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13
14 **UNITED STATES DISTRICT COURT**
15 **CENTRAL DISTRICT OF CALIFORNIA**

16 A.B. and C.D., individually and on
17 behalf of all others similarly situated,

18 Plaintiffs,

19 v.

20 ALLERGAN, INC. f/k/a INAMED
21 CORPORATION, ALLERGAN USA,
22 INC., and ALLERGAN plc.

23 Defendants.

Case No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

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CLASS ACTION COMPLAINT

CASE NO.

<https://www.girardsharp.com/work-pending-allergan-filed>

1 Plaintiffs A.B. and C.D., individually and on behalf of all others similarly situated,
2 file this Class Action Complaint against Defendants Allergan plc, Allergan, Inc., and
3 Allergan USA, Inc. (“Defendants” or “Allergan”) and allege as follows:

4 **NATURE OF THE ACTION**

5 1. Allergan manufactures and sells BIOCELL saline-filled and silicone-filled
6 breast implants and tissue expanders. Allergan’s BIOCELL line of implants are a type
7 of textured breast implants and tissue expanders that were first introduced internationally
8 in the early 1990s and in the United States beginning in 2006.

9 2. The BIOCELL textured implants were originally developed in the 1980s
10 and early 1990s by Santa Barbara-based McGhan Medical Corporation (“McGhan”),
11 which later became Inamed Corporation (“Inamed”). In 2006, Allergan acquired
12 Inamed and its Santa Barbara facilities became the new national research and
13 development center for Allergan’s “medical aesthetics” division, which included breast
14 implants.

15 3. In 2011, the Food and Drug Administration (“FDA”) identified a potential
16 link between textured breast implants and a rare form of lymphoma called breast-
17 implant-associated anaplastic large-cell lymphoma, or BIA-ALCL.

18 4. Following a request from the FDA, on July 24, 2019, Allergan announced it
19 was issuing a worldwide recall of all BIOCELL textured breast implants and tissue
20 expanders. The FDA made its request after receiving reports suggesting that BIOCELL
21 implants and expanders were associated with hundreds of cases of BIA-ALCL around
22 the world. In its notice to the public, the FDA reported receiving 573 cases of BIA-
23 ALCL worldwide, including 33 deaths. The FDA further noted that it had seen “a
24 significant increase in known cases of BIA-ALCL since the agency’s last update earlier
25 this year—an increase of 116 new unique cases and 24 deaths.” Of the 573 known cases
26 of BIA-ALCL, 481 (or about 84%) were attributed to Allergan products, and of the 33
27 reported deaths, “12 of the 13 patients for which the manufacturer of the implant is
28 known are confirmed to have an Allergan breast implant[.]” According to the FDA, the

1 risk of BIA-ALCL is six times higher with Allergan’s textured implants than textured
2 implants from other manufacturers.

3 5. BIA-ALCL is not breast cancer but rather a type of non-Hodgkin’s
4 lymphoma, a cancer of the immune system. BIA-ALCL typically occurs in the scar
5 tissue surrounding the implant. Left untreated, it will spread to surrounding tissue such
6 as lymph nodes near the breast, and may be fatal. BIA-ALCL is typically treated with
7 surgery meant to remove the implant and surrounding scar tissue although some patients
8 will require chemotherapy, radiation therapy, or both.

9 6. The main symptoms of BIA-ALCL are persistent swelling or enlargement
10 of a patient’s breast or surrounding tissue that develops a year or more after surgery
11 (swelling is common immediately after surgery), lumps in the breast or armpit, pain,
12 rash or redness, hardening of the breast, or changes in the shape or size of the breast.

13 7. After Allergan’s recall, a principal FDA deputy commissioner stated that:
14 “Based on new data, our team concluded that action is necessary at this time to protect
15 the public health” and that “[o]nce the evidence indicated that a specific manufacturer’s
16 product appeared to be directly linked to significant patient harm, including death, the
17 FDA took action.”

18 8. The products subject to recall (“recalled BIOCELL products”) include
19 Allergan Natrelle Saline-Filled Breast Implants (formerly called McGhan RTV Saline-
20 Filled Mammary Implants), Allergan Natrelle Silicone-Filled Textured Breast Implants
21 (formerly called Inamed Silicone-Filled Breast Implants), Natrelle 410 Highly Cohesive
22 Anatomically Shaped Silicone-Filled Breast Implants, and Allergan tissue expanders for
23 the breast implants that have BIOCELL texturing.¹

24 9. In a July 30, 2019 letter to “Allergan Plastic Surgery Customer[s]”,
25 Allergan’s Senior Vice President, U.S. Medical Aesthetics, Carrie Strom stated that
26 Allergan is creating a “Replacement Warranty” for patients “currently implanted” with
27

28 _____
¹ The recalled BIOCELL products are listed in Exhibit A.

1 BIOCELL textured implants that will provide smooth device replacements. The letter
2 explained that the warranty program will run until July 24, 2021. The letter also said
3 that “Allergan will not be providing surgical fee assistance” to any patients.

4 10. On August 9, 2019, Allergan sent a letter informing patients, including
5 Plaintiffs, that the recall of the BIOCELL products was due to a “higher occurrence of
6 breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in patients who
7 have, or have had, Allergan BIOCELL textured breast implants.” Allergan’s “recall”
8 and “Replacement Warranty” therefore have a glaring shortcoming—while it has agreed
9 to provide smooth breast implants to replace the problematic textured breast implants,
10 Allergan has declined to cover the surgical fees patients must incur to remove the
11 recalled BIOCELL products.

12 11. As a result of Allergan’s conduct, including its refusal to pay for the
13 removal of the recalled BIOCELL products, as well as the substantially increased risk of
14 BIA-ALCL, Plaintiffs will be forced to expend substantial sums, such as for surgery to
15 remove their implants, medical monitoring, and other medical expenses.

16 **PARTIES**

17 12. Plaintiff A.B. is a citizen and resident of Michigan.

18 13. Plaintiff C.D. is a citizen and resident of California.

19 14. Given the sensitivity of their claims and the nature of the medical products
20 and services at issue, Plaintiffs are proceeding under pseudonyms in this litigation to
21 protect their privacy. If required by the Court, Plaintiffs will seek permission to use a
22 pseudonym.

23 15. Defendant Allergan plc is a publicly traded corporation headquartered in
24 Dublin, Ireland. It has administrative headquarters for the United States in New Jersey.

25 16. Defendant Allergan, Inc., is a wholly-owned subsidiary of Allergan plc and
26 is incorporated under the laws of Delaware, with its principal place of business in New
27 Jersey. Allergan, Inc. was previously headquartered in Irvine, California. Allergan plc
28 continues to maintain a large presence in Irvine, where the U.S. Medical Aesthetics

1 division responsible for breast implants is now based, including thousands of employees
2 and large offices and research and development facilities.

3 17. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc
4 and is incorporated under the laws of Delaware, with its principal place of business in
5 New Jersey.

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

8 **JURISDICTION AND VENUE**

9 19. This Court has jurisdiction over the lawsuit under the Class Action Fairness
10 Act, 28 U.S.C. § 1332, because this is a proposed class action in which: (1) there are at
11 least 100 class members; (2) the combined claims of class members exceed \$5,000,000,
12 exclusive of interest, attorneys' fees, and costs, and (3) Plaintiffs and Defendants are
13 domiciled in different states.

14 20. This Court has personal jurisdiction over Defendants because they have
15 sufficient minimum contacts in California to render the exercise of jurisdiction by this
16 Court proper and fair. Allergan researched, designed, tested, manufactured, and carried
17 out comprehensive decade-long clinical trials for the recalled BIOCELL products in
18 Santa Barbara County, California. Allergan's U.S. Medical Aesthetics division, which is
19 responsible for the development and sale of breast implants—including the recalled
20 BIOCELL products—is now based in Irvine, California. Senior Vice President, U.S.
21 Medical Aesthetics, Carrie Strom, who sent the letter to Allergan's plastic surgery
22 customers informing them of the BIOCELL "Replacement Warranty" is also based in
23 Irvine, California.

24 21. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2)
25 because a substantial part of the acts giving rise to Plaintiffs' claims occurred in this
26 District and because Defendants are subject to personal jurisdiction within this District.

1
2 **PLAINTIFF-SPECIFIC ALLEGATIONS**

3 **Plaintiff A.B.**

4 22. On April 20, 2018, Plaintiff A.B. received Natrelle 410 Style 410MM
5 silicone-filled breast implants included on the list of recalled BIOCELL products, paying
6 approximately \$11,079 for the implants and procedure.

7 23. In February 2019, Plaintiff A.B. began exhibiting symptoms associated
8 with BIA-ALCL, including left breast pain, underarm swelling, and swollen lymph
9 nodes.

10 24. Plaintiff A.B. would not have had the Natrelle 410 implanted had she
11 known prior to the procedure that BIOCELL textured breast implants would subject her
12 to the significantly greater risk of developing BIA-ALCL, as well as the costs associated
13 with removal, medical monitoring, and other fees and procedures to detect and treat
14 BIA-ALCL.

15 25. Plaintiff A.B. wants Allergan to fully pay for the removal of her implants,
16 but (understandably) does not wish to have another Allergan product implanted.
17 Allergan has refused to pay for any surgical costs associated with the recall and the
18 greatly increased risk of BIA-ALCL from using its BIOCELL products.

19 **Plaintiff C.D.**

20 26. In October 2016, Plaintiff C.D. received breast implants included on the list
21 of recalled BIOCELL products as part of reconstructive surgery following her recovery
22 from breast cancer.

23 27. Plaintiff C.D. has begun exhibiting symptoms associated with BIA-ALCL,
24 including discomfort and hardening of the breast around the implant, swelling in the
25 upper abdomen area under the breast, and swelling under her arm.

26 28. Plaintiff C.D. would not have had the recalled BIOCELL products implanted
27 had she known prior to the procedure that BIOCELL textured breast implants would
28 subject her to the significantly greater risk of developing BIA-ALCL, as well as the costs

1 associated with removal, medical monitoring, and other fees and procedures to detect and
2 treat BIA-ALCL.

3 29. Plaintiff C.D. wants Allergan to fully pay for the removal of her implants,
4 but (understandably) does not wish to have another Allergan product implanted.
5 Allergan has refused to pay for any surgical costs associated with the recall and the
6 greatly increased risk of BIA-ALCL from using its BIOCELL products.

7 **FACTUAL ALLEGATIONS**

8 **I. Relevant Background Concerning Breast Implants**

9 30. Breast implants are medical devices that are implanted under the breast
10 tissue or chest muscle to increase breast size or to replace breast tissue that has been
11 removed as a result of cancer or other trauma. Tissue expanders are typically used in
12 breast reconstruction and are a type of inflatable breast implant that stretches the skin
13 and muscle to make room for a more permanent implant in the future.

14 31. There are two primary types of breast implant products: saline-filled
15 (containing sterile saltwater) and silicone-filled (containing silicone gel). They come in
16 a variety of sizes, have different gel viscosity, and can have either a smooth or textured
17 surface. Every year, approximately 400,000 women in the United States receive breast
18 implants either for cosmetic reasons or for breast reconstruction.

19 32. First introduced in the 1960s, breast implants began gaining acceptance
20 and popularity in the 1970s. In 1976, Congress passed the Medical Device Amendment
21 to the Federal Food, Drug and Cosmetic Act granting the FDA authority to review and
22 approve new medical devices, including breast implants. Breast implants were initially
23 classified as Class II devices, which required manufacturers to provide assurances that
24 their products would not cause harm to the recipients but did not require them to conduct
25 any formal testing.

26 33. Public concerns about the safety of breast implants grew during the late
27 1980s and early 1990s with increasing reports of health complications such as gel bleed
28 and capsular contracture (scar tissues becoming unusually hard and contracting around

1 the implant). At the same time, studies began to warn about the dangers of silicone
2 implants and their link to cancer. In response, the FDA re-classified both saline-filled
3 and silicone-filled breast implants as Class III devices, meaning they posed a potential
4 unreasonable risk of illness or injury. In 1991, the FDA began requiring Premarket
5 Approval Applications (“PMAs”) for breast implants.

6 34. In 1992, the FDA issued a moratorium on the sale of silicone-filled breast
7 implants due to increasing concerns about their safety. At the time, McGhan and Mentor
8 Corporation were the only silicone breast implant manufacturers left in the United States
9 market.

10 35. During the late 1990s and early 2000s, McGhan (later Inamed) and Mentor
11 began long-term clinical studies for their silicone implants.

12 36. Allergan’s 2006 acquisition of Inamed was at least partly motivated by the
13 fact that while most of the breast implants in the United States at the time were saline
14 implants, the FDA appeared to be on the verge of lifting the moratorium on silicone
15 implants and Inamed was already selling silicone implants outside of the United States.

16 37. The FDA lifted the moratorium on silicone implants in 2006. Allergan
17 began selling its Inamed Silicone-Filled Breast Implants in the United States shortly
18 thereafter.

19 **II. Breast Implants and BIA-ALCL**

20 38. After health concerns arose during the 1980s and 90s, manufacturers began
21 using surface texturing on breast implants claiming they would reduce the likelihood of
22 common complications such as capsular contracture. Manufacturers rely on different
23 techniques to create their textured implants. The variations in manufacturing techniques
24 result in differences in porosity, complexity, and the depth of the texturing on the
25 implant’s surface. Allergan’s BIOCELL implants use a texturing process called “lost-
26 salt” which uses a layer of salt crystals with a thin overcoat of silicone that is then cured
27 in a laminar flow oven. After the surface is cured, the salt on the surface is washed away
28 leaving a pitted surface with random indentations.

1 39. Reports and studies linking breast implants to BIA-ALCL began to emerge
2 a few years after the FDA’s moratorium was lifted in 2006 and in January 2011, the
3 FDA released a report informing the public about a possible association between breast
4 implants and BIA-ALCL. The FDA observed that “ALCL has been found more
5 frequently in association with breast implants having a textured outer shell rather than a
6 smooth outer shell.”

7 40. While the risk of ALCL is generally believed to be 1:300,000, textured
8 breast implants greatly increase this risk. The FDA recently announced that its studies
9 have shown that the risk of BIA-ALCL in women with textured implants ranges from
10 1:3,817 and 1:30,000. The American Society of Plastic Surgeons estimates the current
11 risk of BIA-ALCL to be between 1:2,207 and 1:86,029 for women with textured
12 implants. Studies in Europe show similar risks and Australia’s Therapeutic Goods
13 Administration (“TGA”) has reported the risk is 1:1,000 to 1:10,000.

14 41. Since the FDA reported a potential link between breast implants and BIA-
15 ALCL, subsequent studies and reports from other international governmental agencies
16 also showed a heightened risk of BIA-ALCL even as Allergan continued to sell the
17 BIOCELL implants. In March 2015, one analysis identified at least 173 cases and the
18 French National Cancer Institute claimed that “[t]here is a clearly established link
19 between the occurrence of this disease and the presence of a breast implant.”

20 42. On May 19, 2016, the World Health Organization designated BIA-ALCL as
21 a form of T-cell lymphoma distinct from other categories of ALCL that can develop
22 following breast implants.

23 43. In November 2016, the Australian TGA announced that it would convene
24 an expert advisory panel as part of its “ongoing monitoring of the association between
25 breast implants and anaplastic large cell lymphoma.”

26 44. In early 2017, the National Comprehensive Cancer Network established
27 guidelines for diagnosing and treating BIA-ALCL in breast implant patients.
28

1 45. On March 21, 2017, the FDA updated its 2011 warning about the link
2 between breast implants and BIA-ALCL. The FDA stated that “[a]t this time, most data
3 suggest that BIA-ALCL occurs more frequently following implantation of breast
4 implants with textured surfaces rather than those with smooth surfaces.”

5 46. A May 2017 global analysis of some forty governmental databases showed
6 363 cases of BIA-ALCL of which 258 were reported to the FDA.

7 47. On March 21, 2018, the FDA released another update, noting that it was
8 aware of 414 total cases of BIA-ALCL.

9 48. On May 9, 2018, the Australian TGA reported a total of 72 cases of ALCL
10 in Australia.

11 49. In December 2018, Allergan textured breast implants lost their European
12 certification and subsequently were suspended from the European and Brazilian markets.

13 50. In February 2019, the FDA sent a letter to health care providers across the
14 United States warning them about the link between textured breast implants and BIA-
15 ALCL.

16 **III. Allergan Enters the Breast Implant Market Through California**

17 51. Many of the BIOCELL breast implants that have been recalled were
18 originally designed, tested, and manufactured by McGhan or Inamed beginning in the
19 1990s. For instance, while the sale of silicone breast implants was prohibited in the
20 United States after 1992, Allergan’s Natrelle 410 silicone breast implant was first
21 introduced in Europe in 1993 as the Biodimensional Style 410 implant.

22 52. McGhan was once a leading manufacturer of silicone products for plastic
23 and reconstructive surgery based in Santa Barbara County, California. In 1985, it
24 became a subsidiary of a publicly held company called First American Corporation
25 through a merger. In 1986, First American Corporation changed its name to Inamed
26 Corporation.

27 53. Inamed was a global healthcare products manufacturer based in Santa
28 Barbara where it maintained its offices and headquarters, performed research and

1 development, and had its manufacturing facilities, including a 225,000 square foot
2 facility. Inamed also maintained large offices, manufacturing, and distribution facilities
3 in Carpinteria, California and Fremont, California. Inamed manufactured some of its
4 breast implant products in Santa Barbara.

5 54. In March 2006, Allergan acquired Inamed and its wholly owned subsidiary,
6 McGhan for approximately \$3.2 billion. Allergan also acquired the BIOCELL
7 trademark and assumed the liability risks for its past and present manufacturing of breast
8 implant products. At the time, Inamed was one of the largest breast implant makers in
9 the world and one of the two largest manufacturers in the United States, primarily
10 competing with Mentor Corporation, now part of Johnson & Johnson.

11 55. When Allergan acquired Inamed in October 2006, it publicly announced
12 that Inamed's Santa Barbara facilities would serve as its national center for research and
13 development in medical aesthetics, which included breast implants. In addition,
14 Allergan maintained secondary manufacturing facilities for the recalled BIOCELL
15 products in Santa Barbara.

16 56. Allergan's Santa Barbara branch was responsible for researching,
17 developing, testing, and seeking FDA approval for Allergan's Natrelle 410 Highly
18 Cohesive Anatomically Shaped Silicone-Filled Breast Implants that are the subject of
19 the recall and this litigation. In a 2013 Summary of Safety and Effectiveness Data
20 ("SSED") filed with the FDA in connection with its PMA for the Natrelle 410 breast
21 implants, Allergan listed an address in Santa Barbara County consisting of 105,000
22 square foot offices and research and development facilities.

23 57. The SSED shows that Allergan's Santa Barbara based employees were
24 responsible for seeking FDA approval for the newer Natrelle 410 Highly Cohesive
25 Anatomically Shaped Silicone-Filled Breast in 2013. Plaintiff A.B. received a variant of
26 this type of implant in April 2018.

27 58. According to the SSED that Allergan filed with the FDA in 2013, the newer
28 implants "are similar" to the previous style 410 design that have been on sale outside the

1 United States since 1993, except that the newer versions “are shaped devices filled with
2 a more cohesive gel.” Moreover, Allergan (then McGhan or Inamed) conducted a
3 clinical study for the Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled
4 Breast starting in 2000. The 2013 SSED states that this study was used as part of the
5 PMA. The clinical study was overseen by Allergan’s Santa Barbara employees.

6 59. The respective SSEDs for the McGhan RTV Saline-Filled Mammary
7 Implants and Inamed Silicone-Filled Breast Implants that are also subject to the recall
8 likewise show that employees in Santa Barbara were responsible for seeking FDA
9 approval for these products.

10 60. The Directions for Use (“DFU”) containing important product and patient
11 information for the recalled BIOCELL products, including Natrelle silicone-filled breast
12 implants, were conceived of, reviewed, and approved by Allergan in Santa Barbara
13 and/or in Irvine, California. The relevant DFUs list either a Santa Barbara or Irvine,
14 California address for Inamed and Allergan.

15 61. Allergan’s Medical Aesthetics division responsible for its BIOCELL breast
16 implants and overseeing the recall—including the deficient replacement warranty—is
17 now based in Irvine, California.

18 **IV. Allergan Tries to Conceal the Risks of the Recalled BIOCELL Products**

19 62. Consumers and physicians depend on the timely and accurate disclosures of
20 problems and health concerns by medical device manufacturers in their decision-
21 making. Since at least 2011, Allergan has known about the connection between its
22 BIOCELL implants and BIA-ALCL but Allergan did not disclose the connection to
23 consumers or the medical community.

24 63. Since April 1991, the FDA has required breast implant manufacturers to
25 obtain premarket approval for any silicone gel-filled breast implants through the PMA
26 process, which allows the FDA to evaluate the safety and effectiveness of Class III
27 medical devices.

28

1 64. As part of the PMA process, a breast implant manufacturer must provide
2 the FDA with a variety of information including known investigations showing whether
3 or not the device is safe and effective, the components and properties of the device, the
4 manufacturing process and methods, and other data relevant for evaluating the safety
5 and effectiveness of the device that is known or should reasonably be known to the
6 manufacturer.

7 65. In 2000, Inamed began conducting a 10-year study to assess the
8 performance and safety of the McGhan Medical RTV Saline-Filled Breast Implant.

9 66. In 2006 Allergan began a series of long-term studies for its Inamed
10 Silicone-Filled Breast Implants to assess the clinical performance of the breast implants,
11 including any health complications and connections to neurological diseases, diseases in
12 the connective tissue, and cancer.

13 67. Under the relevant PMAs, the “[f]ailure to comply with any post-approval
14 requirement constitutes a ground for withdrawal of approval of a PMA.” The PMA also
15 provides that it “is a violation of the act” to commercially distribute “a device that is not
16 in compliance with these conditions[.]”

17 68. Manufacturers selling medical devices in the United States are under
18 continuing obligations to comply with the medical device reporting requirements. For
19 instance, a manufacturer must report to the FDA within 30 calendar days after receiving
20 or becoming aware of information “from any source, that reasonably suggests that a
21 device” “[m]ay have caused or contributed to a death or serious injury” or that a device
22 “[h]as malfunctioned and this device or a similar device . . . would be likely to cause or
23 contribute to a death or serious injury, if the malfunction were to recur.” 21 C.F.R. §
24 803.50(a).

25 69. Information is “reasonably known” if it can be obtained by contacting “a
26 user facility, importer or other initial reporter;” is information that is in a manufacturer’s
27 possession; or is information that “can be obtain[ed] by analysis, testing, or other
28

1 evaluation of the device.” 21 C.F.R. § 803.50(b). Manufacturers must investigate each
2 reported event and evaluate the cause. *Id.*

3 70. A manufacturer must also provide periodic reports to the FDA including
4 “[u]npublished reports of data from any clinical investigations or nonclinical laboratory
5 studies involving the device or related devices and known to or that reasonably should
6 be known to the applicant” and “[r]eports in the scientific literature concerning the
7 device and known to or that reasonably should be known to the applicant.” 21 C.F.R. §
8 814.84.

9 71. Accordingly, manufacturers such as Allergan are required to file adverse
10 event reports with the FDA and continue to have the primary responsibility for timely
11 communicating complete and accurate safety information for breast implants.
12 Manufacturers are further obligated to constantly monitor all reasonably available
13 information and clinical experiences.

14 72. The FDA publishes adverse event reports in a public, searchable database
15 called the Manufacturer and End User Facility Device Experience database or
16 “MAUDE” which is updated monthly.

17 73. Instead of accurately reporting adverse events individually each time an
18 injury or malfunction occurred, however, Allergan’s practice was to “bury evidence of
19 ruptures and other injuries by reporting them as routine events that did not require public
20 disclosure” until 2017. Allergan hid evidence of complications and injuries by filing
21 “Alternative Summary Reports” (“ASR”) that bypass MAUDE. ASRs were initially
22 developed to reduce paperwork. The ASR program allows Allergan to report hundreds
23 or thousands of adverse event reports together on less-detailed quarterly spreadsheets
24 and avoid public disclosure because the reports are generally unavailable to the public.
25 The ASR system is so obscure that a former commissioner, Dr. Robert Califf, stated that
26 he had “never heard anything about it” during his time with the FDA.

27 74. The ASR program, moreover, was intended to exclude severe or
28 unexpected events or injuries necessitating remedial action, which were still supposed to

1 be reported individually. Experts, however, have been skeptical that the ASRs really did
2 exclude the more serious events. Madris Tomes—a former FDA data analyst—stated
3 his “concern has always been that these reports contain serious injuries” Recent
4 developments prove that Allergan did in fact bury serious events in non-public ASRs,
5 including a case of possible BIA-ALCL.

6 75. Further substantiating the fact that severe breast implant events had been
7 buried in ASRs, in 2017, when the FDA began implementing more rigorous reporting
8 requirements, there was a dramatic increase in the number of adverse events related to
9 breast implant injuries—from 200 a year to 4,567 in 2017 and 8,242 in the first half of
10 2018.

11 76. The FDA has now acknowledged that, until recently, there was a
12 “transparency issue” with the injury reports it had been accepting. The FDA said the
13 surge in reports reflected the change in its requirements, rather than “a new public health
14 issue.”

15 77. Accurate reporting of adverse events is critical to ensure that the public is
16 adequately and timely notified of potential problems with a medical device. The FDA
17 relies on the reports to monitor the safety of medical devices. The general public,
18 including physicians and patients, also use the MAUDE database to obtain safety
19 information about medical devices. Researchers, including those studying connections
20 between breast implants and cancer and other health issues, also use the MAUDE
21 database in their studies, such as to obtain the number of reported injuries or deaths. By
22 using ASRs instead of MAUDE, Allergan was able to paint a misleading picture of the
23 number of problems in breast implants to medical professionals and their patients who
24 relied on the public reports, thereby exposing patients to harm.

25 78. Allergan also did not report adverse events from its required post-market
26 approval studies that would have suggested the recalled BIOCELL products have caused
27 or contributed to deaths or serious bodily injury.

28

1 79. As detailed above, after the FDA lifted the moratorium in 2006, Allergan
2 continually received new information showing the connection between its textured
3 breast implants and BIA-ALCL and that the risk associated with its BIOCELL breast
4 implants was significantly greater than its competitors.

5 80. Allergan failed to comply with the conditions of the PMAs and violated
6 federal law by failing to fulfill its obligations to accurately and promptly report adverse
7 events and continuing to sell the recalled BIOCELL products.

8 81. Had Allergan complied with its obligations under federal law, the
9 disclosure of the connection between BIOCELL breast implants and BIA-ALCL would
10 have allowed patients including Plaintiffs, and their treating physicians to make an
11 informed decision regarding whether to use other implants.

12 **CLASS ALLEGATIONS**

13 82. Plaintiffs bring this action on their own behalf, and on behalf of the
14 following class and state subclasses pursuant to Federal Rules of Civil Procedure 23(a),
15 23(b)(2), 23(b)(3), and/or (c)(4):

16 **Nationwide Class:** All individuals in the United States who implanted
17 BIOCELL© saline-filled or silicone-filled breast implants or tissue
18 expanders that have been recalled by the FDA.

19 **California Subclass:** All individuals who implanted BIOCELL© saline-
20 filled or silicone-filled breast implants or tissue expanders that have been
21 recalled by the FDA while in California.

22 **Michigan Subclass:** All individuals who implanted BIOCELL© saline-
23 filled or silicone-filled breast implants or tissue expanders that have been
24 recalled by the FDA while in Michigan.

25 83. Excluded from the class are Defendants, their parents, subsidiaries,
26 affiliates, officers and directors, any entity in which Defendants have a controlling
27 interest, all class members who timely elect to be excluded, governmental entities, and
28 all judges assigned to hear any aspect of this litigation, as well as their immediate family

1 members. Plaintiffs reserve the right to modify, change, or expand the class definition
2 based on facts learned through discovery and further investigation.

3 84. Numerosity: The members of the class are so numerous that joinder is
4 impractical. The class includes at least thousands of individuals.

5 85. Typicality: Plaintiffs' claims are typical of the claims of the class in that
6 Plaintiffs, like all class members, were implanted with recalled BIOCELL products and
7 faced an increased risk of BIA-ALCL.

8 86. Adequacy: Plaintiffs will fairly and adequately protect the interests of the
9 class. Plaintiffs have no interests adverse to the interests of any other class member and
10 are committed to vigorously prosecuting this case. Plaintiffs have retained competent
11 counsel experienced in the prosecution of complex class actions involving defective
12 products.

13 87. Commonality and Predominance: There are questions of law and fact
14 common to the class, and the common questions predominate over any questions
15 affecting only individual class members. Among the questions common to the class are:

16 a. Whether the recalled BIOCELL products significantly increase the
17 risk of developing BIA-ALCL;

18 b. Whether Allergan knew or should have known that the recalled
19 BIOCELL products significantly increase the risk of developing BIA-ALCL;

20 c. Whether Allergan was negligent in selling BIOCELL recalled
21 products;

22 d. Whether Allergan failed to warn consumers regarding the risks of the
23 recalled BIOCELL products;

24 e. Whether Allergan violated federal standards and requirements for the
25 marketing, warning, and reporting of the recalled BIOCELL products;

26 f. Whether Allergan breached implied warranties connected with the
27 recalled BIOCELL products;

28

1 g. Whether Allergan's practices constitute unfair acts or practices under
2 the Unfair Competition Law;

3 h. Whether Plaintiffs and class members are entitled to equitable relief,
4 including injunctive relief; and

5 i. Whether Plaintiffs and class members are entitled to damages or
6 other monetary relief, and if so, in what amount.

7 88. Superiority: A class action is superior to all other methods available for the
8 fair and efficient adjudication of this controversy. Because the amount of each
9 individual class member's claim is small relative to the complexity of the litigation, and
10 given Allergan's financial resources, no class member would be likely to pursue legal
11 redress individually for the violations detailed herein. A class action would also
12 streamline the determination of common claims or issues in this case. Conversely,
13 individual suits would create the potential for inconsistent or contradictory rulings. By
14 contrast, a class action presents fewer management difficulties, allows claims to be heard
15 which would otherwise go unheard, and allows comprehensive supervision by a single
16 court.

17 89. Injunctive Relief: Class certification is also appropriate under Rule
18 23(b)(2) because Allergan acted and refused to act on grounds generally applicable to
19 the class, making appropriate final injunctive relief with respect to the class as a whole.

20 **CLAIMS FOR RELIEF**

21 **FIRST CAUSE OF ACTION**

22 **Strict Liability—Failure to Warn**

23 90. Plaintiffs incorporate the above allegations by reference.

24 91. Allergan manufactured, distributed, and/or sold the BIOCELL breast
25 implants that were implanted in Plaintiffs.

26 92. Allergan had a duty to warn Plaintiffs and their physicians about the
27 dangers of the recalled BIOCELL products which it knew, or in the exercise of ordinary
28

1 care, should have known, at the time the recalled BIOCELL products left Allergan's
2 control.

3 93. The BIOCELL breast implants had potential risks that were known or
4 knowable in light of the scientific and medical knowledge that was generally accepted in
5 the scientific and medical community at the time of the manufacture, distribution, or sale
6 of the implant.

7 94. Allergan failed to warn Plaintiffs and their physicians about the serious risk
8 of using its recalled BIOCELL products, including the greatly increased risk of BIA-
9 ALCL. At the time Plaintiffs received their implants, Allergan was aware of the clear
10 causal connection between its BIOCELL breast implants but did not disclose this
11 information or warn of the significantly greater risk of BIA-ALCL associated with its
12 implants. Allergan obtained this knowledge from performing extensive decades-long
13 clinical studies, reviewing scientific studies and literature, FDA communications,
14 government reports, and from complaints from consumers, among other sources. Rather
15 than disclose the truth, Allergan, in violation of federal law, attempted to conceal the
16 true facts by not reporting all adverse events to the FDA and by filing ASRs to avoid
17 public reporting on MAUDE.

18 95. Allergan also failed to warn Plaintiffs and the public by not submitting
19 accurate adverse event reports that patients and physicians rely on to make informed
20 decisions about selecting the type of breast implants.

21 96. The recalled BIOCELL products were defective and unreasonably
22 dangerous when they left Allergan's possession because they did not contain adequate
23 warnings, including the greatly increased risk of developing BIA-ALCL.

24 97. The potential risks presented a substantial danger to Plaintiffs and ordinary
25 consumers when used or misused in an intended or reasonably foreseeable way.

26 98. Plaintiffs and ordinary consumers would have not recognized the potential
27 for risks.

28

1 99. Allergan failed to adequately warn or instruct concerning the potential risks
2 of recalled BIOCELL products.

3 100. It was foreseeable to Allergan that failure to adequately warn about the
4 risks of its recalled BIOCELL products would cause irreparable harm to those who had
5 the products implanted in their bodies, including the types of emotional distress suffered
6 by Plaintiffs.

7 101. As a result of Allergan's failures to adequately warn, Plaintiffs were
8 harmed as described herein including physical pain and emotional distress. The lack of
9 sufficient warnings was a substantial factor in causing Plaintiffs' harm. If Plaintiffs and
10 their physicians had been provided with the appropriate warnings regarding the causal
11 connection between BIOCELL implants and BIA-ALCL, they would have been able to
12 make an informed decision about using an alternative product that did not present such a
13 high risk of BIA-ALCL.

14 102. Allergan's breach of its duty to warn has caused Plaintiffs damages
15 including surgical costs of removal of the products, ongoing medical monitoring, and
16 other medical expenses.

17 **SECOND CAUSE OF ACTION**

18 **Negligence**

19 103. Plaintiffs incorporate the above allegations by reference.

20 104. Allergan has a continuing duty to monitor the recalled BIOCELL products
21 to discover and report to the FDA any complaints about product performance and safety.
22 Allergan also has a continuing duty to provide warnings and instructions regarding
23 potential safety hazards associated with the use of its products.

24 105. Allergan breached these duties by failing to provide timely and adequate
25 reports regarding the safety hazards associated with the recalled BIOCELL products,
26 including the close causal connection to BIA-ALCL. Through numerous adverse
27 reports, consumer complaints, scientific research and literature, internal clinical
28 research, and communications from the FDA and international governmental

1 organizations that Allergan monitored, Allergan was aware of the clear connection
2 between the recalled BIOCELL products and BIA-ALCL, and that its textured breast
3 implants posed a significantly greater risk than competing textured breast implants.

4 106. Although Allergan knew or should have known that the recalled BIOCELL
5 products posed a serious risk of bodily harm to consumers, Allergan continued to
6 manufacture and market them to consumers and failed to comply with applicable FDA
7 reporting and monitoring requirements.

8 107. Had Allergan properly and timely reported the adverse events to the FDA
9 as required under federal law, material information regarding the true risk of the recalled
10 BIOCELL products—including the substantially greater risk of developing BIA-
11 ALCL—would have reached Plaintiffs and their treating medical professionals in time to
12 avoid their injuries.

13 108. Allergan knew or should have known that consumers such as Plaintiffs
14 would foreseeably suffer injury as a result of its failure to exercise ordinary care and
15 comply with FDA reporting and monitoring requirements, including emotional distress.

16 109. As a direct result of Allergan's breach of duty, Plaintiffs have suffered harm
17 in an amount to be determined at trial, including severe emotional distress.

18 **THIRD CAUSE OF ACTION**

19 **Negligent Recall**

20 110. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL
21 products in the United States. That same day, Allergan voluntarily issued a worldwide
22 recall of BIOCELL products.

23 111. In issuing a voluntary recall, Allergan assumed duties to Plaintiffs to
24 exercise reasonable care in issuing and implementing the recall.

25 112. Allergan breached its duties by failing to adequately warn Plaintiffs of the
26 dangers associated with the use of the recalled BIOCELL products and by refusing to
27 pay for the surgical removal of Plaintiffs' implants notwithstanding the clear connection
28

1 between the recalled BIOCELL products and BIA-ALCL and the continuing risk the
2 implants pose to Plaintiffs' health.

3 113. As a direct result of Allergan's breach of duty, Plaintiffs have suffered harm
4 in an amount to be determined at trial.

5 **FOURTH CAUSE OF ACTION**

6 **Breach of the Implied Warranty of Merchantability**

7 114. Plaintiffs incorporate the above allegations by reference.

8 115. By operations of law, Allergan—as manufacturer of the recalled BIOCELL
9 products and as the provider of the Limited Warranty—impliedly warranted to Plaintiffs
10 that the implants they were purchasing were of merchantable quality and safe for their
11 ordinary and intended use in the human body as an aesthetic breast enhancement.

12 116. Allergan breached the implied warranty of merchantability in connection
13 with the sale and distribution of the recalled BIOCELL products. At the point of sale,
14 the recalled BIOCELL products —while appearing normal—contained latent flaws
15 rendering them unsuitable and unsafe for use in the human body.

16 117. Had Plaintiffs known the recalled BIOCELL products are unsafe for use in
17 the human body, they would not have purchased them and had them implanted in their
18 bodies.

19 118. Allergan has refused to provide appropriate warranty relief, as it will not
20 provide surgical fee assistance to patients notwithstanding the substantially increased
21 risk of developing BIA-ALCL. Plaintiffs reasonably expected that their implants would
22 not present a substantial risk of bodily harm at the time of their purchases.

23 119. As a direct and proximate result of Allergan's' breach of the implied
24 warranty of merchantability, Plaintiffs have sustained damages in an amount to be
25 determined at trial.

26 **FIFTH CAUSE OF ACTION**

27 **Violation of the California Unfair Competition Law, Cal. Bus. & Prof. Code §**
28 **17200, et seq. (“UCL”)**

1 120. Plaintiffs incorporate the above allegations by reference.

2 121. Plaintiff C.D. brings this claim on behalf of the California Subclass.

3 122. The UCL proscribes acts of unfair competition including “any unlawful,
4 unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading
5 advertising.” Cal. Bus. & Prof. Code § 17200.

6 123. Allergan’s conduct is unfair in violation of the UCL, because it is immoral,
7 unethical, unscrupulous, oppressive, and substantially injurious.

8 124. Allergan acted in an immoral, unethical, unscrupulous, outrageous,
9 oppressive, and substantially injurious manner, including as follows:

- 10 a. Selling recalled BIOCELL products that it knew to present a substantially
11 greater risk of developing BIA-ALCL than competing textured breast
12 implants;
- 13 b. Concealing the clear connection between its BIOCELL products and
14 BIA-ALCL from the FDA, consumers, and medical professionals;
- 15 c. Failing to disclose that the recalled BIOCELL products have a
16 substantially greater risk of developing BIA-ALCL than competing
17 textured breast implants and;
- 18 d. Minimizing the scope of the risks associated with using the recalled
19 BIOCELL products in communications with the public.

20 125. The gravity of harm resulting from Allergan’s unfair conduct outweighs any
21 potential utility. The practice of selling breast implants that present a substantial health
22 risk to consumers harms the public at large and is part of a common and uniform course
23 of wrongful conduct.

24 126. The harm from Allergan’s conduct was not reasonably avoidable by
25 consumers because only Allergan was aware of the true facts concerning its BIOCELL
26 implants and BIA-ALCL, and Allergan did not disclose them, despite receiving
27 information establishing a causal connection between the BIOCELL products and BIA-
28 ALCL from clinical testing, medical literature and studies, communications from the

1 FDA and international agencies, and consumer complaints. Plaintiff C.D. did not know
2 of and had no reasonable means of discovering the true risk of using BIOCELL implants.

3 127. There were reasonably available alternatives that would further Allergan's
4 business interest of satisfying and retaining its customers while maintaining profitability,
5 such as: (1) completely and accurately disclosing adverse events to the public; (2)
6 acknowledging the significantly greater risk of BIA-ALCL with its recalled BIOCELL
7 products and paying for surgery to remove the implants for patients with recalled
8 implants; and (3) disclosing the true extent of the risk of BIA-ALCL to prospective
9 purchasers.

10 128. Plaintiff C.D. suffered injury in fact, including lost money or property, as a
11 result of Allergan's unfair acts. Absent Allergan's unfair conduct, Plaintiff C.D. would
12 not have selected Allergan implants.

13 129. Through its unfair conduct, Allergan acquired money that Plaintiff C.D.
14 once had an ownership interest in either directly or through Plaintiff C.D.'s medical
15 professionals.

16 130. Plaintiffs accordingly seek appropriate relief under the UCL, including (a)
17 restitution in full and (b) such orders or judgments as may be necessary to enjoin
18 Allergan from continuing its unfair practices. Plaintiffs also seek reasonable attorneys'
19 fees and costs under applicable law, including California Code of Civil Procedure section
20 1021.5.

21 **SIXTH CAUSE OF ACTION**

22 **Medical Monitoring**

23 131. Plaintiffs incorporate the above allegations by reference.

24 132. As a result of exposure to the recalled BIOCELL products, the need for
25 future monitoring is reasonably certain. Allergan's textured implants significantly
26 increase the risk of BIA-ALCL and Plaintiffs have already exhibited symptoms
27 associated with BIA-ALCL.
28

1 133. Medical monitoring is therefore reasonable in order to properly diagnose
2 the symptoms of BIA-ALCL particularly as it can become fatal when not treated in a
3 timely manner.

4 134. Plaintiffs are therefore entitled to have Allergan pay for the costs of
5 ongoing medical monitoring.

6 **PRAYER FOR RELIEF**

7 **WHEREFORE**, Plaintiffs request, individually and on behalf of the Class, that
8 this Court:

9 A. Certify the class under Fed. R. Civ. P. 23(a), (b)(1), (b)(2), (b)(3),
10 and/or (c)(4), as appropriate; appoint Plaintiffs as representatives of the class; and
11 appoint the undersigned counsel as class counsel;

12 B. Award Plaintiffs compensatory, restitutionary, rescissory, general,
13 consequential, punitive and/or exemplary damages in an amount to be determined at
14 trial;

15 C. Award prejudgment interest as permitted by law;

16 D. Enter an injunction against Allergan and its officers, agents,
17 successors, employees, representatives, assigns, and any and all persons acting in
18 concert with them, to: (1) ensure Allergan’s compliance with California Business and
19 Professions Code section 17200, *et seq.*; and (2) require them to implement a medical
20 monitoring program for Plaintiffs and class members;

21 E. Retain jurisdiction over this action to ensure Allergan complies with
22 such a decree;

23 F. Enter other appropriate equitable relief;

24 G. Award reasonable attorneys’ fees and costs, as provided for by law;
25 and

26 H. Grant such other and further relief as the Court deems just and
27 proper.
28

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff requests a trial by jury of all issues triable as of right.

Dated: August 27, 2019

Respectfully submitted,

By: /s/ Christina C. Sharp

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EXHIBIT A

Exhibit A – Affected Products

Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) approved under P990074. The following are the textured styles:

- Style 163: BIOCELL Textured Shaped Full Height, Full Projection Saline Breast Implants
- Style 168: BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as 168MP (168 Moderate Profile)
- Style 363: BIOCELL Textured Shaped Moderate Height, Full Projection Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height Full Projection
- Style 468: BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants

Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly Inamed Silicone-Filled Breast Implants) approved under P020056. The following are the textured styles:

- Style 110: BIOCELL Textured Round Moderate Projection Gel Filled Breast Implants
- Style 115: BIOCELL Textured Round Midrange Projection Gel Filled Breast 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
- Style TRM: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants

- Style TRF: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TRX: Natrelle Inspira BIOCELL Textured Responsive Silicone-Filled Breast Implants
- Style TCL: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCLP: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCM: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCF: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TCX: Natrelle Inspira BIOCELL Textured Cohesive Silicone-Filled Breast Implants
- Style TSL: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSLP: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSM: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSF: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants
- Style TSX: Natrelle BIOCELL Textured Soft Touch Silicone-Filled Breast Implants

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046. The following are the textured styles:

- Style 410FM

- Style 410FF
- Style 410MM
- Style 410 MF
- Style 410 FL
- Style 410 ML
- Style 410 LL
- Style 410 LM
- Style 410 LF
- Style 410 FX
- Style 410 MX
- Style 410 LX

Allergan tissue expanders for the breast that have BIOCELL texturing originally cleared as:

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