for a majority of the recalled BIOCELL
12 Textured Breast Implants, principally from their California headquarters located in
13 Santa Barbara, California.

14 54. Defendant ALLERGAN SALES, LLC, a Delaware limited liability company
15 formed on February 25, 2002, was engaged in the business of designing, manufacturing,
16 developing, preparing, processing, inspecting, testing, packaging, promoting,
17 marketing, distributing, labelling, or selling for profit, either directly or indirectly,
18 through an agent, affiliate, predecessor or subsidiary, BIOCELL Textured Breast
19 Implants, and did so in part by extensively targeting, marketing to, packaging,
20 distributing, manufacturing, advertising in, and selling to consumers in California.

21 55. Along with Defendant ALLERGAN, INC., Defendant ALLERGAN SALES,
22 LLC manages Defendant ALLERGAN PLC's business operations.

23 56. Defendant ALLERGAN SALES, LLC maintains its principle executive
24 office at 2525 Dupont Drive, Irvine, California. Defendant ALLERGAN SALES, LLC's
25 members are Defendant ALLERGAN HOLDCO U.S., INC. and Defendant ALLERGAN
26 HOLDINGS, INC., both of which are domiciled in California.

27 57. Defendant ALLERGAN HOLDCO U.S., INC., is engaged in developing,
28 manufacturing and commercializing branded pharmaceuticals, devices and biologic

1 products for consumers around the world, including ALLERGAN's BIOCELL Textured
2 Breast Implants. Defendant ALLERGAN HOLDCO U.S., INC. is principally engaged in
3 being an intermediate holding company between Defendant ALLERGAN, INC. and
4 Defendant ALLERGAN SALES, LLC. As recently as August 20, 2019, Defendant
5 ALLERGAN HOLDCO U.S., INC. represented in its periodic SI-550 form to the
6 California Secretary of State that its principle executive office is in Irvine, California.

7 58. Defendant ALLERGAN HOLDINGS, INC., is engaged in developing,
8 manufacturing and commercializing branded pharmaceuticals, devices and biologic
9 products for consumers around the world, including ALLERGAN's BIOCELL Textured
10 Breast Implants. Defendant ALLERGAN HOLDINGS, INC. is principally engaged in
11 being an intermediate holding company of between Defendant ALLERGAN, INC. and
12 Defendant ALLERGAN SALES, LLC. Defendant ALLERGAN HOLDINGS, INC.
13 maintains its principle executive office in Irvine, California.

14 59. Additionally, Defendant ALLERGAN HOLDINGS, INC. is the direct
15 parent company of Allergan Pharmaceuticals Holdings Unlimited Company, which is
16 the direct parent company of Allergan Costa Rica, S.R.L.—the entity responsible for
17 actually manufacturing ALLERGAN's BIOCELL Textured Breast Implants at
18 ALLERGAN's plant in Heredia, Costa Rica.

19 60. Defendant ALLERGAN USA, INC. was and is a wholly owned subsidiary
20 of Defendant ALLERGAN SALES, LLC and is a corporation established pursuant to the
21 laws of Delaware. Defendant ALLERGAN USA, INC. maintains its principle offices at 5
22 Giralda Farms, Madison, New Jersey and at 2525 Dupont Drive, Irvine, California.

23 61. At all relevant times, Defendant ALLERGAN USA INC. was engaged in
24 the business of designing, manufacturing, developing, preparing, processing, inspecting,
25 testing, packaging, promoting, marketing, distributing, labelling, or selling for profit,
26 either directly or indirectly, through an agent, affiliate, predecessor or subsidiary,
27 BIOCELL Textured Breast Implants, and did so in part by extensively targeting,
28

1 marketing to, packaging, distributing, manufacturing, advertising in, and selling to
2 consumers in California.

3 62. At all material times, ALLERGAN or its parents and subsidiaries were
4 engaged in the business of designing, manufacturing, developing, preparing, processing,
5 inspecting, testing, packaging, promoting, marketing, distributing, labelling, or selling
6 for profit, either directly or indirectly, through an agent, affiliate, predecessor, or
7 subsidiary, recalled BIOCELL Textured Breast Implants to patients for breast
8 augmentation and reconstruction, in the United States including California, including
9 the following recalled products:

10 **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV Saline-Filled
11 Mammary Implant) approved under PMA No. P990074. The following are the textured
12 styles:

- 13 • Style 163 – BIOCELL Textured Shaped Full Height, Full Projection Saline
14 Breast Implants
- 15 • Style 168 – BIOCELL Textured Round Moderate Profile Saline Breast
16 Implants, also referred to as 168MP (168 Moderate Profile)
- 17 • Style 363 – BIOCELL Textured Shaped Moderate Height, Full Projection Saline
18 Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full
19 Projection
- 20 • Style 468 – BIOCELL Textured Shaped Full Height Moderate Projection Saline
21 Breast Implants

22 **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed Silicone-
23 Filled Breast Implants) approved under PMA No. P020056. The following are the
24 textured styles:

- 25 • Style 110 – BIOCELL Textured Round Moderate Projection Gel Filled Breast
26 Implants
- 27 • Style 115 – BIOCELL Textured Round Midrange Projection Gel Filled Breast
28 Implants
- Style 120 - BIOCELL Textured Round High Projection Gel Filled Breast
Implants
- Style TRL - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled
Breast Implants
- Style TRLP - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled
Breast Implants

- 1 • Style TRM - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled
- 2 Breast Implants
- 3 • Style TRF - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled
- 4 Breast Implants
- 5 • Style TRX - Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled
- 6 Breast Implants
- 7 • Style TCL – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled
- 8 Breast Implants
- 9 • Style TCLP – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled
- 10 Breast Implants
- 11 • Style TCM – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled
- 12 Breast Implants
- 13 • Style TCF – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled
- 14 Breast Implants
- 15 • Style TCX – Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled
- 16 Breast Implants
- 17 • Style TSL – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 18 Implants
- 19 • Style TSLP – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 20 Implants
- 21 • Style TSM – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 22 Implants
- 23 • Style TSF – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 24 Implants
- 25 • Style TSX – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 26 Implants
- 27 • Style TSL – Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast
- 28 Implants

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under PMA No. P040046. The following are the textured styles:

- Style 410FM
- Style 410FF
- Style 410MM
- Style 410MF
- Style 410FL
- Style 410ML
- Style 410LL
- Style 410LM
- Style 410LF

- Style 410FX
- Style 410MX
- Style 410LX

Allergan Tissue Expanders for the breast that have BioCell texturing originally cleared for commercial distribution under Section 510(k):

- Natrelle 133 Plus Tissue Expander (K143354)
- Natrelle 133 Tissue Expander with Suture Tabs (K102806)

(Collectively, "BIOCELL Textured Breast Implants")

63. Plaintiff is unaware of the true names and capacities of the remaining defendants sued in this action by the fictitious names DOES 1 through 100. Plaintiff will amend this complaint when those names and/or capacities become known to Plaintiff. Plaintiff is informed and believe that each of the fictitiously named defendants is in some manner responsible for the events and allegations set forth in this complaint.

64. At all relevant times, defendants, and each of them, were the agents and employees of each of the remaining defendants and were at all times acting within the purpose and scope of said agency and employment, and each defendant has ratified and approved the acts of its agents.

GENERAL ALLEGATIONS

A. Federal law and requirements

65. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, impose a regime of detailed federal oversight administered by the FDA for medical devices. Depending on the nature of the device and the risks it presents, that oversight ranges from general federal regulations governing the labeling and manufacture of all medical devices, to a rigorous regime of premarket approval for certain devices.

66. FDA may grant premarket approval ("PMA") for a device only if it finds, among other things, that (a) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (b) the

1 proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and
2 (D). After premarket approval, a manufacturer generally must receive FDA's approval of
3 a supplemental application before making any change to the device itself that would
4 affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a).

5 67. PMA is specific to individual devices, but such devices are thereafter also
6 subject to the more general provisions of the MDA and FDA's regulations. Of particular
7 importance are the requirements that a medical device manufacturer:

8 (a) Collect and report to the FDA within certain timeframes information on
9 certain adverse events associated with its device. See 21 U.S.C. 360i(a); 21
10 C.F.R. Part 803.

11 (b) Implement quality systems and current good manufacturing practices with
12 respect to the device. See 21 U.S.C. 351(h); 21 C.F.R. Part 820.

13 68. Additionally, within the MDA exists an express preemption provision
14 applicable to PMA devices which states:

15 [N]o State or political subdivision of a State may establish or continue in effect
16 with respect to a device intended for human use any requirement -

17 (1) which is different from, or in addition to, any requirement applicable
18 under [the FDCA] to the device, and

19 (2) which relates to the safety or effectiveness of the device or to any other
20 matter included in a requirement applicable to the device under [the
21 FDCA]. 21 U.S.C. 360k(a).

22 **1. No express preemption of state-law claims paralleling MDA and federal**
23 **regulatory requirements**

24 69. As set forth in the MDA's express preemption provision, a state
25 requirement is preempted only if it is "different from, or in addition to," federal
26 requirements. 21 U.S.C. 360k(a)(1). Through that qualification, Section 360k(a) permits a
27
28

1 State to provide a traditional damages remedy for violations of common-law duties
2 when those duties parallel federal requirements.⁷

3 70. For example, where both the FDCA (as implemented by FDA) and State
4 law require a manufacture to deliver warnings regarding its device through an
5 appropriate channel—such as the FDA—those duties are parallel such that preemption
6 is inapplicable. That parallelism is reinforced by the FDCA's command that either
7 inadequate warnings (21 U.S.C. 352(f)(2)) or a failure to submit required adverse event
8 reports to FDA (21 U.S.C. 352(r)(2), 360i(a)) will render a device misbranded, and
9 therefore “prohibited [from] introduction or delivery for introduction into interstate
10 commerce.” 21 U.S.C. 331(a).

11 71. As the Ninth Circuit reasoned in *Stengel v. Medtronic Inc.*, such a “claim
12 rests on a state-law duty that parallels a federal-law duty under the MDA” 704 F.3d
13 1224, 1233 (2013) (en banc). Specifically, the plaintiff alleged that the manufacturer's
14 failure to warn the FDA of adverse health consequences constituted a violation of both
15 the MDR requirements and the general duty of reasonable care under State law, which
16 includes a duty to warn. *Ibid.*

17 72. This is because the MDR regulations are related to the manufacturer's duty
18 to provide the FDA with information regarding a device's safety and effectiveness, and
19 this information is disseminated to the public. Manufacturers provide these reports to
20 the FDA, the FDA then disseminates the reports to the public, and the reports are then
21 relied upon by physicians and authors of medical journals in comparing the relative
22 safety of medical devices.

23 73. Likewise, California imposes a duty on manufacturers to warn of potential
24 risks or dangers of their products, which sounds in both negligence and strict liability.
25 See *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1110-1112. This is a continuing duty

26 ⁷ As the Supreme Court stated in *Riegel v. Medtronic, Inc.*, “§ 360k does not prevent a State from providing
27 a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case
28 ‘parallel,’ rather than add to, federal requirements.” (2008) 553 U.S. 312, 330 (citing *Medtronic, Inc. v. Lohr*
(1996) 518 U.S. 470, 495).

1 that lasts as long as the product is in use. *Valentine v. Baxter Healthcare Corp.* (1999) 68
2 Cal.App.4th 1467, 1482; see also CACI Nos. 1205, 1222. The state-law duty to warn may
3 in some circumstances be satisfied by giving the information to a third party who can
4 reasonably be relied on to convey the danger. *Persons v. Salomon North America, Inc.*
5 (1990) 217 Cal.App.3d 168, 175-178. California follows the Restatement Second of Torts
6 standard for a manufacturer's reasonable reliance on an intermediary to convey
7 warnings. *Id.* at 175 (adopting Restatement Second of Torts, § 388, com. n). The focus of
8 this standard is whether, in light of all the circumstances, a manufacturer or supplier
9 acted reasonably in relying on a third party to pass warnings on to the ultimate user. *Id.*
10 at 175-178.

11 74. Thus, a factfinder could infer that a manufacturer's failure to provide
12 information regarding a device's safety and effectiveness as required by FDA regulations
13 is a parallel violation of the state duty to provide reasonable and adequate information
14 about a device's risks.

15 75. This parallelism is reinforced under California's doctrine of negligence per
16 se where the failure to exercise due care is presumed from a violation of a "statute,
17 ordinance, or regulation of a public entity." Cal. Evid. Code, § 669(a)(1). By its terms, this
18 doctrine applies to the law of any public entity, not just California public entities. See,
19 e.g., *DiRosa v. Showa Denko K.K.* (1996) 44 Cal.App.4th 799, 808. Thus, under California
20 law, a money damages remedy exists for negligent violation of the FDCA and
21 regulations promulgated thereunder which proximately cause injuries, and there is no
22 need for California's Legislature to act in order to create such a remedy.

23 76. The foregoing principles refute any anticipated contention by ALLERGAN
24 that Section 360k(a) expressly preempts Plaintiff's state law claims set forth below.
25 Under *Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, the U.S. Supreme Court held the
26 premarket approval of the plaintiff's device established preemptive requirements with
27 respect to the design and labeling of the device. Those would preempt any claim
28 alleging in substance that FDA should have conditioned its approval on adopting some

1 other design or labeling. Such were the nature of the claims at issue in *Riegel*, and those
2 claims were therefore preempted.

3 77. But where, as here, a plaintiff's claims are based on conduct *after* a device
4 received premarket approval, that conduct is governed not by the terms of the device's
5 premarket approval, but rather by FDA's general regulations governing medical devices
6 generally. Accordingly, state law claims—whether styled as arising from a failure to
7 make adverse event reports to FDA or from a failure to maintain appropriate quality
8 control systems—are not expressly preempted.

9 **2. No implied preemption of state-law claims premised on violations of the**
10 **MDA and federal regulatory requirements**

11 78. Where a plaintiff alleges that a defendant had made fraudulent
12 misrepresentations to the FDA in the course of obtaining premarket approval for a
13 medical device, such “fraud on-the-FDA claims” are impliedly preempted because they
14 conflict with the FDA's responsibility to police fraud on the agency and they seek to
15 enforce an exclusively federal requirement not grounded in traditional tort law. *Buckman*
16 *Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341, 348-353.

17 79. Central to the doctrine of implied preemption is that a state law claim
18 cannot exist solely by virtue of the federal enactments—State law has no role to play in
19 policing the relationship between a federal agency and the entity it regulates.
20 Conversely, claims relying on traditional State tort law which had predated the federal
21 enactments in question are unaffected. Therefore, a claim against a device manufacturer
22 is viable if the plaintiff is suing for conduct that violates the FDCA (or else her claim is
23 expressly preempted by Section 360k(a)), but the plaintiff must not be suing because the
24 conduct violates the FDCA (such a claim would be impliedly preempted under
25 *Buckman*).

26 80. Thus, as recognized in *Stengel*, a manufacturer's failure to report, for
27 example, is more than a mere misrepresentation to the FDA because it simultaneously
28 misled the device's current and potential users, to whom the manufacturer owed an

1 independent duty under state law. Thus, such claims are grounded in a traditional
2 category of state law failure-to-warn claims that predate the federal enactments in
3 question, and the claims therefore do not exist solely by virtue of those enactments. As a
4 result, such claims are not impliedly preempted by the MDA.

5
6 **B. Statement of Facts Relating to Preemption Applicable to Plaintiff's Failure to**
7 **Warn and Negligence Claims**

8 81. All three generations of the recalled BIOCELL Textured Breast Implants
9 received premarket approval under PMA Order Nos. P990074 (2000), P020056 (2006),
10 and P040046 (2013).

11 82. In 2011 and in 2015, the recalled Natrelle 133 Plus Tissue Expander
12 (K143354) and Natrelle 133 Tissue Expander with Suture Tabs (K102806) were approved
13 for sale under section 510(k), respectively.⁸

14 83. Under federal law and regulation, Allergan was under a continuing duty
15 to monitor its BIOCELL Textured Breast Implants after premarket approval and to
16 discover and report to the FDA any complaints about the device's performance and any
17 adverse health consequences of which it became aware and that are or may be
18 attributable to its BIOCELL Textured Breast Implants. See 21 C.F.R. § 803.50 *et seq*; 21
19 C.F.R. § 820.198(a)(3); 21 U.S.C. 360i.

20 84. Pursuant to these regulations, ALLERGAN was obligated to file within a
21 mandatory timeframe detailed medical device reports (MDRs) for *all* BIA-ALCL events
22 related to its BIOCELL Textured Breast Implants that it had knowledge of, foreign or
23

24
25 ⁸ A medical device marketed after the MDA's effective date may bypass the PMA process if the device is
26 "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to 1976).
27 This exception to premarket approval is known as the "510(k)" process and simply requires the
28 manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device, and to
explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve
the new device for sale in the United States. *The MDA does not require an FDA determination that the
device is, in fact, substantially equivalent to a grandfathered device.*

1 domestic, and this includes any event that could reasonably be interpreted as possible
2 BIA-ALCL given the nature of the facility, doctor or patient complaint.

3 85. Notwithstanding this obligation, ALLERGAN failed to investigate
4 complaints of adverse events and submit such adverse events concerning the BIOCELL
5 Textured Breast Implants as MDRs in violation of general medical device regulations
6 designed to ensure patient safety.

7 86. As a result, Allergan failed to properly perform its duties and failed to
8 inform the FDA of the increased risk of BIA-ALCL associated with its BIOCELL
9 Textured Breast Implants using medical device reports; even though it should have been
10 aware of the many adverse events that did occur and was actually aware of these
11 adverse events—but failed to file medical device reports pursuant to 21 C.F.R. Part 803;
12 21 C.F.R. § 820.198; and 21 U.S.C. 360i.

13 **1. ALLERGAN violated 21 C.F.R. § 803.50 *et seq* by failing to file MDRs**
14 **following receipt of both foreign and domestic complaints of BIA-ALCL**

15 87. A manufacturer must report adverse events no later than 30 calendar days
16 after the day that it received or otherwise become aware of information, *from any*
17 *source*, that reasonably suggests that a device may have caused or contributed to a death
18 or serious injury, or malfunctioned. 21 C.F.R. § 803.50 (emphasis added).

19 88. This reporting duty is triggered not just for events occurring within the
20 United State and its territories, but also adverse events occurring in a foreign country
21 concerning the device. Under the FDA's Medical Device Reporting for Manufacturers
22 Guidance for Industry, the FDA considers an event that occurs in a foreign country
23 reportable under the MDR regulations if it involves a device that has been cleared or
24 approved in the United States— or a device similar to a device marketed by the
25 manufacturer that has been cleared or approved in the United States – and is also
26 lawfully marketed in a foreign country.

27 89. Thus, even when a device is manufactured to modified specifications to
28 meet standards in different countries, if these changes do not substantially alter the

performance of the device, then any device events that are MDR reportable events relating to such modified devices should be reported under the MDR regulations.

90. Notwithstanding this reporting obligation for events worldwide, between 2007 and 2010—following premarket approval for its first generation of silicone-filled breast implants in 2006—internal ALLERGAN documents show ALLERGAN received 22 worldwide complaints of BIA-ALCL in women implanted with the silicone brand of the breast implants:

Year	Description	Worldwide by Surface Type			
		Smooth	Textured (Biocell, Microcell, Unknown AGN Textured)	Unknown	Total
2004	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2005	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2006	Count of ALCL Complaints by Received Year	0	0	0	0
	Sales Volume by Distribution Year			NA	
2007	Count of ALCL Complaints by Received Year	1	2	0	3
	Sales Volume by Distribution Year			NA	
2008	Count of ALCL Complaints by Received Year	0	5	4	9
	Sales Volume by Distribution Year			NA	
2009	Count of ALCL Complaints by Received Year	0	3	3	6
	Sales Volume by Distribution Year			NA	
2010	Count of ALCL Complaints by Received Year	1	0	3	4
	Sales Volume by Distribution Year			NA	
2011	Count of ALCL Complaints by Received Year	0	9	0	9
	Sales Volume by Distribution Year			NA	
2012	Count of ALCL Complaints by Received Year	1	14	2	17
	Sales Volume by Distribution Year			NA	
2013	Count of ALCL Complaints by Received Year	1	21	0	22
	Sales Volume by Distribution Year			NA	
2014	Count of ALCL Complaints by Received Year	0	18	8	26
	Sales Volume by Distribution Year			NA	
2015	Count of ALCL Complaints by Received Year	0	32	4	36
	Sales Volume by Distribution Year			NA	
Total (2004-2015)	Count of ALCL Complaints by Received Year	4	104	24	132
	Sales Volume by Distribution Year			NA	

91. Despite the public health crisis implicated by such statistics, ALLERGAN unlawfully failed to report these events of BIA-ALCL to the FDA *at all*.⁹⁻¹⁰ Moreover, the internal ALLERGAN data set forth above does not account for the untold number of

⁹ The FDA's Manufacturer and User Facility Device Experience (MAUDE database) is available online and can be searched to locate MDRs. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.

¹⁰ The first instance of ALLERGAN filing an adverse event report for a complaint of BIA-ALCL in connection with its silicone filled breast implants was received by the FDA on May 4, 2011. See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=2097844.

1 complaints of BIA-ALCL in women implanted with their saline filled brand of BIOCELL
2 Textured Breast Implants.¹¹

3 92. Such information, had it been disclosed by ALLERGAN, would have
4 enabled physicians and patients to take proper precautions to determine whether the
5 increased risk of BIA-ALCL should be avoided by electing not to use Allergan's
6 BIOCELL textured implants. Or, the FDA would have recalled the BIOCELL textured
7 implants before Plaintiff ever had them implanted.

8 93. Also, under state law, which does not impose duties or requirements
9 materially different from those imposed by federal law, the manufacturer must timely
10 and appropriately report adverse events concerning the safety of its products.
11 ALLERGAN was under a continuing duty under state law to adequately report injuries
12 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
13 FDA.

14 94. As a result of ALLERGAN's post-market failure to appropriately report
15 adverse events as required by federal statute and FDA regulations, and as a result of
16 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
17 nature of the product became known only after having been implanted in Plaintiff, and
18 otherwise never would have been implanted in the Plaintiff at all.

19 **2. ALLERGAN violated 21 C.F.R. §§ 803.50 and 803.52 by concealing**
20 **pertinent adverse event reports by burying them in unscrutinized**
21 **spreadsheets**

22 95. As complaints of BIA-ALCL continued to rise in frequency as outlined in
23 the chart above, rather than complying with the federal statute and regulations on
24 medical device reporting, ALLERGAN began using Alternative Summary Reports
25
26

27 ¹¹ Due to safety concerns, from April 1992 until November 2006 silicone gel-filled breast implants were
28 only available in the U.S. to women enrolled in clinical studies, whereas saline-filled breast implants
remained in the market during this time via 510(k) approval and, after 2001, premarket approval.

1 (ASRs) to report of BIA-ALCL events associated with its BIOCELL Textured Breast
2 Implants.¹²

3 96. ASRs differ from MDRs in that eligible events are aggregated into a single
4 periodic report where only rudimentary information about a particular adverse event is
5 set forth in a line item format within a dense spreadsheet containing thousands of other
6 adverse events.

7 97. Whereas 21 C.F.R. § 803.52 mandates that a traditional medical device
8 report must contain dozens of categories and subcategories of information, including
9 unique product identification, a detailed event description with a discussion of how the
10 device was involved, and a manufacturer's narrative, an ASR merely contains generic
11 device and problem coding that was never made available to the public or physicians
12 before late 2019.¹³

13 98. While the FDA allowed manufacturers to use the ASR reporting system to
14 report *specific* adverse events in lieu of MDR reporting, this was only allowed where
15 compliance with some of the reporting requirements "*is not necessary to protect the*
16 *public health*" because such events were "*known and well-documented.*" 60 Fed. Reg.
17 63,592 (December 11, 1995) (emphasis added). In the case of breast implants,
18 manufacturers like ALLERGAN could *only* summarize reports of "rupture, leaks,
19 deflation/inflation, wrinkling, capsular contracture, and non-specific complaints."¹⁴

20 99. Moreover, under the FDA's October 19, 2000 ASR Guidance for Industry,
21 the FDA requested that any medical device manufacturer seeking to use the ASR
22 reporting system affirmatively apply for an exemption, in writing, for specific device
23 events, as required by 21 C.F.R. § 803.19(b), with the following information: a statement
24 notifying the FDA of the request to participate in the ASR program; an explanation why
25 the request is justified; identification of the device manufacturer; the product
26

27 ¹² Note: The ASR program is also referred to by the FDA as Postmarket Spreadsheet Reporting (PSR).

28 ¹³ Compare **Exhibit A**, a single MDR, with **Exhibit B**, 105 ASRs.

¹⁴ See https://www.accessdata.fda.gov/cdrh_docs/pdf/P990074B.pdf.

1 classification codes for the device that will be included in the ASR report; and the
2 reporting site registration number, contact person, and address of the firm who will be
3 submitting the ASR reports to the FDA.

4 100. ALLERGAN failed to comply with 21 C.F.R. § 803.19(b) and the
5 corresponding ASR Guidance and used the ASR reporting system to report BIA-ALCL
6 events associated with its BIOCELL Textured Breast Implants despite never being
7 granted an exemption to do so by the FDA.

8 101. The FDA's October 19, 2000 ASR Guidance was clear, device
9 manufacturers could not lawfully use the ASR reporting system under any
10 circumstances for unusual, unique, or even uncommon events. BIA-ALCL, and the
11 symptoms associated therewith, are unequivocally an unusual, unique, or uncommon
12 events—but an event type ALLERGAN was aware of since at least 1997 when the first
13 known event appeared in the medical literature with a description of its characteristics.

14 102. Likewise, the FDA was unambiguous in its May 2, 2019 statement
15 regarding the agency's efforts to protect women's health and help to ensure the safety of
16 breast implants: "[The ASR] program was established in 1997 to more efficiently review
17 adverse events for well-established risks but was not allowed for patient deaths and
18 *unusual, unique or uncommon adverse events, which, in the case of breast implants,*
19 *included BIA-ALCL.*"

20 103. On information and belief, hundreds of complaints related to BIA-ALCL
21 and symptoms associated therewith surfaced from 1997 to 2019. ALLERGAN was
22 aware of these events, and that they were unusual, unique, or uncommon events relating
23 to BIA-ALCL. ALLERGAN—rather than reporting these events in compliance with the
24 MDR reporting requirements—misused the ASR reporting system in violation of 21
25 C.F.R. § 803.19(b); 21 C.F.R. § 803.50; 21 C.F.R. § 820.198(a)(3); 21 U.S.C. 360i; and its duty
26 to report to the FDA.

27 104. The first identified misuse of the ASR system to report an event of BIA-
28 ALCL occurred in 2009 when a healthcare professional reported to an ALLERGAN

employee the events of BIA-ALCL and seroma.¹⁵ However, following the FDA's decision to end the ASR program due to manufacturer abuse, the FDA in late 2017 also began to require manufacturers to also submit companion MDRs so that some information collected through the ASR program would be visible publicly. As a result, it became known that ALLERGAN has been misusing the ASR program to report ineligible events since as early as March 1997.¹⁶

105. In fact, ALLERGAN started late filing hundreds of MDRs related to BIA-ALCL events it had known about for many years but had buried in the ASR spreadsheets to belatedly comply with 21 C.F.R. § 803.50; 21 C.F.R. § 820.198(a)(3); and 21 U.S.C. 360i—and also in violation of these statute and regulations—after the FDA ended the ASR program in late 2017. Two such examples of the now thousands of MDRs recently filed and available only after 2017 in the FDA's Adverse Event Database clearly demonstrate Allergan's years/decades-long delay in filing these MDRs:

ALLERGAN (COSTA RICA) STYLE 410 COHESIVE SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED	Back to Search Results
Catalog Number N-27-MM135-400	
Device Problem Adverse Event Without Identified Device or Use Problem	
Event Type Injury	
Manufacturer Narrative	
Information in this medwatch was previously reported via 410 psr on 17/jul/2014. The event of lymphoma is a physiological complication and analysis of the device generally does not assist allergan in determining a probable cause for this event. Further information from the reporter regarding event, product, or	
Report Date 01/23/2019	

ALLERGAN (COSTA RICA) STYLE 120 SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED	Back to Search Results
Catalog Number 120-500	
Device Problem Adverse Event Without Identified Device or Use Problem	
Event Date 03/22/2010	
Event Type Injury	
Manufacturer Narrative	
Information contained in this report was previously submitted through responsive psr on (b)(6) 2010. A review of the device history record has been initiated. If any new, changed or corrected information is noted, a supplemental medwatch will be submitted. The events of lymphoma, and "melanoma" are physiological	
Report Date 07/15/2019	

106. The FDA was not aware, did not consent, and did not grant any exemption to ALLERGAN to use ASR reporting for BIA-ALCL events.

¹⁵ See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=2842518.

¹⁶ See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=7326850.

1 107. Medical device reporting serves a critical public safety function and failing
2 to follow the federal statutes and regulations on such reporting can cause patients
3 serious injuries. This is precisely why MDR reporting was required for events or risks,
4 like BIA-ALCL, that were not well-known or established. As the FDA plainly stated in
5 their June 21, 2019 statement: "The ASR Program allowed the FDA to more efficiently
6 review reports of *well-known, well-understood* adverse events, so we [can] focus on
7 identifying and taking action on new safety signals and less understood risks."

8 108. The FDA did not review or investigate reports for ASR-reported events;
9 and reserved its resources for events requiring a medical device report. ASR reported
10 events were not even available to FDA Supervisory Consumer Safety Officers for review
11 in advance of conducting periodic site visits to ALLERGAN's California headquarters.

12 109. Because this information about BIA-ALCL was routinely transmitted by
13 ALLERGAN to the FDA in the unscrutinized spreadsheets, the recall for ALLERGAN's
14 BIOCELL Textured Breast Implants took approximately 20 years to be initiated by the
15 FDA and only because ALLERGAN failed to lawfully report BIA-ALCL events to the
16 FDA.

17 110. Use of the ASR reporting system buried patient injury events and they
18 were not investigated by the FDA, and could not be discovered by physicians either.
19 Had ALLERGAN lawfully reported BIA-ALCL events from 1997 until the time of
20 Plaintiff's implantation or symptoms, she would not have suffered her injuries because
21 either: (a) a recall would have been initiated before Plaintiff's implantation date of the
22 subject devices; or (b) the risks would have been well-understood and Plaintiff or her
23 physician would have been informed of the risk of BIA-ALCL. Instead, the Plaintiff and
24 her physician were both unaware of the extent of the risk of BIA-ALCL when the subject
25 devices were implanted causing her serious injuries.

26 111. Accordingly, Plaintiff SUSAN MROWIEC was injured as a result of
27 Defendants' post-market failure to properly submit MDRs as required (by statute and
28 that FDA's regulations), and as a result of Defendants' post-market negligence,

1 ALLERGAN's BIOCELL Textured Breast Implants belatedly became known to be
2 defective and unreasonably dangerous only *after* having been implanted in Plaintiff.

3 112. As a result of its failure to establish and maintain effective post-market
4 surveillance and reporting to ensure defect-free products, Plaintiff suffered severe
5 injuries.

6 113. Also, under state law, which does not impose duties or requirements
7 materially different from those imposed by federal law, the manufacturer must timely
8 and appropriately report adverse events concerning the safety of its products.
9 ALLERGAN was under a continuing duty under state law to adequately report injuries
10 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
11 FDA.

12 114. As a result of ALLERGAN's post-market failure to appropriately report
13 adverse events as required by federal statute and FDA regulations, and as a result of
14 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
15 nature of the product became known only after having been implanted in Plaintiff, and
16 otherwise never would have been implanted in the Plaintiff at all.

17 **3. ALLERGAN failed to investigate and evaluate complaints of BIA-ALCL**
18 **per 21 C.F.R. 820.198 and 803.18(e) and prepare corresponding medical**
19 **device reports**

20 115. Pursuant to 21 C.F.R. § 820.198(a), ALLERGAN was required to have a
21 formally designated unit for the purposes of receiving, reviewing and evaluating
22 complaints of adverse events. 21 C.F.R. §§ 803.17, 803.18, and 820.198.

23 116. The FDA's definition of "complaint" is all encompassing and includes
24 "any written, electronic, or oral communication that alleges deficiencies related to the
25 identity, quality, durability, reliability, safety, effectiveness, or performance of a device
26 after it is released for distribution." 21 C.F.R. § 820.3(b).

27 117. Typically, complaints are prepared and transmitted to the company by
28 physicians, nurse, hospitals, attorneys, and even the patients themselves on the

1 comprehensive FDA Form 3500B for voluntary reporters—designed with the intent of
2 streamlining the manufacturer’s reporting by mirroring the information contained in
3 FDA’s Form 3500A for mandatory reporters, like ALLERGAN.

4 118. Upon receipt of a complaint by *any* employee, ALLERGAN was required
5 to evaluate all available information related to the complaint to determine whether it
6 represents an MDR reportable event. 21 C.F.R. §§ 820.198(a) and 803.18. Said evaluation
7 must include information in the manufacturer’s possession or that is reasonably
8 available to ALLERGAN, such as information can be obtained by contacting a user
9 facility (e.g. hospital, surgical center), importer or other initial reporter related to the
10 adverse event. 21 C.F.R. § 803.50.

11 119. If the adverse event complaint qualifies for reporting to FDA under 21
12 C.F.R. Part 803—i.e., the device may have caused or contributed to a death or serious
13 injury, or malfunctioned—then ALLERGAN was required to conduct an investigation of
14 the event. 21 C.F.R. §§ 803.3 and 803.50.¹⁷ Said investigation must include a
15 determination (1) whether the device failed to meet specifications; (2) whether the device
16 was being used for treatment or diagnosis; and (3) the relationship, if any, of the device
17 to the reported incident or adverse event. 21 C.F.R. § 820.198(d).

18 120. Accordingly, under these general complaint handling requirements,
19 ALLERGAN was under the continuing duty to receive, evaluate, and investigate such
20 events related to BIA-ALCL and make a determination as to the relationship between
21 the BIOCELL Textured Breast Implants and BIA-ALCL.

22 121. Notwithstanding ALLERGAN’s complaint handling obligations for
23 adverse events of BIA-ALCL and symptoms associated therewith, on numerous
24 occasions ALLERGAN ignored complaints of such events.

25
26
27
28 ¹⁷ Death or serious injury includes events occurring from: 1) Failure; 2) Malfunction; 3) Improper or
inadequate design; 4) Manufacture; 5) Labeling; or 6) User error. 21 C.F.R. § 803.3.

122. Two such examples of these ignored complaints further demonstrate ALLERGAN's cavalier and unlawful attitude towards the risks of BIA-ALCL:¹⁸

MCGHAN MCGHAN 363 LF SALINE FILLED BREAST IMPLANTS		Back to Search Results
Model Number 363LF-300		
Event Date 12/07/2016		
Event Type Injury		
Event Description		
Pt had mcghan 363lf saline filled implants placed on (b)(6) 2016. Presented with large right breast seroma on (b)(6) 2016. Ultrasound guided aspiration of seroma performed on (b)(6) 2016 after ultrasound and mri showed large loculated right breast fluid collection. Aspirated fluid showed cd30+ and alk1 - cells, leading to the diagnosis of alcl. She had bilateral capsulectomies and removal of implants on (b)(6) 2017. Pathology did not reveal any extension of the alcl into the capsular. She is currently being worked up by our oncologists were as well as our geneticists.		

INAMED INAMED SALINE BREAST IMPLANT		Back to Search Results
Event Type No Answer Provided		
Event Description		
Alcl case report: this pt had bilateral breast augmentation performed in 2005. She recently developed a seroma that was aspirated and found to have atypical t cells. I performed bilateral implant removal and total capsulectomy. Her final pathology revealed alcl of the left breast.		

123. Rather than conducting the required investigations into complaints transmitted by concerned physicians and/or patients, ALLERGAN, in violation of their general complaint handling requirements, allowed the complaints to fall on deaf ears.

124. As a result, ALLERGAN never conducted the required evaluation to determine whether the complaint qualified for public medical device reporting (instances of BIA-ALCL most assuredly qualify), never conducted the required investigation to determine the relationship between the event and the device, and therefore deprived the FDA or public of vital knowledge necessary to make informed decisions about the BIOCELL Textured Breast Implants.

125. Such information, had it been disclosed by ALLERGAN, would have enabled physicians and patients to take proper precautions to determine whether the increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL Textured Breast Implants before Plaintiff ever had them implanted.

¹⁸ The FDA makes publicly available complaints submitted on the FDA's Form 3500B for voluntary reporters, even when, as here, there is no corresponding medical device report submitted by the manufacturer.

1 126. Also, under state law, which does not impose duties or requirements
2 materially different from those imposed by federal law, the manufacturer must timely
3 and appropriately report adverse events concerning the safety of its products.
4 ALLERGAN was under a continuing duty under state law to adequately report injuries
5 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
6 FDA.

7 127. As a result of ALLERGAN's post-market failure to appropriately report
8 adverse events as required by federal statute and FDA regulations, and as a result of
9 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
10 nature of the product became known only after having been implanted in Plaintiff, and
11 otherwise never would have been implanted in the Plaintiff at all.

12 **4. ALLERGAN failed to timely submit reports of BIA-ALCL per 21 C.F.R. §**
13 **803.50(a) and attempted to transmit such reports years after first**
14 **receiving notice of the event**

15 128. As aforementioned, after ALLERGAN's misuse of the ASR program came
16 to light in late 2017, ALLERGAN belatedly started late filing thousands of MDRs for a
17 variety adverse event types that were not eligible for ASR reporting dating back to 1997.
18 Amongst these late reports were hundreds of adverse events related to BIA-ALCL and
19 symptoms associated therewith that ALLERGAN had known about for many years, but
20 the existence of which the FDA and the public had no knowledge of.

21 129. It was, in part, because of these late MDRs establishing the true extent of
22 the nexus between BIA-ALCL and the presence of an ALLERGAN's BIOCELL Textured
23 Breast Implant, that the FDA was equipped with sufficient knowledge to initiate the July
24 2019 worldwide recall.

25 130. Two particularly egregious examples are as follows, revealing
26 ALLERGAN failed to submit the mandatory MDRs until *twelve years* and *twenty-nine*
27 *years* after the underlying adverse event, with latter only being reported to the FDA,
28 and therefore disclosed to the public, as recent as December 11, 2019:

ALLERGAN (COSTA RICA) STYLE 163 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE	Back to Search Results
<p>Catalog Number 163-440</p> <p>Device Problem No Apparent Adverse Event</p> <p>Event Date 01/01/2007</p> <p>Event Type Injury</p> <p>Event Description</p> <p>Health professional reported patient "developed rapid late seroma. Diagnosed with bia-alcl right breast, stage ie, underwent bilateral capsulectomies and implant removal. Received chop, ice, chemotherapy and radiation therapy followed by stem cell transplant postoperatively. Follow up imaging with pet, no recurrence of disease. Remains healthy. "</p> <p>Manufacturer Narrative</p> <p>Unique identifier (udi) #: not applicable. Device labeling addresses: there were no reported events of lymphoma/alcl, for patients in the core study, in the labeling for silicone implants. Potential adverse events that may occur with silicone gel-filled breast implant surgery include: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy. After breast implant surgery the following may occur and/or persist, with varying intensity and/or for a varying length of time: hematoma/seroma, implant extrusion, necrosis, delayed wound healing, and breast tissue atrophy/chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.</p>	
Report Date 08/28/2019	
ALLERGAN (COSTA RICA) STYLE 120 SILICONE GEL FILLED BREAST IMPLANT PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED	Back to Search Results
<p>Catalog Number 120-260</p> <p>Device Problem Patient-Device Incompatibility</p> <p>Event Date 10/08/1990</p> <p>Event Type Injury</p> <p>Manufacturer Narrative</p> <p>The events of capsular contracture and lymphoma-alcl are physiological complications and analysis of the device generally does not assist allergan in determining a probable cause for these events. The reason for reoperation: capsular contracture, baker grade iii and "being treated for alcl. " further information from the reporter regarding event, product, or patient details has been requested. No additional information is available at this time. These are known potential adverse events addressed in the product labeling.</p> <p>Event Description</p> <p>Healthcare professional reported capsular contracture, baker grade iii and "being treated for alcl. " patient reported "joint pain, muscle pain and stiffness," and a bilateral exchange from textured to smooth breast implants due to the patient's concern with the product. Patient also reported "inability to walk, numbness in extremities, tingling in extremities, flu like symptoms, losing vision, seeing spots, memory loss, anxiety, suicidal thoughts, depression, sties in eyes, reoccurring staph in nose, chills, dizziness," these events are not related to the device. Device remains implanted. This record is for the left side.</p>	
Report Date 12/11/2019	

131. Contrary to ALLERGAN's unlawful reporting practices, MDR reportable events must be submitted to the FDA within *30 calendar days* after the day the manufacturer becomes aware of the event. 21 C.F.R. §§ 803.10 and 803.50. The only exception is when a medical device report is required to be submitted within *5 workdays* after the day the manufacturer becomes aware of the need to submit such a report. 21 C.F.R. §§ 803.10(c)(2) and 803.53.

132. A manufacturer is considered to have "become aware" of an event whenever any of its employees becomes aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report. 21 C.F.R. § 803.3.

1 133. Notwithstanding these strict and mandatory reporting deadlines, as
2 demonstrated above, ALLERGAN has been submitting late adverse event reports to the
3 FDA related to BIA-ALCL, often times many years, sometimes decades, after first
4 receiving knowledge of the event.

5 134. Such information, had it been timely disclosed by ALLERGAN, would
6 have enabled physicians and patients to take proper precautions to determine whether
7 the increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's
8 BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL
9 Textured Breast Implants before Plaintiff ever had them implanted.

10 135. Also, under state law, which does not impose duties or requirements
11 materially different from those imposed by federal law, the manufacturer must timely
12 and appropriately report adverse events concerning the safety of its products.
13 ALLERGAN was under a continuing duty under state law to adequately report injuries
14 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
15 FDA.

16 136. As a result of ALLERGAN's post-market failure to appropriately report
17 adverse events as required by federal statute and FDA regulations, and as a result of
18 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
19 nature of the product became known only after having been implanted in Plaintiff, and
20 otherwise never would have been implanted in the Plaintiff at all.

21 **5. ALLERGAN failed to provide all information reasonably known to it**
22 **per 21 C.F.R. § 803.50(b) in its reports of BIA-ALCL but rather simply**
23 **regurgitated its misleading and deficient labeling**

24 137. A medical device report must contain all the information required by 21
25 C.F.R. § 803.52 that is known, or reasonably known to the manufacturer.

26 138. Information considered reasonably known includes any information: 1)
27 that can be obtained by contacting a user facility, importer, or other initial reporter; 2)
28

1 that is in the manufacturer's possession; or 3) that can be obtained by analysis, testing or
2 other evaluation of the device. 21 C.F.R. § 803.50(b).

3 139. Far from providing all information reasonably known it, as part of its
4 manufacturing narrative in medical device reports concerning BIA-ALCL, ALLERGAN,
5 more often than not, simply recited its device labeling with the unsubstantiated and
6 misleading claim that "device labeling addresses" the issue already, thereby indicating
7 that no further investigatory or remedial action was needed.

8 140. Notwithstanding the fact that ALLERGAN has had to update its device
9 labeling on multiple occasions due to inaccurate information regarding BIA-ALCL, as
10 reflected in the following medical device report dated November 12, 2019 for a BIA-
11 ALCL event occurring in 2010, ALLERGAN has pointed to completely inapplicable parts
12 of its labeling to attempt to explain away and disregard events of BIA-ALCL:

ALLERGAN (COSTA RICA) STYLE 168 SALINE FILLED BREAST IMPLANT PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE		Back to Search Results
Catalog Number 168-800 Device Problem Fluid Leak Event Date 10/20/2010 Event Type Death Event Description Initially, pt reported right side lymphoma, deflation, infection, irritation/inflammation with right breast implant. F/u with the implanting surgeon's office noted the pt was seen in the emergency room for what was thought to be a right breast abscess or an infection. The pt was then sent to see the implanting surgeon, who performed an antibiotic wash and had the pt have an ultrasound as well. Operative notes were requested and state, "on the right side, once incised, we encountered a large volume of purulent fluid. This was sent for culture. We found a completely deflated saline implant. The capsule was angry and inflamed. The pathology final diagnosis: alcl; cd30+ alk- including cd45+. The pt was to see an oncologist at a later date. Additional info provided by the surgeons' offices notes that the pt was seen by the oncologist and breast implant that was removed was discarded. Manufacturer Narrative Medwatch submitted to the fda on 02/14/2011. Explanted devices were requested to be returned to allergan, but were discarded by the facility and not available for analysis. Device labeling: "pts should be advised that implants are not considered lifetime devices and they will likely undergo implant removal, with or without replacement, over the course of their life. " "if any unusual symptoms occur after surgery, such as fever or noticeable swelling or redness in one breast, you should contact your surgeon immediately. " "published studies indicate that breast cancer is no more common in women with implants than those without. "		
Report Date 11/12/2019		

22 141. As shown in the November 12, 2019 example—which is just one of many
23 with this deficiency—ALLERGAN has claimed that its representations in the device
24 labeling that "implants are not considered lifetime devices" or "if any unusual
25 symptoms occur after surgery . . . you should contact your surgeon immediately"
26 constitute a sufficient warning of the risks of BIA-ALCL.

27 142. Worse yet, the notion that "published studies indicate that breast cancer is
28 no more common in women with implants than those without" has any relevancy on an

1 event of BIA-ALCL is as ridiculous as it is insulting to those affected. Again, BIA-ALCL
2 is a cancer of the immune system, and *not* a type of breast cancer—a fact ALLERGAN
3 has been well aware of since 1997.

4 143. By failing to provide all information reasonably known to it, and instead
5 misleadingly regurgitating irrelevant and inapplicable parts of its device labeling,
6 ALLERGAN violated 21 C.F.R. §§ 803.50(b) and 803.52.

7 144. Such information, had it been disclosed by ALLERGAN, would have
8 enabled physicians and patients to take proper precautions to determine whether the
9 increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's
10 BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL
11 Textured Breast Implants before Plaintiff ever had them implanted.

12 145. Also, under state law, which does not impose duties or requirements
13 materially different from those imposed by federal law, the manufacturer must timely
14 and appropriately report adverse events concerning the safety of its products.
15 ALLERGAN was under a continuing duty under state law to adequately report injuries
16 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
17 FDA.

18 146. As a result of ALLERGAN's post-market failure to appropriately report
19 adverse events as required by federal statute and FDA regulations, and as a result of
20 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
21 nature of the product became known only after having been implanted in Plaintiff, and
22 otherwise never would have been implanted in the Plaintiff at all.

23 **6. ALLERGAN failed to use the appropriate device problem code for**
24 **reports of BIA-ALCL instead representing that there was “no apparent**
25 **adverse event”**

26 147. The FDA receives a significant number of MDRs in any given month or
27 year. Accordingly, it has implemented and relied upon a problem coding system to
28

1 enable FDA officials to conduct trend and risk analysis for a device without the
2 immediate need to read and review every MDR.

3 148. There exist four categories of problem codes: 1) Device Problem Code; 2)
4 Patient Problem Code; 3) Evaluation Results Code; and 4) Evaluation Conclusion Code.
5 However, only the Device Problem Code on MDRs is made publicly available on the
6 FDA's MAUDE interface.

7 149. These codes must be provided to the FDA in an adverse event report
8 pursuant to 21 C.F.R. § 803.52. The codes must represent the manufacturers best
9 knowledge of the adverse event and a manufacturer is not limited to more than one code
10 per category for an event. When entering the device problem code, manufacturers are
11 expected to select the lowest-level (i.e. most detailed) code or codes that most accurately
12 describe the device failures or problems observed during the event.

13 150. To the extent the FDA's coding manual does not provide a matching or
14 similar code(s) that would best describe the patient or device problem or the evaluation
15 result and conclusion, a manufacturer has the ability to contact the FDA to assign a new
16 code(s) as applicable.

17 151. However, in violation of 21 C.F.R. § 803.52, rather than providing an
18 accurate device problem code for events of BIA-ALCL, ALLERGAN had a pattern and
19 practice of providing the Device Problem Code No. 3189, meaning "No Apparent
20 Adverse Event."

21 152. As the title suggests, Device Problem Code No. 3189: No Apparent
22 Adverse Event has a unique meaning to the FDA that "[a] report has been received but
23 the description provided *does not appear to relate to an adverse event*. This code allows
24 a report to be recorded for *administration purposes*, even if it *doesn't meet the*
25 *requirements for adverse event reporting*."¹⁹

26
27
28 ¹⁹ See <https://www.fda.gov/media/109148/download>.

1 153. ALLERGAN knew this code was “for FDA use only” because “an event
2 that is not an adverse event is, by definition, not a reportable adverse event.”²⁰

3 154. ALLERGAN nevertheless utilized this code in their medical device
4 reporting for events of BIA-ALCL, which had the intended consequence of excluding
5 these reports from the FDA’s trend analysis.

6 155. As a result of ALLERGAN’s deceitful coding practices in violation of 21
7 C.F.R. § 803.52, for years the FDA was deprived of the necessary information to
8 expeditiously determine the need for regulatory action, such as a recall, without having
9 to first review and analysis each MDR for the device.

10 156. If the FDA’s trend analysis had not been undermined by ALLERGAN’s
11 reporting practices, the recall would have been initiated before Plaintiff’s implantation
12 date of the subject devices; or the risks would have been well-understood and Plaintiff
13 or her physician would have been informed of the risk of BIA-ALCL.

14 157. Worse yet, this practice of representing events of BIA-ALCL as “no
15 apparent adverse event” was not limited to its domestic reporting practices, but also was
16 ALLERGAN’s standard operating procedure internationally. On multiple occasion in its
17 Incident Report Forms to European regulatory authorities, ALLERGAN ranked cases of
18 BIA-ALCL in the fields of “All Other Reportable Incident” and “No Threat of Public
19 Health.” As a result, ALLERGAN was reprimanded by French regulatory authorities in
20 May 2015. Nonetheless, ALLERGAN continued to use the “No Apparent Adverse
21 Event” code domestically for events of BIA-ALCL.

22 158. Such information, had it been disclosed by ALLERGAN, would have
23 enabled physicians and patients to take proper precautions to determine whether the
24 increased risk of BIA-ALCL should be avoided by electing not to use Allergan’s
25 BIOCELL textured implants. Or, the FDA would have recalled the BIOCELL textured
26 implants before Plaintiff ever had them implanted.

27
28 ²⁰ See <https://www.fda.gov/medical-devices/mdr-adverse-event-codes/coding-faqs>.

1 159. Also, under state law, which does not impose duties or requirements
2 materially different from those imposed by federal law, the manufacturer must timely
3 and appropriately report adverse events concerning the safety of its products.
4 ALLERGAN was under a continuing duty under state law to adequately report injuries
5 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
6 FDA.

7 160. As a result of Allergan's post-market failure to appropriately report
8 adverse events as required by federal statute and FDA regulations, and as a result of
9 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
10 nature of the product became known only after having been implanted in Plaintiff, and
11 otherwise never would have been implanted in the Plaintiff at all.

12 **C. Statement of Facts Relating to Preemption Applicable to Plaintiff's**
13 **Manufacturing Defect and Negligence Claims**

14 161. As noted above, ALLERGAN has received pre-market approval from the
15 FDA for all three generations of BIOCELL Textured Breast Implants. As such,
16 ALLERGAN was under a continuing duty to follow the general requirements set forth
17 current good manufacturing practices ("CGMPs") provisions of the MDA governing the
18 safety and effectiveness of a PMA medical device. See 21 U.S.C. 351; 21 C.F.R. Part 820.

19 162. Pursuant to these regulations, ALLERGAN was obligated to implement
20 and maintain quality control systems to validate processes and conduct inspections and
21 testing to ensure the purity and stability of the implants and not produce adulterated
22 implants, specifically those with excessive particles on the implant surface at the time of
23 manufacture in violation of 21 U.S.C. 351; 21 C.F.R. §§ 820.70 and 820.75.

24 163. Notwithstanding this obligation, ALLERGAN produced, at times,
25 adulterated BIOCELL Textured Breast Implants that had numerous unwanted particles
26 and solid fragments of silicone on the implant surface in violation of CGMP regulations
27 designed to ensure device quality and patient safety.
28

1 164. As a result, ALLERGAN failed to properly perform its duties and failed to
2 implement and maintain quality control systems with respect to the texturization
3 process for manufacturing its BIOCELL Textured Breast Implants, even though it was
4 aware that its textured implants regularly contained contaminants, fragments, particles,
5 and impurities in violation of 21 C.F.R. Part 820 and 21 U.S.C. 351.

6 165. On information and belief, BIOCELL Textured Breast Implants were
7 adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream
8 of commerce by ALLERGAN, in that the methods used in, or the facilities or controls
9 used for, their manufacture, packing, storage, or installation were not in conformity with
10 the CGMP design controls enumerated in 21 C.F.R. Part 820 designed to prevent
11 exposing patients to risks of serious injury or death when the device is used as intended
12 by the surgeon.

13 166. ALLERGAN violated these regulations, in part, by failing to establish
14 norms and guidelines for biocompatibility, mechanical properties of the shell, modes of
15 sterilization, packaging, and most importantly, surface texturing. As a result,
16 ALLERGAN's BIOCELL textured surface—produced through its unique lost-salt
17 technique—leaves many irregular depressions on the surface of the shell. These pores
18 are—in both diameter and height—significantly larger and much more aggressive than
19 the manufacturing and design specifications mandated by the FDA as part of the PMAs,
20 as well as industry standards where nodules are typically a fraction of the size.

21 167. Moreover, this extreme texturing process routinely leads to the shedding
22 of debris from the implant surface, resulting in significantly greater quantities of silicone
23 particles in the surrounding capsules than the industry standard and the product
24 specifications. These shredded particles, over time, give rise to chronic inflammation
25 which in turn leads to BIA-ALCL.

26 168. It was the duty of ALLERGAN to comply with the FDA's Quality System
27 Regulations and Current Good Manufacturing Practices. Yet notwithstanding this duty,
28 ALLERGAN violated the FDCA and the regulations promulgated pursuant to it.

1 169. As a consequence, ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21
2 C.F.R. Part 820 by introducing or delivering for introduction into interstate commerce a
3 device that was adulterated.

4 170. ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820 by
5 receiving in interstate commerce a device that was adulterated and delivering the device
6 for pay or otherwise.

7 171. ALLERGAN violated 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820 by
8 manufacturing a device that was adulterated.

9 172. ALLERGAN violated 21 C.F.R. § 820.30 by failing to establish and maintain
10 procedures for validating the device design of BIOCELL Textured Breast Implants to
11 ensure that the implants conformed to patients' needs and intended uses, including
12 failing to test production units under actual or simulated use conditions.

13 173. ALLERGAN violated 21 C.F.R. § 820.50 by failing to establish and maintain
14 procedures to ensure that all purchased or otherwise received product and services
15 conform to specified requirements, including evaluating and selecting potential
16 suppliers, contractors, and consultants on the basis of their ability to meet quality
17 requirements; defining the type and extent of control to be exercised over the product,
18 services, suppliers, contractors, and consultants, based on the evaluation results; and
19 establishing and maintaining records of acceptable suppliers, contractors, and
20 consultants.

21 174. ALLERGAN violated 21 C.F.R. § 820.70(a) by failing to develop, conduct,
22 control, and monitor production processes to ensure that the BIOCELL Textured Breast
23 Implants conformed to their specifications, as well as maintaining process controls to
24 ensure conformance to specifications. This includes, but is not limited to, ensuring that
25 the any BIOCELL Textured Breast Implants did not exceed the maximum allowable
26 roughness.

27 175. ALLERGAN violated 21 C.F.R. § 820.70(h) with respect to its lost-salt
28 process of texturizing by failing to establish and maintain procedures for the use and

1 removal of such manufacturing materials to ensure that the amount of silicone particles
2 embedded on the implant due to this texturizing process is limited to an amount that
3 does not adversely affect the device's quality.

4 176. ALLERGAN violated 21 C.F.R. § 820.90(a) by failing to establish and
5 maintain procedures to control texturized implants that do not conform to specification,
6 including failing to adequately identify, document, evaluate, segregate, and dispose of
7 nonconforming implants.

8 177. ALLERGAN, in violation of 21 C.F.R. § 820.100(a), failed to establish and
9 maintain procedures for implementing corrective and preventive action in order to
10 properly detect recurring quality problems related to the lost-salt process, investigate
11 causes of nonconformities, identifying necessary action to correct and prevent
12 recurrence of nonconforming implants, implementing changes in methods to correct
13 such quality problems, and validating the corrective and preventive action.

14 178. ALLERGAN violated 21 C.F.R. § 820.22 by failing to establish procedures
15 for quality audits to determine the effectiveness of the quality system and to ensure
16 corrective action related to BIOCELL Textured Breast Implants be taken as necessary.

17 179. ALLERGAN failed to adequately inspect, test, and validate BIOCELL
18 Textured Breast Implants after completion of assembly and immediately before delivery
19 for implantation into consumers, like Plaintiff SUSAN MROWIEC, to mitigate the
20 development of bacterial accumulation and other risks which cause BIA-ALCL, as
21 mandated by 21 C.F.R. § 820.160.

22 180. Upon information and belief, when BIOCELL Textured Breast Implants
23 were manufactured, ALLERGAN had the technological capability to manufacture
24 BIOCELL Textured Breast Implants in a reasonably safe manner and ALLERGAN is
25 held to the level of knowledge of an expert in the field. ALLERGAN itself had
26 alternative measures to make a safer product but chose not to do so in the interests of
27 further its profits.

28

1 181. Plaintiff SUSAN MROWIEC was injured as a result of Defendants' post-
2 market failure to properly implement Good Manufacturing Practices, and as a result of
3 Defendants' post-market negligence, ALLERGAN's BIOCELL Textured Breast Implants
4 belatedly became known to be defective and unreasonably dangerous only after having
5 been implanted in Plaintiff.

6 182. As a result of its failure to establish and maintain effective post-market
7 quality control standards and good manufacturing practices to ensure defect-free
8 products, Plaintiff suffered severe injuries.

9 183. Also, under state law, which does not impose duties or requirements
10 materially different from those imposed by federal law, the manufacturer must
11 adequately inspect, test, and validate its product and its components, and monitor its
12 manufacturing and quality control processes to ensure there are no deviations from
13 product specifications or regulations that could affect the safety of its products, such as
14 the BIOCELL Textured Breast Implants.

15 184. As a result of ALLERGAN's post-market failure to properly implement
16 quality control procedures required by federal statute and FDA regulations, as a as a
17 result of ALLERGAN's post-market negligence, the products were defective and
18 unreasonably dangerous when implanted in Plaintiff.

19 **D. Statement of Facts Applicable to Plaintiff's Intentional and Negligent**
20 **Misrepresentation Claims**

21 **1. ALLERGAN spent years downplaying or dismissing the growing link**
22 **between BIA-ALCL and the presence of an ALLERGAN BIOCELL**
23 **Textured Breast Implant**

24 185. The first line of BIOCELL Textured Breast Implants was submitted for
25 PMA in November 1999 and approved by the FDA in May 2000 under PMA No.
26 P990074. These previously unregulated implants were then known as McGhan Medical
27 RTV Saline-Filled Breast Implants and utilized ALLERGAN's BIOCELL lost-salt
28 technology.

186. But approximately three years prior to that approval, in 1997, the first reported case of ALCL in a patient with a McGhan Medical RTV Saline-Filled Breast Implant (Style 168—one of the recalled implant styles) was published in the journal of Plastic and Reconstructive Surgery. Notably, the location for the lymphoma was encased in the right breast area, evidencing it was related to the implant itself.

187. Since then, there have been dozens of medical studies and regulatory alerts examining the progression of BIA-ALCL related knowledge, with one of the earliest studies being commissioned by ALLERGAN.

188. In 2003, a team of ALLERGAN consultants, advisors, and research coordinators initiated a 14-year prospective clinical study concerning 42,035 BIOCELL Textured Breast Implants and their link to BIA-ALCL.

189. Importantly, the ALLERGAN Study was not designed to determine whether there exists a link between BIOCELL Textured Breast Implants to BIA-ALCL—*that fact was already presumed by the ALLERGAN Study*. Instead, the ALLERGAN Study was seeking to determine if employing certain sterilization techniques at the time of implantation of a BIOCELL Textured Breast Implants would mitigate the risk of developing BIA-ALCL in light of the disease's nexus to bacterial accumulation.²¹

190. Also in 2003, a case report and review of the literature in The Archives of Pathology and Laboratory Medicine, *Anaplastic Large Cell Lymphoma Arising in a Silicone Breast Implant Capsule: A Case Report and Review of the Literature*, that a silicone gel-filled implant placed in the left breast in 1991 resulted in BIA-ALCL in the left breast diagnosed in March 2000. Notably, pathology of the left breast capsule showed refractile material consistent with silicone particles in close proximity to the tumor cells.

191. In 2007, ALLERGAN received at least three complaints of BIA-ALCL in women implanted with silicone filled breast implants, two of which were confirmed to have been implanted with ALLERGAN textured breast implants. The number of

²¹ *Macrot textured Breast Implants with Defined Steps to Minimize Bacterial Contamination around the Device: Experience in 42,000 Implants*. Plastic and Reconstructive Surgery. 140. 427-431.

1 complaints received by ALLERGAN of BIA-ALCL in women implanted with saline
2 filled breast implants for the same time period is still unknown.

3 192. BIA-ALCL first garnered attention after 2008, when a study described four
4 patients with a CD30-positive T-cell lymphoproliferative disorder surrounding breast
5 implants.

6 193. In November 2008, the Journal of the American Medical Association
7 published a study by a group of Dutch researchers that had identified 11 patients with
8 breast implants and reported BIA-ALCL of the breast diagnosed between 1990 and 2006.
9 The study found a positive association between breast implants and the development of
10 ALCL, with an odds ratio of 18:1—meaning that patients with implants were 18 times
11 more likely to develop BIA-ALCL than patients without breast implants.

12 194. In 2008, ALLERGAN received at least nine complaints of BIA-ALCL in
13 women implanted with silicone filled breast implants, five of which were confirmed to
14 have been implanted ALLERGAN textured breast implants. The number of complaints
15 received by ALLERGAN of BIA-ALCL in women implanted with saline filled breast
16 implants for the same time period is still unknown.

17 195. On November 24, 2008, a healthcare professional reports to an
18 ALLERGAN employee the events of BIA-ALCL and seroma. Rather than reporting the
19 event to the FDA in an MDR, ALLERGAN buries the complaint in the 2009 Alternative
20 Summary Reporting spreadsheet.

21 196. In 2009, ALLERGAN received at least six complaints of BIA-ALCL in
22 women implanted with silicone filled breast implants, three of which were confirmed to
23 have been implanted with ALLERGAN textured breast implants. The number of
24 complaints received by ALLERGAN of BIA-ALCL in women implanted with saline
25 filled breast implants for the same time period is still unknown.

26 197. In 2010, ALLERGAN received at least four complaints of BIA-ALCL in
27 women implanted with silicone filled breast implants. The number of complaints of BIA-
28

1 ALCL in women implanted with saline filled breast implants for the same time period is
2 still unknown.

3 198. On May 25, 2010, ALLERGAN files an MDR for the first time following an
4 event of BIA-ALCL associated with one of their saline-filled breast implants which
5 resulted in the death of the patient. The entirety of ALLERGAN's manufacturer
6 narrative for this death was redacted by ALLERGAN as "(b)(4)" meaning the
7 information constitutes "trade secrets and commercial or financial information."

8 199. In January 2011, the FDA issued a report titled "Anaplastic Large Cell
9 Lymphoma (ALCL) In Women with Breast Implants." The report stated that "in a
10 thorough review of scientific literature published from January 1997 through May 2010,
11 the FDA identified 34 unique cases of ALCL." The FDA concluded, *"The FDA believes*
12 *that there is a possible association between breast implants and ALCL."* The FDA
13 further noted that, "ALCL has been found *more frequently in association with breast*
14 *implants having a textured outer shell rather than a smooth outer shell."*

15 200. Despite the FDA's January 2011 Report, a spokeswoman for ALLERGAN,
16 whose products were linked to the cases, downplayed the concerns in an emailed
17 statement: *"A woman is more likely to be struck by lightning than get this condition,"*
18 said Caroline Van Hove. "Patients' safety is Allergan's absolute first priority and *we*
19 *continue all efforts to collect and analyze further information about the very rare*
20 *occurrence of ALCL in patients with breast implants."*

21 201. In 2011, ALLERGAN received at least nine complaints of BIA-ALCL in
22 women implanted with silicone filled breast implants, all nine of which were confirmed
23 to have been implanted with ALLERGAN textured breast implants. The number of
24 complaints received by ALLERGAN of BIA-ALCL in women implanted with saline
25 filled breast implants for the same time period is still unknown.

26 202. On March 16, 2011, the FDA received the first MDR from ALLERGAN for
27 an event of BIA-ALCL associated with one of their silicone filled breast implants where
28 the operative notes described a "moderate brown liquid" in the implant capsule.

1 203. In 2012, the first cases of BIA-ALCL in women with breast implants began
2 to be reported in Australia. This prompted ALLERGAN to publish a second study, in
3 May 2012, estimating the incidence of developing BIA-ALCL at 1.46 for every 100,000
4 breast implants.

5 204. The ALLERGAN-sponsored study was described as using “crude figures,”
6 but nevertheless was used by the company to downplay the risk to patients and
7 effectively served to silence debate among academics and regulators on the emerging
8 issue.

9 205. In 2012, ALLERGAN received at least seventeen complaints of BIA-ALCL
10 in women implanted with silicone filled breast implants, fourteen of which were
11 confirmed to have been implanted with ALLERGAN textured breast implants. The
12 number of complaints received by ALLERGAN of BIA-ALCL in women implanted with
13 saline filled breast implants for the same time period is still unknown.

14 206. In 2013, ALLERGAN received at least twenty-two complaints of BIA-
15 ALCL in women implanted with silicone filled breast implants, twenty-one of which
16 were confirmed to have been implanted with ALLERGAN textured breast implants. The
17 number of complaints received by ALLERGAN of BIA-ALCL in women implanted with
18 saline filled breast implants for the same time period is still unknown.

19 207. On December 8, 2014, a major analysis of the breast implant and BIA-
20 ALCL connection was published, which identified 173 cases of BIA-ALCL. The authors
21 reviewed 37 articles in the world literature reporting on 79 patients and collected
22 another 94 unreported cases. The study confirmed that there are no known pure smooth
23 implant cases. *Additionally, the study determined that out of 170 breast implants, in 61*
24 *cases the manufacturer was unknown yet in 97 cases (or 56%) the implants were*
25 *BIOCELL Textured Breast Implants.*

26 208. In 2014, ALLERGAN received at least twenty-six complaints of BIA-ALCL
27 in women implanted with silicone filled breast implants, eighteen of which were
28 confirmed to have been implanted with ALLERGAN textured breast implants. The

1 number of complaints received by ALLERGAN of BIA-ALCL in women implanted with
2 saline filled breast implants for the same time period is still unknown.

3 209. Also, in March 2015, the French National Cancer Institute (Agence
4 Nationale de Sécurité du Médicament, "ANSM") announced, "There is a *clearly*
5 *established link* between the occurrence of this disease and the presence of a breast
6 implant."

7 210. In 2015, ALLERGAN received at least thirty-six complaints of BIA-ALCL
8 in women implanted with silicone filled breast implants, thirty-two of which were
9 confirmed to have been implanted with ALLERGAN textured breast implants. The
10 number of complaints received by ALLERGAN of BIA-ALCL in women implanted with
11 saline filled breast implants for the same time period is still unknown.

12 211. In 2016, more information continued to come out addressing the link
13 between breast implants and BIA-ALCL as regulatory agencies around the world began
14 making more definitive and stronger statements alerting of the link. For example, in
15 May 19, 2016, the World Health Organization ("WHO") issued a guidance definitively
16 linking breast implants to ALCL and officially named the disease "breast implant
17 associated ALCL."

18 212. In July 2016, the ANSM released an update stating that, based upon 29
19 cases of ALCL reported, and due to the predominance of textured cases, it was calling
20 for all implant manufacturers selling in France to submit clear data for textured implants
21 within the year or their respective devices would be restricted from sale.

22 213. In November 2016, Australia's Therapeutic Goods Administration
23 ("TGA") convened an expert advisory panel to discuss the association between breast
24 implants and BIA-ALCL and to provide ongoing advice. In December 2016, the TGA
25 issued a report about BIA-ALCL which indicated a substantially higher risk associated
26 with textured versus smooth implants. Furthermore, the TGA-reported incidence rate
27 was in the range of 1:1,000-10,000 for patients with textured implants.

28

1 214. On December 28, 2016, ALLERGAN sponsored a third study purported to
2 examine the incidence of capsular contracture, malposition and late seroma in patients
3 that received the ALLERGAN's Style 410 breast implant. The study found that out of the
4 17,656 patients, four developed ALCL. This would in fact suggest an incidence rate, at
5 the time of the study, of close to 1:4,000 for the now recalled Style 410 implants.
6 Nevertheless, the study found that the incidence of capsular contracture, implant
7 malposition and late seroma were low enough to conclude that, "[t]hese data reaffirm
8 the safety of the Natrelle 410 breast implant."

9 215. In April 2017, researchers from the M.D. Anderson Cancer Center in
10 Houston performed a literature review on the etiology of ALCL and confirmed that
11 "textured implants are commonly implicated in the development" of BIA-ALCL.
12 Additionally, the study pulled information from the adverse events reports from the
13 FDA's MAUDE database to determine the distribution of BIA-ALCL by manufacturer.
14 **The data showed that out of the US cases reported to the FDA MAUDE database, 184**
15 **(or 80.3%) of the ALCL cases reported were ALLERGAN's BIOCELL Textured Breast**
16 **Implants.**

17 216. In March 2018, the FDA issued an update which reported a total of 414
18 received reports of BIA-ALCL— up from 359 a year earlier. The report stated that the
19 lifetime risk for BIA-ALCL is between 1 in 3,817 and 1 in 30,000 women with textured
20 breast implants.

21 217. In August 2018, the FDA reported that of the 272 cases of BIA-ALCL for
22 which the implant surface was known, approximately 89% were textured. The FDA
23 further noted that the real number of cases and size of the risk was not known, because
24 there was a lack of information about how many women in the United States and
25 worldwide had received implants.

26 218. On August 3, 2018, researchers from the M.D. Anderson Cancer Center
27 reported that the risk of BIA-ALCL for patients implanted with ALLERGAN's BIOCELL
28 Textured Breast Implants after a decade of could be as great as 1 in 2,200. This estimate

1 was extrapolated from ALLERGAN's own two studies of its Style 410 BIOCELL
2 Textured Breast Implants, published on December 28, 2016, as discussed above. At the
3 time the study was published, four women out of 17,656 had developed BIA-ALCL. By
4 August 2018, eight women of the 17,656 had developed BIA-ALCL.

5 219. As discussed further below, and despite these mounting issues,
6 ALLERGAN continued to downplay and dismiss the prevalence of BIA-ALCL in
7 connection with its Textured Breast Implants, and continued to market, sell, distribute,
8 and push those implants onto consumers, including Plaintiff, around the world.

9 **2. As early as 2010, when ALLERGAN would publicly address BIA-ALCL**
10 **in its adverse event reports, they were riddled with half-truths and**
11 **misrepresentations**

12 220. Despite actually possessing exclusive knowledge about the risks of BIA-
13 ALCL particular to the BIOCELL Textured Breast Implants, for decades ALLERGAN
14 failed to publish, disseminate, or otherwise communicate, in any form, and by any
15 means, the true risk of BIA-ALCL. ALLERGAN omitted material information about the
16 disease not just to the FDA, but also to the medical and scientific community, device
17 user facilities, and consumers like Plaintiff as part of a deliberate and intentional effort to
18 induce such persons and entities to rely on the omissions and to allow the BIOCELL
19 Textured Breast Implants to be in and remain in the marketplace for purchase. Through
20 its omissions alone, ALLERGAN actively conspired to and did conceal the risks of BIA-
21 ALCL associated with the BIOCELL Textured Breast Implants.

22 221. Moreover, despite the growing number of complaints, studies and
23 concerns regarding the link between textured implants and BIA-ALCL, ALLERGAN
24 continued to make false and misleading statements regarding BIA-ALCL and the
25 presence of an ALLERGAN BIOCELL Textured Breast Implant.

26 222. In particular, ALLERGAN's false and incomplete statements surfaced in its
27 hundreds of adverse event reports prepared following events of BIA-ALCL.

28

1 223. ALLERGAN had a duty on all matters related to events of BIA-ALCL
2 associated with their BIOCELL Textured Breast Implants to report in a manner that
3 avoided making any written or oral communication containing an untrue statement or
4 omitting any material fact necessary to make statements made, in light of the
5 circumstances under which they were made, not misleading.

6 224. However, as part of a scheme designed to downplay the risks of BIOCELL
7 Textured Breast Implants in the MDRs and to induce the FDA, the medical and scientific
8 community, device user facilities, and consumers like Plaintiff into believing that there
9 was no unique risks of BIA-ALCL associated with their BIOCELL Textured Breast
10 Implants in order to sell more implants, ALLERGAN willfully concealed and failed to
11 disclose all information reasonably known to it in the adverse event reports.

12 225. In hundreds of adverse event reports following complaints from health
13 care facilities, hospitals, physicians, nurse, and the patients themselves pertaining to
14 events related to BIA-ALCL, rather than providing an honest account of the relationship
15 between the device and the occurrence of BIA-ALCL in the report based on the
16 knowledge in its possession as required by the applicable regulations, ALLERGAN for
17 years provided incomplete information and/or simply quoted its device labeling.

18 226. For example, in an MDR dated November 1, 2010, ALLERGAN stated in
19 its narrative for an event of BIA-ALCL:

20 Device labeling addresses [. . .] *There were no reported events of cancer*
21 *including lymphoma for patients in the a95/r95 study included in the*
22 *labeling for saline breast implants* [. . .] "If unusual symptoms occur after
23 surgery, such as fever or noticeable swelling or redness in one breast, you
24 should contact your surgeon immediately. "

25 227. Again, in a medical device report regarding BIA-ALCL dated March 25,
26 2011, ALLERGAN stated:

27 Device labeling addresses: there were no reported event of lymphoma/alcl
28 for pts in the (b)(4) study included in the labeling for saline breast
implants. "if unusual symptoms occur after surgery, such as fever or

noticeable swelling or redness in one breast, you should contact your surgeon immediately. "

228. On March 12, 2012:

Device labeling reviewed: there were no reported events of lymphoma/alcl, for pts in the core study, in the labeling for silicone implants.

229. On December 27, 2012:

Allergan product labeling for saline implants: there were no reported events of lymphoma/alcl, for patients in the (b)(4) study, as well as the (b)(4) study ((b)(4) study) included in the labeling for saline breast implants.

230. On May 2, 2014:

Device labeling reviewed: there were no reported events of lymphoma/alcl observed in the care study, in the labeling for silicone implants. There were no reported events of lymphoma/alcl observed in the (b)(4) study included in the labeling for saline breast implants.

231. On March 3, 2015:

Potential adverse events that may occur with saline-filled breast implant surgery include: [. . .] Published studies indicate that breast cancer is no more common in women with implants than those without implants. *A large, long-term follow-up found no significant increases in the risk rates for a wide variety of cancers, including stomach cancer, leukemia, and lymphoma.*

232. On June 25, 2015:

Based on the info reported to fda and found in medical literature, *a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl)*, a type of non-hodgkins' lymphoma. Women with breast implants may have a very small but increased risk of developing alcl in the fluid or scar capsule adjacent to the implant. *Alcl has been reported globally in pts with an implant history that includes allergan's and other mfrs' breast implants.*

233. On March 21, 2016:

Device labeling addresses: "lymphoma, including anaplastic large t-cell lymphoma (alcl) - information from medical literature has suggested a possible association, *without evidence of causation*, between breast implants and the very rare occurrence of alcl in the breast. *The disease is*

1 *exceptionally rare*, may present as a late occurring peri-prosthetic seroma,
2 and *occurs in women with and without breast implants*.

3 234. On July 26, 2017:

4 Device labeling: alcl has been reported globally in patients with an *implant*
5 *history that includes allergan's and other manufacturers' breast implants*.

6 You should consider the possibility of alcl when you have a patient with
late onset, persistent peri-implant seroma.

7 235. Finally, after a decade of disinformation but nonetheless still inadequately,
8 on February 24, 2018, ALLERGAN begins to state:

9 Based on information reported to global regulatory agencies and found in
10 medical literature, *an association* has been identified *between breast*
11 *implants and the development of anaplastic large cell lymphoma (alcl)*, a
12 type of non-hodgkin's lymphoma. Women with breast implants may have
13 a very small but increased risk of developing breast implant associated alcl
14 (bia-alcl) in the fluid or scar capsule adjacent to the implant, with
15 documented potential for local, regional, and distant spread of the cancer
16 with mortality reported in rare cases. *Bia-alcl has been reported globally*
17 *in patients with an implant history that includes allergan's and other*
18 *manufacturers' breast implants with various surface properties, styles,*
19 *and shapes*. Most of the cases in the literature reports describe a history of
the use of *textured implants*.

20 236. In light of ALLERGAN's sophisticated knowledge of the nature of the BIA-
21 ALCL and its relationship to its BIOCELL Textured Breast Implant—which was
22 exclusively known internally within ALLERGAN as early as 2003—each of the above-
23 representations by ALLERGAN, and the hundreds more like them, were false,
24 incomplete, and misleading in the context in which they were made, and were known to
be so when made.

25 237. The principle fraudulent omission in these adverse events was the failure
26 to acknowledge that BIA-ALCL is exclusively found in textured implants and that
27 ALLERGAN's BIOCELL Textured Breast Implants are, *by far*, associated with more cases
28 than any other type of textured implant.

1 238. These representations created the false impression that the full extent of
2 BIA-ALCL's relationship with the textured breast implants was already a known and
3 disclosed risk, and further that ALLERGAN's breast implants were no more likely to be
4 found in individuals suffering from BIA-ALCL than other companies' products.

5 239. Plaintiff, by and through the FDA, medical and scientific community, and
6 her device user facility, justifiably relied upon ALLERGAN's misleading and incomplete
7 representations concerning BIA-ALCL and its nexus to the BIOCELL Textured Breast
8 Implants. Unaware of the true risks of BIA-ALCL, Plaintiff succumbed to the
9 misrepresentations of ALLERGAN, and on or about April 2017, was implanted with
10 BIOCELL Textured Breast Implants.

11 240. Had Plaintiff known the true facts relating to BIA-ALCL and its nexus to
12 the BIOCELL Textured Breast Implants, Plaintiff would not have elected to be implanted
13 with BIOCELL Textured Breast Implants, but rather would have chosen a different style
14 of implant or forwent implantation altogether.

15 **E. Statement of Facts Relating to Causation Applicable to All Counts**

16 **1. The connection between ALLERGAN's failure to report and Plaintiff's**
17 **injuries**

18 241. As a result of Allergan's failure to appropriately file MDRs to the FDA as
19 required by 21 U.S.C. 360i and 21 C.F.R. § 803.50—its BIOCELL textured implants were
20 misbranded post-market.

21 242. Plaintiff further alleges that Defendants failed to take reasonable post-
22 market corrective action to warn, either directly or through an appropriate channel,
23 physicians who had implanted its devices, and patients in whom they had been
24 implanted, of the risks of BIA-ALCL.

25 243. Such warnings, had they been given, would have caused physicians and
26 patients, like Plaintiff, to take proper precautions to determine whether the substantially
27 increased risk of BIA-ALCL should be avoided by electing not to use ALLERGAN's
28

1 BIOCELL Textured Breast Implants. Or, the FDA would have recalled the BIOCELL
2 Textured Breast Implants before Plaintiff ever had them implanted.

3 244. Allergan was or should have been aware as early as 1997 that its BIOCELL
4 Textured Breast Implants carried a much greater risk of BIA-ALCL than other textured
5 implant products, or compared to smooth implant products—yet Allergan failed to give
6 effective post-market notice to the FDA, physicians, and patients to put them on
7 adequate notice of the problem, and failed to inform them of how to avoid that risk.

8 245. Also, under state law, which does not impose duties or requirements
9 materially different from those imposed by federal law, the manufacturer must timely
10 and appropriately report adverse events concerning the safety of its products.
11 ALLERGAN was under a continuing duty under state law to adequately report injuries
12 and problems with its devices, including the BIOCELL Textured Breast Implants, to the
13 FDA.

14 246. As a result of Allergan's post-market failure to properly implement
15 procedures required by federal statute and FDA regulations, and as a result of
16 ALLERGAN's post-market negligence, the defective and unreasonably dangerous
17 nature of the product became known only after having been implanted in Plaintiff, and
18 otherwise would have never would have been implanted in the Plaintiff at all.

19 **2. The connection between ALLERGAN's failure to implement quality**
20 **control systems and Plaintiff's injuries**

21 247. As a result of ALLERGAN's failure to establish such quality systems as
22 required by 21 C.F.R. Part 820—its BIOCELL Textured Implants were adulterated within
23 the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by
24 ALLERGAN.

25 248. Plaintiff further alleges that Defendants failed to take reasonable post-
26 market corrective and preventive action in order to properly detect recurring quality
27 problems related to the lost-salt process and implement changes in methods to correct
28 such quality problems.

1 249. Such corrective and preventive action, had they been implemented, would
2 have prevented Plaintiff from being exposed to an aggressive, potentially fatal form of
3 lymphoma. Or, the FDA would have recalled the BIOCELL Textured Breast Implants
4 before Plaintiff ever had them implanted.

5 250. Also under state law, which does not impose duties or requirements
6 materially different from those imposed by federal law, the manufacturer must
7 adequately inspect, test, and validate its product and its components, and monitor its
8 manufacturing and quality control processes to ensure there are no deviations from
9 product specifications or regulations that could affect the safety of its products, such as
10 the BIOCELL Textured Breast Implants.

11 251. As a result of ALLERGAN's post-market failure to properly implement
12 quality control procedures required by federal statute and FDA regulations, as a as a
13 result of ALLERGAN's post-market negligence, the products were defective and
14 unreasonably dangerous when implanted in Plaintiff.

15 252. ALLERGAN was or should have been aware as early as 1997 that its
16 BIOCELL Textured Breast Implants carried a much risk of BIA-ALCL than other
17 textured implant products, or compared to smooth implant products—yet ALLERGAN
18 failed to implement effective post-market action to mitigate or eliminate the risk of BIA-
19 ALCL, and failed to inform physicians and patients of how that risk could be avoided.

20 **3. The connection between ALLERGAN's misrepresentations and**
21 **Plaintiff's injuries**

22 253. As discussed above, adverse event reports published in the FDA's
23 MAUDE database represent a public communication by a manufacturer about a device's
24 performance and its relationship to a particular adverse health event.

25 254. These adverse event reports are routinely reviewed by the FDA to monitor
26 device performance, detect potential device-related safety issues, and contribute to
27 benefit-risk assessments of these products.

28

1 255. Moreover, such reports are relied upon by the medical and scientific
2 community, including cancer researchers as described above, as a valuable source of
3 information in learning about the genesis of an adverse health event and any adverse
4 health trends associated with a medical device.

5 256. Device user facilities, including hospitals, outpatient facilities, nursing
6 homes and surgical facilities, routinely analyze the medical device reports when
7 determining the risks of selling one particular medical device over another, or one brand
8 over another. For example, with respect to breast implants, a device user facility relies
9 upon the information contained in the medical device reports when deciding whether to
10 sell smooth or textured implants, or ALLERGAN's brand over a competitor.

11 257. To the extent the medical device reports contain false, inaccurate, or
12 incomplete information, the FDA is deprived of vital information needed to detect
13 potential device-related safety issues and disseminate public alerts about particular
14 device problem and/or its association to a particular disease.

15 258. Likewise, the medical and scientific community is deprived of the
16 information needed to educate their patients and obtain informed consent about the
17 risks in choosing a particular device.

18 259. Further, device user facilities are unable to make informed decisions about
19 the risks of offering for purchase a particular medical device over others on the market.

20 260. ALLERGAN fraudulently omitted in its adverse event reports associated
21 with the BIOCELL Textured Breast Implants that BIA-ALCL is exclusively found in
22 textured implants and that ALLERGAN's BIOCELL Textured Breast Implants are
23 associated with more cases than any other type of textured implant.

24 261. These incomplete representations created the false impression that the full
25 extent of BIA-ALCL's relationship with the textured breast implants was already a
26 known and disclosed, and further that ALLERGAN's breast implants were no more
27 likely to be found in individuals suffering from BIA-ALCL than other companies'
28 products.

1 262. Moreover, ALLERGAN had actual knowledge of the material facts as
2 alleged herein regarding the risks of BIA-ALCL and the presence of an ALLERGAN
3 BIOCELL Textured Breast Implant. However, for decades, ALLERGAN outright failed
4 or refused disclose such facts in any form, whether it by through their adverse event
5 reports or any other communication, although such facts were readily available.

6 263. Plaintiff, by and through the FDA, medical and scientific community, and
7 her device user facility, justifiably relied upon ALLERGAN's omissions, and misleading
8 and incomplete representations concerning BIA-ALCL and its nexus to the BIOCELL
9 Textured Breast Implants. Unaware of the true risks of BIA-ALCL, Plaintiff succumbed
10 to the omissions and misrepresentations of ALLERGAN, and in or about 2014 and 2016,
11 was implanted with BIOCELL Textured Breast Implants.

12 264. As a result of Allergan's failure to disclose all of the known risks associated
13 with BIOCELL Textured Breast Implants and BIA-ALCL, including in the adverse event
14 reports, and as a result of ALLERGAN's fraudulent misrepresentations and omissions,
15 the defective and unreasonably dangerous nature of the product became known only
16 after having been implanted in Plaintiff, and otherwise would have never would have
17 been implanted in the Plaintiff at all.

18
19 **FIRST CAUSE OF ACTION**

20 **(Strict Product Liability-Failure to Warn)**

21 **Against All Defendants**

22 265. Plaintiff incorporates by reference all preceding paragraphs of this
23 Complaint as if fully set forth herein and further alleges as follows:

24 266. At all times pertinent hereto, Defendants directly or through their agents,
25 apparent agents, servants or employees designed, manufactured, tested, marketed, and
26 commercially distributed its BIOCELL Textured Breast Implants to clinics, hospitals and
27 plastic surgeons, who ultimately operated and implanted them in consumers' bodies.
28

1 267. Defendants directly or through their agents, apparent agents, servants or
2 employees designed, manufactured, tested, marketed, and commercially distributed the
3 BIOCELL Textured Breast Implants implanted into Plaintiff's body.

4 268. The BIOCELL Textured Breast Implants that were implanted into Plaintiff
5 were defective and unreasonably dangerous when they left the possession of the
6 Defendants as a result of inadequate warnings, including:

- 7 (a) failing to provide adequate warnings, information, or both, to alert
8 consumers and their prescribing physicians that the BIOCELL Textured
9 Breast Implants posed an unreasonably high risk of causing BIA-ALCL
10 once implanted;
- 11 (b) failing to properly market the BIOCELL Textured Breast Implants in light
12 of the BIOCELL Textured Breast Implants' cancerous propensities;
- 13 (c) failing to ensure the performance of the BIOCELL Textured Breast
14 Implants conformed to the representations made by Defendants
15 concerning the risk of BIA-ALCL; and
- 16 (d) representing that the BIOCELL Textured Breast Implants were suitable for
17 their intended use; and
- 18 (e) failing to handle the BIOCELL Textured Breast Implants in a manner that
19 conformed to applicable federal laws and regulations.

20 269. Such warnings, if given, would have caused such physicians and patients
21 to be informed when selecting the appropriate breast implant and would have enabled
22 patients, including Plaintiff, to avoid the risks of developing BIA-ALCL.

23 270. Rather, Defendants continued to disseminate product labeling that was
24 inadequate and defective despite having received post-market information regarding
25 BIA-ALCL after the FDA approved such labeling—information Defendants failed to
26 report to FDA in violation of the MDA and the regulations promulgated thereunder.

27 271. At all relevant times, under federal law and regulation, Defendants were
28 under a continuing duty to monitor the product after premarket approval, and to

1 discover and report to the FDA any complaints about the product's performance and
2 any adverse health consequences or AERs of which it became aware and that are, or may
3 be, attributable to the product.

4 272. Defendants failed to submit appropriate medical device reports to inform
5 the FDA of the danger of developing BIA-ALCL in connection with the BIOCELL
6 Textured Breast Implants, as required by 21 C.F.R. § 803.50, even though they should
7 have been aware of such adverse incidents and were actually aware of such incidents,
8 including at least 22 events of BIA-ALCL Defendants had received between 2007-2010.

9 273. Instead, ALLERGAN exploited the FDA's non-public ASR program to
10 bury evidence of its BIOCELL Textured Breast Implants causing BIA-ALCL. As a result,
11 Defendants failed to fulfill its duty to report to the FDA per 21 C.F.R. § 803.50 and warn
12 physicians or patients—including Plaintiff—implanted with ALLERGAN's BIOCELL
13 Textured Breast Implants of the dangers of BIA-ALCL.

14 274. In addition to its unlawful use of the ASR program, ALLERGAN failed to:

- 15 (a) Investigate and evaluate complaints of BIA-ALCL per 21 C.F.R. §§ 820.198
16 and 803.18(e) and prepare corresponding medical device reports;
- 17 (b) Timely submit reports of BIA-ALCL per 21 C.F.R. § 803.50(a) and instead
18 attempted to transmit such reports years after first receiving notice of the
19 event;
- 20 (c) Provide all information reasonably known to it per 21 C.F.R. § 803.50(b) in
21 its reports of BIA-ALCL but rather simply regurgitated its misleading and
22 deficient labeling; and
- 23 (d) Use the appropriate device problem code for reports of BIA-ALCL per 21
24 C.F.R. § 803.52 but instead represented there was "no apparent adverse
25 event."

26 275. Defendants, as developers and manufacturers of the BIOCELL Textured
27 Breast Implants, are held to the level of knowledge of experts in the field of that type of
28

1 breast implant and had a duty to warn its consumers and prescribing physicians of the
2 dangers associated with the implants and failed to do so.

3 276. At the time Plaintiff's physician implanted the BIOCELL Textured Breast
4 Implants, her physician did not have substantially the same knowledge as the
5 Defendants about the unreasonably high risks of causing BIA-ALCL because the
6 Defendants failed to provide adequate warnings of those risks.

7 277. As the direct and proximate result of Defendants' failure to warn of the
8 defective condition of the BIOCELL Textured Breast Implants, the Plaintiff was
9 implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful
10 removal procedures to mitigate the risk of developing BIA-ALCL, as well as any
11 treatment, therapy, recovery, and expense associated with the removal of the BIOCELL
12 Textured Breast Implants, the potential for the development of BIA-ALCL, and any
13 condition or symptoms associated with BIA-ALCL or the prevention of that issue.

14 278. As a further proximate result of Defendants' failure to warn of the
15 defective condition of the BIOCELL Textured Breast Implants, Plaintiff suffered
16 debilitating physical pain and mental suffering, was/will be required to undergo
17 additional surgeries and other procedures, incurred substantial hospital, medical,
18 nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety,
19 depression and disability; loss of earnings; and loss of quality of life, and all of these
20 injuries are permanent and continuing.

21 279. The FDCA contains an express preemption provision, 21 U.S.C. 360k(a),
22 which as relevant, states: "no State or political subdivision of a State may establish or
23 continue in effect with respect to a device intended for human use any requirement-- (1)
24 which is different from, or in addition to, any requirement applicable under this Act to
25 the device, and (2) which relates to the safety or effectiveness of the device or to any
26 other matter included in a requirement applicable to the device under this Act."

27 280. This cause of action is based on the Defendants' post-market violations of
28 federal safety statutes and regulations.

281. Moreover, Plaintiff does not bring the underlying action as an implied statutory cause of action but rather she is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal statutes and regulations.

282. Plaintiff's strict product liability for failing to warn claim is, thus, not preempted by Section 360k(a), because the violations alleged are all based on federal statutory and regulatory standards which includes no "requirement which is different from, or in addition to, any requirement applicable under" the FDCA and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the FDCA and regulations promulgated thereunder.

SECOND CAUSE OF ACTION

(Strict Product Liability-Manufacturing Defect)

Against All Defendants

283. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

284. At all times material hereto, Defendants, directly or indirectly, created, manufactured, assembled, designed, sterilized, tested, packaged, labeled, marketed, promoted, advertised, sold and/or distributed into the stream of commerce BIOCELL Textured Breast Implants, including the BIOCELL Textured Breast Implants implanted into Plaintiff.

285. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed the BIOCELL Textured Breast Implants implanted into Plaintiff's body.

286. The BIOCELL Textured Breast Implants that were implanted into Plaintiff were defective and unreasonably dangerous when they left the possession of the Defendants in one or more of the following ways:

- (a) manufacturing and selling BIOCELL Textured Breast Implants that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval, and/or other federal regulations;
- (b) manufacturing and selling BIOCELL Textured Breast Implants with nonconforming materials and uncertified components, inconsistent with the specifications set forth in the PMA, its Supplements, the Conditions of Approval, or other federal regulations;
- (c) manufacturing, distributing, and selling BIOCELL Textured Breast Implants knowing, or while capable of knowing, that they created an unreasonably high risk of causing BIA-ALCL when implanted into patients, including the Plaintiff;
- (d) incorporating components into BIOCELL Textured Breast Implants that could not stand up to normal usage;
- (e) failing or refusing to properly meet the applicable standard of care by not complying with applicable federal laws and regulations in manufacturing, marketing, selling, and distributing the BIOCELL Textured Breast Implants;
- (f) failing or refusing to include adequate warnings with the device that would alert Plaintiff and her prescribing physician to the potential risks and serious side effects of the BIOCELL Textured Breast Implants;
- (g) failing or refusing to exercise reasonable care in its inspecting and testing of the BIOCELL Textured Breast Implants both before and after they were placed on the market which, if properly performed, would have shown that the device caused serious side effects, including BIA-ALCL;
- (h) failing or refusing to warn, or adequately warn, the Plaintiff or her prescribing physicians that the BIOCELL Textured Breast Implants created a higher risk of causing BIA-ALCL than other similar textured implants currently on the market;

- (i) failing or refusing to provide adequate post marketing warnings or instructions to the Plaintiff and her prescribing physicians of the significant risk of causing BIA-ALCL;
- (j) failing or refusing to exercise reasonable care in its manufacturing and quality control processes;
- (k) placing an unsafe and defective breast implant into the stream of commerce; and
- (l) underplaying the significant risks posed by the BIOCELL Textured Breast Implants to the public, including the Plaintiff and her prescribing physicians in order to make a profit from sale of the device.

287. Such measures, if implemented, would have mitigated or eliminated the risk posed by silicone particles shredding from the BIOCELL Textured Breast Implants and would have enabled patients, including Plaintiff, to avoid the risks of developing BIA-ALCL.

288. At all relevant times, under federal law and regulation, Defendants were also required to comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices under 21 C.F.R. Part 820, which, among other things, requires that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

289. It was the duty of the Defendants to comply with the FDCA, and the regulations promulgated pursuant to it. Yet, notwithstanding this duty, Defendants violated the FDCA and regulations in one or more of the following ways:

- (a) introducing or delivering for introduction into interstate commerce a device that was adulterated (21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820);

- 1 (b) receiving in interstate commerce a device that was adulterated and
2 delivering the device for pay or otherwise (21 U.S.C. §§ 331, 351(h) and 21
3 C.F.R. Part 820);
- 4 (c) manufacturing a device that was adulterated (21 U.S.C. §§ 331, 351(h) and
5 21 C.F.R. Part 820);
- 6 (d) failing to establish and maintain procedures for validating the device
7 design of BIOCELL Textured Breast Implants to ensure that the implants
8 conformed to patients' needs and intended uses, including failing to test
9 production units under actual or simulated use conditions (21 C.F.R.
10 §820.30);
- 11 (e) failing to establish and maintain procedures to ensure that all purchased or
12 otherwise received product and services conform to specified
13 requirements, including evaluating and selecting potential suppliers,
14 contractors, and consultants on the basis of their ability to meet quality
15 requirements; defining the type and extent of control to be exercised over
16 the product, services, suppliers, contractors, and consultants, based on the
17 evaluation results; and establishing and maintaining records of acceptable
18 suppliers, contractors, and consultants (21 C.F.R. §820.50);
- 19 (f) failing to develop, conduct, control, and monitor production processes to
20 ensure that the BIOCELL Textured Breast Implants conformed to their
21 specifications, as well as maintaining process controls to ensure
22 conformance to specifications. This includes, but is not limited to, ensuring
23 that the any BIOCELL Textured Breast Implants did not exceed the
24 maximum allowable roughness (21 C.F.R. §820.70(a));
- 25 (g) failing to establish and maintain procedures with respect to its lost-salt
26 process of texturizing for the use and removal of such manufacturing
27 materials to ensure that the amount of silicone particles embedded on the
28

1 implant due to this texturizing process is limited to an amount that does
2 not adversely affect the device's quality (21 C.F.R. §820.70(h));

3 (h) failing to establish and maintain procedures to control texturized implants
4 that do not conform to specification, including failing to adequately
5 identify, document, evaluate, segregate, and dispose of nonconforming
6 implants (21 C.F.R. §820.90(a));

7 (i) failing to establish and maintain procedures for implementing corrective
8 and preventive action in order to properly detect recurring quality
9 problems related to the lost-salt process, investigate causes of
10 nonconformities, identifying necessary action to correct and prevent
11 recurrence of nonconforming implants, implementing changes in methods
12 to correct such quality problems, and validating the corrective and
13 preventive action (21 C.F.R. §820.100(a));

14 (j) failing to establish procedures for quality audits to determine the
15 effectiveness of the quality system and to ensure corrective action related
16 to BIOCELL Textured Breast Implants be taken as necessary (21 C.F.R.
17 §820.22);

18 (k) failing to adequately inspect, test, and validate BIOCELL Textured Breast
19 Implants after completion of assembly and immediately before delivery for
20 implantation into consumers, like Plaintiff, to mitigate the development of
21 bacterial accumulation and other risks which cause BIA-ALCL (21 C.F.R.
22 §820.160); and

23 (l) failing to monitor, receive, review, and evaluate and/or investigate
24 complaints received from breast implant patients and their physicians,
25 failing to timely identifying any problems with one of its devices and,
26 failing to take appropriate corrective actions to ensure consumer safety (21
27 C.F.R. § 820.198).

1 290. Because Defendants failed to follow specifications, regulations, and
2 required good manufacturing practices, Plaintiff's BIOCELL Textured Breast Implants
3 were at a heightened risk of causing the development of BIA-ALCL.

4 291. Upon information and belief, Defendants had the technological capability
5 to manufacture BIOCELL Textured Breast Implants in a reasonably safe manner and is
6 held to the level of knowledge of an expert in the field.

7 292. As the direct and proximate result of Defendant's acts and omissions
8 concerning the BIOCELL Textured Breast Implants, the Plaintiff was implanted with
9 BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal
10 procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment,
11 therapy, recovery, and expense associated with the removal of the BIOCELL Textured
12 Breast Implants, the potential for the development of BIA-ALCL, and any condition or
13 symptoms associated with BIA-ALCL or the prevention of that issue.

14 293. As a further proximate result of Defendant's acts and omissions concerning
15 the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and
16 mental suffering, was/will be required to undergo additional surgeries and other
17 procedures, incurred substantial hospital, medical, nursing and pharmaceutical
18 expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss
19 of earnings; and loss of quality of life, and all of these injuries are permanent and
20 continuing.

21 294. The FDCA contains an express preemption provision, 21 U.S.C. 360k(a),
22 which as relevant, states: "no State or political subdivision of a State may establish or
23 continue in effect with respect to a device intended for human use any requirement-- (1)
24 which is different from, or in addition to, any requirement applicable under this Act to
25 the device, and (2) which relates to the safety or effectiveness of the device or to any
26 other matter included in a requirement applicable to the device under this Act."

27 295. This cause of action is based on the Defendants' post-market violations of
28 federal safety statutes and regulations.

296. Moreover, Plaintiff does not bring the underlying action as an implied statutory cause of action but rather she is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal statutes and regulations.

297. Plaintiff's manufacturing defect claim is, thus, not preempted by Section 360k(a), because the violations alleged are all based on federal statutory and regulatory standards which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the FDCA and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the FDCA and regulations promulgated thereunder.

THIRD CAUSE OF ACTION

(Negligence)

Against All Defendants

298. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

299. At all times pertinent hereto, Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed their BIOCELL Textured Breast Implants to clinics, hospitals and plastic surgeons, who ultimately operated and implanted them in consumers' bodies.

300. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, tested, marketed, and commercially distributed the BIOCELL Textured Breast Implants implanted into Plaintiff's body.

301. Defendants owed Plaintiff, and the public, a duty to use reasonable care in testing and inspecting their BIOCELL Textured Breast Implants, in designing the BIOCELL Textured Breast Implants placed into Plaintiff and in manufacturing and marketing those BIOCELL Textured Breast Implants.

1 302. The BIOCELL Textured Breast Implants that were implanted into Plaintiff
2 were defective and unreasonably dangerous when they left the possession of the
3 Defendants in that the BIOCELL Textured Breast Implants did not conform to applicable
4 federal laws and regulations.

5 303. At all relevant times, Defendants violated the FDA's Quality System
6 Regulations and Current Good Manufacturing Practices under 21 C.F.R. Part 820,
7 because ALLERGAN produced adulterated BIOCELL Textured Breast Implants that had
8 numerous unwanted particles and solid fragments of silicone on the implant surface in
9 violation of CGMP regulations designed to ensure device quality and patient safety.

10 304. Such measures, if implemented, would have caused mitigated or
11 eliminated the risk posed by silicone particles shredding from the BIOCELL Textured
12 Breast Implants and would have enabled patients, including Plaintiff, to avoid the risks
13 of developing BIA-ALCL.

14 305. Defendants also violated the above described post-market reporting
15 requirements under 21 C.F.R. Part 803 for the BIOCELL Textured Breast Implants, by
16 virtue of their abuses of the FDA's ASR Program and other reporting violations. As a
17 result, Defendants negligently failed to adequately warn of the dangers of BIA-ALCL
18 and test its product before Plaintiff was implanted with ALLERGAN's BIOCELL
19 Textured Breast Implants.

20 306. Such warnings, if given, would have enabled the FDA, as well as the
21 medical and scientific community, to ensure physicians and patients were adequately
22 informed when selecting the appropriate breast implant and would have enabled
23 patients, including Plaintiff, to avoid being exposed to BIA-ALCL.

24 307. Plaintiff was implanted with BIOCELL Textured Breast Implants without
25 adequate warning and with manufacturing defects, in violation of the general regulatory
26 requirements, resulting in serious injury to Plaintiff. The injuries Plaintiff suffered are
27 expected to have resulted from such defects. Plaintiff and her physician were unaware
28

1 that the BIOCELL Textured Breast Implants were defective at the time of implant and
2 thereafter.

3 308. As the direct and proximate result of Defendant's negligent acts and
4 omissions concerning the BIOCELL Textured Breast Implants, the Plaintiff was
5 implanted with BIOCELL Textured Breast Implants and suffered, or will suffer, painful
6 removal procedures to mitigate the risk of developing BIA-ALCL, as well as any
7 treatment, therapy, recovery, and expense associated with the removal of the BIOCELL
8 Textured Breast Implants, the potential for the development of BIA-ALCL, and any
9 condition or symptoms associated with BIA-ALCL or the prevention of that issue.

10 309. As a further proximate result of Defendant's negligent acts and omissions
11 concerning the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating
12 physical pain and mental suffering, was/will be required to undergo additional surgeries
13 and other procedures, incurred substantial hospital, medical, nursing and
14 pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and
15 disability; loss of earnings; and loss of quality of life, and all of these injuries are
16 permanent and continuing.

17 310. The FDCA contains an express preemption provision, 21 U.S.C. § 360k(a),
18 which as relevant, states: "no State or political subdivision of a State may establish or
19 continue in effect with respect to a device intended for human use any requirement-- (1)
20 which is different from, or in addition to, any requirement applicable under this Act to
21 the device, and (2) which relates to the safety or effectiveness of the device or to any
22 other matter included in a requirement applicable to the device under this Act."

23 311. This cause of action is based on the Defendants' post-market violations of
24 federal safety statutes and regulations.

25 312. Moreover, Plaintiff does not bring the underlying action as an implied
26 statutory cause of action but rather she is pursuing parallel state common law claims
27 based upon Defendants' violations of the applicable federal statutes and regulations.
28

1 313. Under California's doctrine of negligence per se, failure to exercise due
2 care is presumed from a violation of a "statute, ordinance, or regulation of a public
3 entity." Cal. Evid. Code, § 669(a)(1). By its terms, this doctrine applies to the law of any
4 public entity, not just California public entities. See, e.g., *DiRosa v. Showa Denko K.K.*
5 (1996) 44 Cal.App.4th 799, 808. Thus, under California law, a money damages remedy
6 exists for negligent violation of the FDCA and regulations promulgated thereunder
7 which proximately cause injuries, and there is no need for California's Legislature to act
8 in order to create such a remedy.

9 314. Plaintiff's negligence claim is, thus, not preempted by Section 360k(a),
10 because the violations alleged are all based on federal statutory and regulatory
11 standards which includes no "requirement, which is different from, or in addition to,
12 any requirement applicable under" the FDCA and regulations promulgated thereunder.
13 As such, the claims set forth in this cause of action contain requirements that are parallel
14 to the FDCA and regulations promulgated thereunder.

15 16 **FOURTH CAUSE OF ACTION**

17 **(Fraud – Intentional Misrepresentation and Concealment)**

18 **Against All Defendants**

19 315. Plaintiff incorporates by reference all preceding paragraphs of this
20 Complaint as if fully set forth herein and further alleges as follows:

21 316. Each Defendant actively participated in, agreed to, aided and abetted,
22 conspired in, and/or furthered a fraudulent scheme, as set forth herein, which conduct
23 constitutes fraud and deceit.

24 317. Defendants superior knowledge and expertise, their relationship of trust
25 and confidence with doctors and the public, their specific knowledge regarding the risks
26 and dangers of BIA-ALCL and their international dissemination of promotional and
27 marketing information about BIOCELL Textured Breast Implants for the purpose of
28 maximizing its sale, each give rise to the affirmative duty to meaningfully disclose

1 important material facts concerning the safety of the BIOCELL Textured Breast Implants,
2 specifically regarding the risks of developing BIA-ALCL.

3 318. Defendants omitted material information to the FDA, the medical and
4 scientific community, device user facilities, and consumers like Plaintiff as part of a
5 deliberate and intentional effort to induce such persons and entities to rely on the
6 omissions and to allow the BIOCELL Textured Breast Implants to be in and remain in
7 the marketplace for purchase. Through their omissions, Defendants actively conspired to
8 and did conceal the risks of BIA-ALCL associated with the BIOCELL Textured Breast
9 Implants.

10 319. Defendants omitted material information regarding the risks of BIA-ALCL
11 and the presence of an ALLERGAN BIOCELL Textured Breast Implants with intent to
12 defraud the FDA, the medical and scientific community, device user facilities, and
13 consumers like Plaintiff.

14 320. Defendants intentionally failed to disclose material facts to the FDA, the
15 medical and scientific community, device user facilities, and consumers like Plaintiff that
16 they had a duty to disclose, including the risks of BIA-ALCL associated with the
17 BIOCELL Textured Breast Implants. Each Defendant was aware of and/or approved the
18 material omissions by or on behalf of Defendants.

19 321. Moreover, Defendants made representations about BIA-ALCL but did not
20 disclose facts which materially qualified the facts disclosed, which rendered their
21 disclosure likely to mislead. The true facts about BIA-ALCL and the correlation with
22 ALLERGAN BIOCELL Textured Breast Implants were known to Defendants, and
23 Defendants knew they were not known to or reasonably discoverable by Plaintiff.

24 322. Defendants knew that their half-truths, concealment and failure to disclose
25 to Plaintiff, by and through the FDA, medical and scientific community, and her device
26 user facility, all information reasonably available to them related to the nexus between
27 BIA-ALCL and their BIOCELL Textured Breast Implants, would mislead Plaintiff by
28 creating the false impression that the full extent of BIA-ALCL's relationship with the

1 BIOCELL Textured Breast Implants was already a known and disclosed by ALLERGAN,
2 and further that ALLERGAN's breast implants were no more likely to be found in
3 individuals suffering from BIA-ALCL than other companies' products. Defendants also
4 knew that if Plaintiff became aware of the cancerous propensities associated the
5 BIOCELL Textured Breast Implants, Plaintiff would not agree to purchase said implants.

6 323. Nevertheless, in willful disregard of Plaintiff's rights and the duties owed
7 to Plaintiff by Defendants, and each of them, concealed and failed to disclose to Plaintiff
8 all information reasonably available to them related to the nexus between BIA-ALCL
9 and their BIOCELL Textured Breast Implants with the express purpose of inducing
10 Plaintiff against her own interest to purchase their cancer-inducing breast implants.

11 324. Likewise, Defendants had a statutory and regulatory duty on all matters
12 related to adverse events of BIA-ALCL associated with their BIOCELL Textured Breast
13 Implants to report in a manner that avoided making any written or oral communication
14 containing an untrue statement or omitting any material fact necessary to make
15 statements made, in light of the circumstances under which they were made, not
16 misleading.

17 325. However, as part of their scheme designed to downplay the risks of
18 BIOCELL Textured Breast Implants in the medical device reports and to induce the
19 FDA, the medical and scientific community, device user facilities, and consumers like
20 Plaintiff into believing that there was no unique risks of BIA-ALCL associated with their
21 BIOCELL Textured Breast Implants in order to sell more implants, Defendants willfully
22 concealed and failed to disclose all information reasonably known to it in the MDRs.

23 326. The principle fraudulent omission in these MDRs was the failure to
24 acknowledge that BIA-ALCL is exclusively found in textured implants and that
25 ALLERGAN's BIOCELL Textured Breast Implants are associated with more cases than
26 any other type of textured implant—by far.

27 327. Moreover, Defendants omitted, suppressed, and concealed material facts
28 concerning the dangers and risks of injuries associated with BIOCELL Textured Breast

1 Implants and BIA-ALCL, including by exploiting the FDA's non-public ASR program to
2 hide evidence of it BIOCELL Textured Breast Implants causing BIA-ALCL. Specifically,
3 Defendants deliberately failed to file medical device reports associated with BIA-ALCL
4 events despite its obligations under 21 U.S.C. 360 and 21 C.F.R. § 803.50—and
5 deliberately and willfully concealed the increased risk of BIA-ALCL associated with its
6 BIOCELL Textured Breast Implants when it either did not reports these events in any
7 form to the FDA, or unlawfully used the ASR reporting system to report these
8 complaints.

9 328. Defendants intended the FDA, the medical and scientific community, and
10 device user facilities, and patients to rely on the Defendants' important material
11 representations and concealment regarding the safety of the BIOCELL Textured Breast
12 Implants and their link to BIA-ALCL.

13 329. Plaintiff, by and through the FDA, medical and scientific community, and
14 her device user facility, did in fact rely on and were induced by Defendants'
15 misrepresentations, omissions, or active concealment of the dangers of BIOCELL
16 Textured Breast Implants and the link to BIA-ALCL.

17 330. Plaintiff, her physician, her device user facility, and the medical and
18 scientific community did not know that the representations made by the Defendants
19 were false and were justified in relying upon Defendants' representations.

20 331. As the direct and proximate result of Defendant's fraudulent
21 misrepresentations and intentional concealment of facts concerning the BIOCELL
22 Textured Breast Implants, upon which Plaintiff reasonably relied, she was implanted
23 with BIOCELL Textured Breast Implants and suffered, or will suffer, painful removal
24 procedures to mitigate the risk of developing BIA-ALCL, as well as any treatment,
25 therapy, recovery, and expense associated with the removal of the BIOCELL Textured
26 Breast Implants, the potential for the development of BIA-ALCL, and any condition or
27 symptoms associated with BIA-ALCL or the prevention of that issue.
28

332. As a further proximate result of Defendant's fraudulent misrepresentations and intentional concealment of facts concerning the BIOCELL Textured Breast Implants, Plaintiff suffered debilitating physical pain and mental suffering, was/will be required to undergo additional surgeries and other procedures, incurred substantial hospital, medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress, anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of these injuries are permanent and continuing.

333. Defendants' fraudulent misrepresentations evidenced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff, as well as their goal to place company profits over the safety of hundreds of thousands of consumers, subjecting Defendants to punitive and exemplary damages according to the reprehensibility of their conduct and based on the wealth of said Defendants.

FIFTH CAUSE OF ACTION

(Negligent Misrepresentation and Concealment)

Against All Defendants

334. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

335. Each Defendant negligently participated in, agreed to, aided and abetted, conspired in, and/or furthered a fraudulent scheme, as set forth herein, which conduct constitutes negligent misrepresentation and concealment.

336. Defendants superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of BIA-ALCL and their international dissemination of promotional and marketing information about BIOCELL Textured Breast Implants for the purpose of maximizing its sale, each give rise to the affirmative duty to meaningfully disclose

1 important material facts concerning the safety of the BIOCELL Textured Breast Implants,
2 specifically regarding the risks of developing BIA-ALCL.

3 337. Defendants negligently omitted material information to the FDA, the
4 medical and scientific community, device user facilities, and consumers like Plaintiff
5 which induced such persons and entities to rely on the omissions and to allow the
6 BIOCELL Textured Breast Implants to be in and remain in the marketplace for purchase.
7 Through their negligent omissions, Defendants concealed the risks of BIA-ALCL
8 associated with the BIOCELL Textured Breast Implants.

9 338. Defendants negligently omitted material information regarding the risks of
10 BIA-ALCL and the presence of an ALLERGAN BIOCELL Textured Breast Implants to
11 the FDA, the medical and scientific community, device user facilities, and consumers
12 like Plaintiff.

13 339. Defendants negligently failed to disclose material facts to the FDA, the
14 medical and scientific community, device user facilities, and consumers like Plaintiff that
15 they had a duty to disclose, including the risks of BIA-ALCL associated with the
16 BIOCELL Textured Breast Implants. Each Defendant was aware of and/or approved the
17 material omissions by or on behalf of Defendants.

18 340. Moreover, Defendants made representations about BIA-ALCL but did not
19 disclose facts which materially qualified the facts disclosed, which rendered their
20 disclosure likely to mislead. The true facts about BIA-ALCL and the correlation with
21 ALLERGAN BIOCELL Textured Breast Implants were known to Defendants, and
22 Defendants knew they were not known to or reasonably discoverable by Plaintiff.

23 341. Defendants knew that their half-truths, concealment and negligent failure
24 to disclose to Plaintiff, by and through the FDA, medical and scientific community, and
25 her device user facility, all information reasonably available to them related to the nexus
26 between BIA-ALCL and their BIOCELL Textured Breast Implants, would mislead
27 Plaintiff by creating the false impression that the full extent of BIA-ALCL's relationship
28 with the BIOCELL Textured Breast Implants was already a known and disclosed by

1 ALLERGAN, and further that ALLERGAN's breast implants were no more likely to be
2 found in individuals suffering from BIA-ALCL than other companies' products.
3 Defendants also knew that if Plaintiff became aware of the cancerous propensities
4 associated the BIOCELL Textured Breast Implants, Plaintiff would not agree to purchase
5 said implants.

6 342. Nevertheless, in a negligent disregard of Plaintiff's rights and the duties
7 owed to Plaintiff by Defendants, and each of them, concealed and negligently failed to
8 disclose to Plaintiff all information reasonably available to them related to the nexus
9 between BIA-ALCL and their BIOCELL Textured Breast Implants, thereby inducing
10 Plaintiff against her own interest to purchase their cancer-inducing breast implants.

11 343. Likewise, Defendants had a statutory and regulatory duty on all matters
12 related to adverse events of BIA-ALCL associated with their BIOCELL Textured Breast
13 Implants to report in a manner that avoided making any written or oral communication
14 containing an untrue statement or omitting any material fact necessary to make
15 statements made, in light of the circumstances under which they were made, not
16 misleading.

17 344. However, Defendants negligently downplayed the risks of BIOCELL
18 Textured Breast Implants in the medical device reports, thereby inducing the FDA, the
19 medical and scientific community, device user facilities, and consumers like Plaintiff into
20 believing that there were no unique risks of BIA-ALCL associated with their BIOCELL
21 Textured Breast Implants. As a result, ALLERGAN negligently concealed and failed to
22 disclose all information reasonably known to it in the MDRs.

23 345. The principle fraudulent omission in these MDRs was the failure to
24 acknowledge that BIA-ALCL is exclusively found in textured implants and that
25 ALLERGAN's BIOCELL Textured Breast Implants are associated with more cases than
26 any other type of textured implant—by far.

27 346. Moreover, Defendants negligently omitted, suppressed, and concealed
28 material facts concerning the dangers and risks of injuries associated with BIOCELL

1 Textured Breast Implants and BIA-ALCL, including by exploiting the FDA's non-public
2 ASR program to hide evidence of it BIOCELL Textured Breast Implants causing BIA-
3 ALCL. Specifically, Defendants negligently failed to file medical device reports
4 associated with BIA-ALCL events despite its obligations under 21 U.S.C. 360 and 21
5 C.F.R. § 803.50—and negligently concealed the increased risk of BIA-ALCL associated
6 with its BIOCELL Textured Breast Implants when it either did not reports these events
7 in any form to the FDA, or unlawfully used the ASR reporting system.

8 347. Defendants intended the FDA, the medical and scientific community, and
9 device user facilities, and patients to rely on the Defendants' important material
10 representations regarding the safety of the BIOCELL Textured Breast Implants and its
11 link to BIA-ALCL.

12 348. Plaintiff, by and through the FDA, the medical and scientific community,
13 and her device user facility, did in fact rely on and were induced by Defendants'
14 negligent misrepresentations, omissions, or concealment of the dangers of BIOCELL
15 Textured Breast Implants and the link to BIA-ALCL.

16 349. Plaintiff, her physician, her device user facility, and the medical and
17 scientific community did not know that the representations made by the Defendants
18 were false and were justified in relying upon Defendants' representations.

19 350. As the direct and proximate result of Defendant's negligent
20 misrepresentations and concealment of facts concerning the BIOCELL Textured Breast
21 Implants, upon which Plaintiff reasonably relied, she was implanted with BIOCELL
22 Textured Breast Implants and suffered, or will suffer, painful removal procedures to
23 mitigate the risk of developing BIA-ALCL, as well as any treatment, therapy, recovery,
24 and expense associated with the removal of the BIOCELL Textured Breast Implants, the
25 potential for the development of BIA-ALCL, and any condition or symptoms associated
26 with BIA-ALCL or the prevention of that issue.

27 351. As a further proximate result of Defendant's negligent misrepresentations
28 and concealment of facts concerning the BIOCELL Textured Breast Implants, Plaintiff

1 suffered debilitating physical pain and mental suffering, was/will be required to
2 undergo additional surgeries and other procedures, incurred substantial hospital,
3 medical, nursing and pharmaceutical expenses therefrom; suffered emotional distress,
4 anxiety, depression and disability; loss of earnings; and loss of quality of life, and all of
5 these injuries are permanent and continuing.

6
7 **PUNITIVE DAMAGE ALLEGATIONS**

8 **(Brought by Plaintiff Against Defendants)**

9 352. Plaintiff incorporates by reference all preceding paragraphs of this
10 Complaint as if fully set forth herein and further alleges as follows:

11 353. The acts, conduct, and omissions of Defendants, and each of them, as
12 alleged throughout this Complaint were willful and malicious and were done with a
13 conscious disregard for the rights of Plaintiff as a user of Defendants' BIOCELL Textured
14 Breast Implants and for the primary purpose of increasing Defendants' profits from the
15 sale and distribution of BIOCELL Textured Breast Implants. Defendants' outrageous and
16 unconscionable conduct warrants an award of exemplary and punitive damages against
17 each Defendant in an amount appropriate to punish and make an example of each
18 Defendant.

19 354. Prior to the manufacturing, sale, and distribution of BIOCELL Textured
20 Breast Implants, Defendants and each of them knew that said implants were in a
21 defective condition as previously described herein and knew that those who were
22 implanted with BIOCELL Textured Breast Implants would be at a heightened risk of
23 developing BIA-ALCL, and would therefore experience and did experience severe
24 physical, mental and emotional injuries. Further, Defendants and each of them through
25 their officers, directors, managers, and agents, had knowledge that the BIOCELL
26 Textured Breast Implants presented a substantial and unreasonable risk of harm due to
27 BIA-ALCL to the public, including Plaintiff, and as such, was unreasonably subjected to
28 the risk of injury or death from the implantation of BIOCELL Textured Breast Implants.

355. Despite such knowledge, Defendants, and each of them, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in said BIOCELL Textured Breast Implants and failed to warn the public, including Plaintiff, of the risk of developing BIA-ALCL occasioned by said defects inherent in said BIOCELL Textured Breast Implants. Said Defendants and their individual agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of said BIOCELL Textured Breast Implants knowing persons would be exposed to serious danger in order to advance Defendants' own pecuniary interests and monetary profits.

356. Defendants conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary decent people and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

1. Past and future medical and incidental expenses, according to proof;
2. Past and future loss of earnings and/or earning capacity, according to proof;
3. Past and future general damages, according to proof;
4. Punitive and exemplary damages in an amount to be determined at trial;
5. Prejudgment and post judgment interest;
6. Costs to bring this action; and
7. Such other and further relief as the court may deem just and proper.

Dated: August 9, 2020

COWPER LAW LLP

By: /s/ C. Moze Cowper
C. Moze Cowper
Noel E. Garcia
Counsel for the Plaintiff

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JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: August 9, 2020

COWPER LAW LLP

By: /s/ C. Moze Cowper
C. Moze Cowper
Noel E. Garcia
Counsel for the Plaintiff