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8 themselves and all others similarly situated

9
10 **UNITED STATES DISTRICT COURT**
11 **CENTRAL DISTRICT OF CALIFORNIA**
12 **SOUTHERN DIVISION**

13 F.A., S.B., K.B., M.C., M.D.E., A.F., M.G.,
14 T.K., C.L., C.M., G.A.M., M.M.P., M.S.,
15 and A.V., individually and on behalf of all
others similarly situated,

16 Plaintiffs,

17 v.

18
19 ALLERGAN, INC. f/k/a INAMED
20 CORPORATION; ALLERGAN USA,
INC.; ALLERGAN plc; and DOES 1
through 20, inclusive,

21 Defendants.
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Case No. 8:19-cv-2337

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1 Plaintiffs F.A., S.B., K.B., M.C., M.D.E., A.F., M.G., T.K., C.L., C.M., G.A.M.,
 2 M.M.P., M.S., and A.V. (“Plaintiffs”), bring this Class Action Complaint against
 3 Defendants ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA,
 4 INC., and ALLERGAN plc (collectively “Defendants” or “Allergan”), on behalf of
 5 themselves and all other others similarly situated, and allege as follows:

6 INTRODUCTION

7 1. Plaintiffs bring this class action against Allergan for manufacturing and selling
 8 BIOCELL textured breast implants and tissue expanders that expose women to a higher
 9 risk of breast implant-associated anaplastic large cell lymphoma (“BIA-ALCL”), a deadly
 10 cancer of the immune system. Although it knew of the increased risks of BIA-ALCL as
 11 early as 2011, Allergan failed to warn women considering their implants. Although
 12 Allergan has now issued a recall pursuant to FDA’s directive, it refuses to take full
 13 responsibility and refuses to cover the significant costs associated with removal and
 14 replacement of the defective devices and medical monitoring, among other damages.

15 2. Following a request by the FDA, Allergan announced a worldwide recall of
 16 all BIOCELL textured breast implants and tissue expanders on July 14, 2019. The models
 17 included in the recall are:

- 18 • **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV
 19 Saline-Filled Mammary Implant) approved under P990074. The following are the
 textured styles:
 - 20 ○ Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline
 Breast Implants
 - 21 ○ Style 168, BIOCELL Textured Round Moderate Profile Saline Breast
 Implants, also referred to as 168MP (168 Moderate Profile)
 - 22 ○ Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection
 Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height
 Full Projection
 - 23 ○ Style 468, BIOCELL Textured Shaped Full Height Moderate Projection
 Saline Breast Implants
- 24 • **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed
 25 Silicone-Filled Breast Implants) approved under P020056. The following are the
 textured styles:
 - 26 ○ Style 110, BIOCELL Textured Round Moderate Projection Gel Filled Breast
 Implants
 - 27
 - 28

- 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)

3. Allergen has refused to pay for the removal of the recalled products or any of the consequences of additional surgery that women who choose removal will have to undergo, or for medical monitoring of the substantially increased risk of BIA-ALCL that all women implanted with the devices have been subjected to.

4. Prior to issuing a request for the recall, the Food and Drug Administration (“FDA”) had received reports establishing that BIOCELL implants and expanders were associated with an increase in reported cases of BIA-ALCL: 573 cases of BIA-ALCL worldwide including 33 deaths. Of the 573 known cases of BIA-ALCL, 481 (or about 84%) were attributed to Allergan products, and of the 33 reported deaths, “12 of the 13 patients for which the manufacturer of the implant is known are confirmed to have an Allergan breast implant[.]” According to the FDA, the risk of BIA-ALCL is six times higher with Allergan’s textured implants than textured implants from other manufacturers.

5. Amid these revelations and lawsuits like this one, the FDA is now requiring a written warning on the packaging of Allergan’s textured breast implants and tissue expanders, to inform consumers of the well-documented risks.

6. Plaintiffs bring this Action to make Allergan take responsibility for exposing women to a higher risk of BIA-ALCL and to make all women implanted with these defective devices whole by covering all costs associated with the removal, replacement, and recovery, medical monitoring, and all damages arising out of the sale and implanting of these defective devices.

PARTIES

7. Plaintiff F.A. is an individual who resides in Plattsburgh, New York.

8. Plaintiff S.B. is an individual who resides in Huachuca City, Arizona.

9. Plaintiff K.B. is an individual who resides in Cottage Grove, Oregon.

10. Plaintiff M.C. is an individual who resides in Yosemite, California.

11. Plaintiff M.D.E. is an individual who resides in Jacksonville, Florida.

12. Plaintiff A.F. is an individual who resides in Derby, Connecticut.

13. Plaintiff M.G. is an individual who resides in Midland, Michigan.

14. Plaintiff T.K. is an individual who resides in Superior, Wisconsin.

15. Plaintiff C.L. is an individual who resides in Scottsdale, Arizona.

16. Plaintiff C.M. is an individual who resides in Birmingham, Alabama.

17. Plaintiff G.A.M. is an individual who resides in Mulberry, Florida.

18. Plaintiff M.M.P. is an individual who resides in Mesa, Arizona.

19. Plaintiff M.S. is an individual who resides in Tulsa, Oklahoma.

20. Plaintiff A.V. is an individual who resides in Florida, Jacksonville.

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

22. Defendant ALLERGAN plc is a publicly traded corporation headquartered in Dublin, Ireland. It has administrative headquarters for the United States in New Jersey. ALLERGAN plc also maintains a large presence in Irvine, California, where its U.S. Medical Aesthetics division responsible for breast implants is now based, including thousands of employees and large offices and research and development facilities.

23. Defendant ALLERGAN, INC. f/k/a INAMED CORPORATION, is a wholly-owned subsidiary of ALLERGAN plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey. ALLERGAN, INC. f/k/a INAMED CORPORATION was previously headquartered in Irvine, California.

1 24. Defendant ALLERGAN USA, INC. is a wholly owned subsidiary of
2 ALLERGAN plc and is incorporated under the laws of Delaware, with its principal place
3 of business in New Jersey.

4 25. Plaintiffs are unaware of the true names, capacities, relationship and extent of
5 participation in the conduct alleged herein, of the Defendants sued herein as DOES 1
6 through 20, but are informed and believe that said Defendants are legally responsible for
7 the wrongful conduct alleged herein and therefore sue these Defendants by fictitious
8 names. Plaintiffs will amend this complaint to allege the true names and capacities of the
9 DOES Defendants when ascertained.

10 **JURISDICTION AND VENUE**

11 26. This Court has jurisdiction over Plaintiffs' claims under the Class Action
12 Fairness Act, 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds \$5 million
13 exclusive of interest and costs. Some Class Members and Defendants are citizens of
14 different states. There are at least 100 putative Class Members throughout the State of
15 California.

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

25 28. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2) and
26 (b)(3) because a substantial part of the acts giving rise to Plaintiffs' claims occurred in this
27 District, and because Defendants are subject to personal jurisdiction within this District.
28

1 29. Plaintiffs are informed and believe that each Defendant acted in all respects
2 pertinent to this action as the agent of the other Defendants, carried out a joint scheme,
3 business plan or policy in all respects pertinent hereto, and the acts of each Defendant are
4 legally attributable to the other Defendants.

5 **FACTUAL ALLEGATIONS**

6 **I. The Parties**

7 30. On or about December 2010, Plaintiff F.A. received Allergan Natrelle Saline-
8 Filled Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style
9 168, BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to
10 as 168MP (168 Moderate Profile). She paid approximately \$10,500 for the implants and
11 procedure.

12 31. In or about 2000, Plaintiff S.B. received Allergan textured breast implants.
13 Upon information and belief, her implants are included on the list of recalled BIOCELL
14 implants, and she paid approximately \$6,000 for the implants and procedure.

15 32. Plaintiff S.B. has begun exhibiting symptoms associated with BIA-ALCL,
16 including pain and achiness in the area of her breasts.

17 33. May 2013, Plaintiff K.B. received Allergan Natrelle Silicone-Filled Textured
18 Breast Implants (formerly Inamed Silicone-Filled Breast Implants), Style TSF, Natrelle
19 BIOCELL Textured Soft Touch Silicone-Filled Breast Implants. She paid approximately
20 \$17,000 for the implants and procedure.

21 34. On or about 1992, Plaintiff M.C. received Allergan Natrelle Saline-Filled
22 Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), Style 168,
23 BIOCELL Textured Round Moderate Profile Saline Breast Implants, also referred to as
24 168MP (168 Moderate Profile). She paid approximately \$4,500 for the implants and
25 procedure.

26 35. Plaintiff M.C. has begun exhibiting symptoms associated with BIA-ALCL,
27 such as hardening and swelling in the area of her left breast, and pain in the underarm area
28 of her left side.

1 36. On January 3, 2018, Plaintiff M.D.E. received Allergan Natrelle Silicone-
2 Filled Textured Breast Implants, Style TCF, Natrelle Inspira BIOCELL Textured Cohesive
3 Silicone-Filled Breast Implants. They are included on the list of recalled BIOCELL
4 implants, and she paid approximately \$9,000 for the implants and procedure.

5 37. On January 7, 2011, Plaintiff A.F. received an Allergan Natrelle Silicone-
6 Filled Textured Breast Implant, Style 110, BIOCELL Textured Round Moderate
7 Projection Gel Filled Breast Implants, in her right breast. It is included on the list of
8 recalled BIOCELL implants. She paid approximately \$3,500 for the implants and
9 procedure.

10 38. Plaintiff A.F. has begun exhibiting symptoms associated with BIA-ALCL,
11 including a change in the shape of her right breast (asymmetry), and a change in the size of
12 both breasts.

13 39. In or about March 2012, Plaintiff M.G. received Allergan textured breast
14 implants. Upon information and belief, her implants are included on the list of recalled
15 BIOCELL implants, and she paid approximately \$9,000 for the implants and procedure.

16 40. Plaintiff M.G. has begun exhibiting symptoms associated with BIA-ALCL,
17 including extreme pain in her right breast, and itchiness both in and outside the breast.

18 41. On or about June 2018, Plaintiff T.K. received Allergan tissue expanders for
19 the breast that have BIOCELL texturing originally cleared as Natrelle 133. On November
20 19, 2019, Plaintiff T.K. received Natrelle 410 Highly Cohesive Anatomically Shaped
21 Silicone Filled Breast Implants, Style 410 FX. She paid approximately \$7,500 for the
22 implants and procedure.

23 42. Plaintiff T.K. has begun exhibiting symptoms associated with BIA-ALCL,
24 including redness, swelling, and itchiness in the area of her breasts. Plaintiff T.K. also
25 experiences sharp pain both underneath and on top of her breasts.

26 43. In or about May 2005, Plaintiff C.L. received Allergan textured breast
27 implants. Upon information and belief, they are included on the list of recalled BIOCELL
28 implants. She paid approximately \$7,000 for the implants and procedure.

1 44. On or about 1995, Plaintiff C.M. received Allergan Natrelle Saline-Filled
2 Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant), style 468,
3 BIOCELL Textured Shaped Full Height Moderate Projection Saline Breast Implants.
4 They are included on the list of recalled BIOCELL implants, and she paid approximately
5 \$6,000 for the implants and procedure.

6 45. On May 29, 2014, Plaintiff G.A.M. received Allergan Natrelle Silicone-Filled
7 Textured Breast Implants, Style 115, BIOCELL Textured Round Midrange Projection Gel
8 Filled Breast Implants. They are included on the list of recalled BIOCELL implants, and
9 she paid approximately \$5,695 for the implants and procedure.

10 46. On August 31, 2017, Plaintiff M.M.P. received Natrelle 410 Highly Cohesive
11 Anatomically Shaped Silicone Filled Breast Implants, Style 410 LX. They are included on
12 the list of recalled BIOCELL implants, and she paid approximately \$4,000 for the implants
13 and procedure.

14 47. In or about May 20, 2013, Plaintiff M.S. received Allergan Natrelle Silicone-
15 Filled Textured Breast Implants, Style TSF, Natrelle BIOCELL Textured Soft Touch
16 Silicone-Filled Breast Implants. They are included on the list of recalled BIOCELL
17 implants. She paid approximately \$20,000 for the implants and procedure.

18 48. Plaintiff M.S. has begun exhibiting symptoms associated with BIA-ALCL,
19 including pain in her right breast, and hardening of both breasts.

20 49. In or about October 2015, Plaintiff A.V. received Allergan textured breast
21 implants. Upon information and belief, her implants are included on the list of recalled
22 BIOCELL implants, and paid approximately \$8,400 for the implants and procedure.

23 50. Plaintiffs would not have had and/or selected these implants had they known
24 prior to the procedure that they would subject them to the significantly greater risk of
25 developing BIA-ALCL, as well as the costs associated with removal, medical monitoring,
26 and other fees and procedures to detect and treat BIA-ALCL.

1 51. Plaintiffs want Allergan to fully pay for the removal of their implants, but
 2 Allergan has refused to pay for any surgical costs associated with the recall or medical
 3 monitoring of the greatly increased risk of BIA-ALCL.

4 52. Allergan manufactures and sells BIOCELL breast implants and tissue
 5 expanders. Allergan's BIOCELL line of implants are a type of breast implant and tissue
 6 expander that are textured to reduce the likelihood of common complications like capsular
 7 contracture.

8 53. The products that were recalled include:

- 9 • **Allergan Natrelle Saline-Filled Breast Implants** (formerly McGhan RTV
 10 Saline-Filled Mammary Implant) approved under P990074. The following are the
 11 textured styles:
 - 12 ○ Style 163, BIOCELL Textured Shaped Full Height, Full Projection Saline
 13 Breast Implants
 - 14 ○ Style 168, BIOCELL Textured Round Moderate Profile Saline Breast
 15 Implants, also referred to as 168MP (168 Moderate Profile)
 - 16 ○ Style 363, BIOCELL Textured Shaped Moderate Height, Full Projection
 17 Saline Breast Implants, Allergan catalog includes 363LF, or 363 Low Height
 18 Full Projection
 - 19 ○ Style 468, BIOCELL Textured Shaped Full Height Moderate Projection
 20 Saline Breast Implants
- 21 • **Allergan Natrelle Silicone-Filled Textured Breast Implants** (formerly Inamed
 22 Silicone-Filled Breast Implants) approved under P020056. The following are the
 23 textured styles:
 - 24 ○ Style 110, BIOCELL Textured Round Moderate Projection Gel Filled Breast
 25 Implants
 - 26 ○ Style 115, BIOCELL Textured Round Midrange Projection Gel Filled Breast
 27 Implants
 - 28 ○ 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)

II. Allergan's Textured Implants Greatly Increase the Risk of Cancer

1 54. The FDA has confirmed 457 cases of BIA-ALCL in the United States, all
2 linked to textured breast implants. The current lifetime risk of BIA-ALCL runs between 1
3 in 3,817 and 1 in 30,000. The American Society of Plastic Surgeons estimates the current
4 risk of BIA-ALCL to be between 1 in 2,207 and 1 in 86,029 for women with textured
5 implants.

6 55. On March 21, 2017, the FDA stated “[a]t this time, most data suggest that
7 BIA-ALCL occurs more frequently following implantation of breast implants with
8 textured surfaces rather than those with smooth surfaces.” In May 2017, a global analysis
9 of about forty governmental databases showed 363 cases of BIA-ALCL, 258 of which
10 were reported to the FDA.

11 56. On March 21, 2018, the FDA released another warning stating that it was
12 aware of 414 total cases of BIA-ALCL. Still, Allergan continued to manufacture and sell
13 the recalled implants and tissue expanders.

14 57. In December 2018, Allergan textured breast implants lost their European
15 certification and subsequently were suspended from the European and Brazilian markets.

16 58. In February 2019, the FDA sent a letter to health care providers across the
17 United States warning them about the link between textured breast implants and BIA-
18 ALCL.

19 59. It was not until July 24, 2019 that Allergan announced a worldwide recall of
20 all BIOCELL textured breast implants and tissue expanders. It waited this long despite
21 knowing for years about the growing data that these devices were unsafe and could cause
22 cancer. And it did not properly disclose this information to patients.

23 **III. The Recalled Implants Are from California**

24 60. Many of the BIOCELL breast implants that have been recalled were
25 originally designed, tested, and manufactured in California.

26 61. McGhan (later acquired by Allergan) was once a leading manufacturer of
27 breast implants, and made several of the devices recalled by Allergan. The recalled devices
28 include Allergan Natrelle Saline-Filled Breast Implants (formerly McGhan RTV Saline-

1 Filled Mammary Implant). The company was based in Santa Barbara County, California.
2 In 1985, it became a subsidiary of a publicly held company called First American
3 Corporation, which later changed its name to Inamed Corporation.

4 62. Inamed (later acquired by Allergan) also made several of the devices recalled
5 by Allergan including Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly
6 Inamed Silicone-Filled Breast Implants). This company was also based in Santa Barbara,
7 California, where it maintained its offices and headquarters, performed research and
8 development, and had its manufacturing facilities, including a 225,000 square foot facility.
9 Inamed also maintained large offices, manufacturing, and distribution facilities in
10 Carpinteria, California and Fremont, California. Inamed manufactured some of its breast
11 implant products in Santa Barbara, California.

12 63. In March 2006, Allergan acquired Inamed and its wholly owned subsidiary,
13 McGhan for approximately \$3.2 billion. Allergan acquired the BIOCELL trademark and
14 assumed the liability risks for its past and present manufacturing of breast implant
15 products.

16 64. In October 2006, Allergan publicly announced that Inamed's Santa Barbara
17 facilities would serve as its national center for research and development in medical
18 aesthetics, which included breast implants. In addition, Allergan maintained secondary
19 manufacturing facilities for the recalled BIOCELL products in Santa Barbara, California.

20 65. In 2013, Allergan filed a Summary of Safety and Effectiveness Data
21 ("SSED") with the FDA, and listed its research and development facility in Santa Barbara
22 County. The facility is about 105,000 square feet.

23 66. The respective SSEDs for the devices subject to the recall show that
24 employees in Santa Barbara, California were responsible for seeking FDA approval for
25 these products.

26 67. The Directions for Use ("DFU") containing important product and patient
27 information for the recalled BIOCELL products, were conceived of, reviewed, and
28

1 approved by Allergan in Santa Barbara and/or in Irvine, California. The relevant DFUs
2 list either a Santa Barbara or Irvine, California address for Inamed and Allergan.

3 68. Allergan's Medical Aesthetics division responsible for its BIOCELL breast
4 implants and overseeing the recall, including the deficient replacement warranty, is now
5 based in Irvine, California.

6 **IV. Allergan Failed to Disclose the Risks of Its Implants to Patients**

7 69. Patients and their physicians are entitled to know the potential risks of
8 textured implants. The risks of these devices are now public, and because of lawsuits like
9 this one, the FDA is now requiring a written warning on the packaging of Allergan's
10 textured breast implants, to inform consumers of the well-documented risks.

11 70. Yet, Allergan did not properly make these disclosures. Since at least 2011
12 when it was first reported by the FDA, Allergan knew about the link between its
13 BIOCELL implants and BIA-ALCL.

14 71. Indeed, since April 1991, the FDA has required breast implant manufacturers
15 to obtain premarket approval for breast implants through the Premarket Approval
16 Applications ("PMAs") process, which allows the FDA to evaluate the safety and
17 effectiveness of medical devices. This process includes known investigations showing
18 whether or not the device is safe and effective, and other data relevant for evaluating the
19 safety and effectiveness of the device that is known or should reasonably be known to the
20 manufacturer.

21 72. In 2000, Inamed began conducting a 10-year study to assess the performance
22 and safety of the McGhan Medical RTV Saline-Filled Breast Implant. In 2006, Allergan
23 began long-term studies for its Inamed Silicone-Filled Breast Implants to determine any
24 health concerns including cancer.

25 73. Allergan is required to file adverse event reports with the FDA, and has the
26 responsibility for timely communicating complete and accurate safety information. It is
27 further obligated to monitor all reasonably available information and clinical experiences.
28

1 74. The FDA publishes adverse event reports in a public, searchable database
2 called the Manufacturer and End User Facility Device Experience database or “MAUDE”
3 which is updated monthly.

4 75. It has been reported that instead of accurately reporting adverse events
5 individually each time an injury occurred, Allergan sought to “bury evidence of ruptures
6 and other injuries by reporting them as routine events that did not require public
7 disclosure.” It did this by filing Alternative Summary Reports (“ASR”).

8 76. For nearly two decades, the FDA has allowed manufacturers to submit
9 quarterly spreadsheets through the Alternative Summary Reports Program, summarizing
10 reports of common problems of approved devices. ASRs cannot include severe or
11 unexpected events or injuries necessitating remedial action, which should still be disclosed
12 to the public through MAUDE. Yet, it is believed that these incidents were kept hidden in
13 ASRs.

14 77. In fact, in 2017 when the FDA began implementing more rigorous reporting
15 requirements, there was a dramatic increase in the number of adverse events related to
16 breast implant injuries. It went from 200 a year, to 4,567 in 2017 and 8,242 in the first half
17 of 2018.

18 78. In an effort to increase transparency, on June 21, 2019, the FDA formally
19 ended the Alternative Summary Reporting Program. The FDA said the surge in reports
20 reflected the change in its requirements, rather than a new public health issue.

21 79. Accurate reporting of adverse events is critical to ensure that the public is
22 adequately and timely notified of potential problems with a medical device. This includes
23 devices manufactured and sold by Allergan.

24 80. The general public, including physicians and patients, receive information
25 from databases like the MAUDE. Researchers, including those studying connections
26 between breast implants and cancer and other health issues, also use the MAUDE database
27 in their studies of defective medical devices.

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

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

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

11 84. Allergan failed to comply with the conditions of the PMAs by failing to fulfill
12 its obligations to accurately and promptly report adverse events and continuing to sell the
13 recalled BIOCELL products.

14 85. Had Allergan complied with its obligations under federal law, the disclosure
15 of the connection between BIOCELL breast implants and BIA-ALCL would have allowed
16 patients including Plaintiffs, and their treating physician to make an informed decision
17 regarding whether to use other implants.

18 **CLASS ACTION ALLEGATIONS**

19 86. Plaintiffs bring this action in each of their individual capacity and as a class
20 action pursuant to Federal Rule of Civil Procedure 23 on behalf of the following proposed
21 nationwide class and state subclass:

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

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

26 87. Excluded from the Class are Defendants, as well as their officers, employees,
27 agents or affiliates, and any judge who presides over this action, as well as all past and
28 present employees, officers and directors of Defendants. Plaintiffs reserve the right to

1 expand, limit, modify, or amend the Class and definitions, including the addition of one or
 2 more subclasses, in connection with their motion for class certification, or at any other
 3 time, based upon, *inter alia*, changing circumstances and/or new facts obtained during
 4 discovery.

5 88. The Class meets the requirements of Federal Rules of Civil Procedure 23(a)
 6 and 23(b)(1), (b)(2), and (b)(3) for all of the following reasons.

7 89. **Numerosity** – Although the exact number of Class members is uncertain,
 8 and can only be ascertained through appropriate discovery, the number is great enough
 9 such that joinder is impracticable. The disposition of the claims of these Class members in
 10 a single action will provide substantial benefits to all parties and the Court. Information
 11 concerning the exact size of the putative class is within the possession of Defendants. The
 12 parties will be able to identify each member of the Class after Defendants' document
 13 production and/or related discovery.

14 90. **Commonality** – Common questions of fact and law exist as to all Class
 15 members and predominate over any questions that affect only individual Class members,
 16 including by example only and without limitation, the following:

- 17 a. Whether the recalled BIOCELL products significantly increase the risk
 18 of developing BIA-ALCL;
- 19 b. Whether Allergan knew or should have known that the recalled
 20 BIOCELL products significantly increase the risk of developing BIA-
 21 ALCL;
- 22 c. Whether Allergan was negligent in selling BIOCELL recalled products;
- 23 d. Whether Allergan failed to warn consumers regarding the risks of the
 24 recalled BIOCELL products;
- 25 e. Whether Allergan violated federal standards and requirements for the
 26 marketing, warning, and reporting of the recalled BIOCELL products;
- 27 f. Whether Allergan breached implied warranties connected with the
 28 recalled BIOCELL products;

- g. Whether Allergan's practices constitute unfair acts or practices under the Unfair Competition Law;
- h. Whether Plaintiffs and class members are entitled to equitable relief, including injunctive relief; and
- i. Whether Plaintiffs and class members are entitled to damages or other monetary relief, and if so, in what amount.

91. **Typicality** – All of Plaintiffs' claims are typical of the claims of the proposed Class they seek to represent in that: Plaintiffs, like all class members, were implanted with recalled BIOCELL products and faces an increased risk of BIA-ALCL; Plaintiffs' claims arise from the same practice or course of conduct that forms the basis of the Class claims; Plaintiffs' claims are based upon the same legal and remedial theories as the proposed Class and involve similar factual circumstances; there is no antagonism between the interests of Plaintiffs and absent Class members; the injuries that Plaintiffs suffered are similar to the injuries that Class members have suffered.

92. **Adequacy** – Plaintiffs will fairly and adequately represent the Class in that: (1) there is no conflict between Plaintiffs' claims and those of other Class members; (2) Plaintiffs have retained counsel who are skilled and experienced in class actions and who will vigorously prosecute this litigation; (3) Plaintiffs' claims are typical of the claims of Class members.

93. **Predominance** – The proposed action meets the requirements of Federal Rule of Civil Procedure 23(b)(3) because questions of law and fact common to the Class predominate over any questions which may affect only individual Class members.

94. **Superiority** – A class action is superior to all other methods available for the fair and efficient adjudication of this controversy. Because the amount of each individual class member's claim is small relative to the complexity of the litigation, and given Allergan's financial resources, no class member would be likely to pursue legal redress individually for the violations detailed herein. A class action would also streamline the determination of common claims or issues in this case. Conversely, individual suits would

1 create the potential for inconsistent or contradictory rulings. By contrast, a class action
2 presents fewer management difficulties, allows claims to be heard which would otherwise
3 go unheard, and allows comprehensive supervision by a single court.

4 95. Injunctive Relief - Class certification is also appropriate under Rule
5 23(b)(2) because Allergan acted and refused to act on grounds generally applicable to
6 the class, making appropriate final injunctive relief with respect to the class as a whole.

7 **FIRST CAUSE OF ACTION**
8 **STRICT LIABILITY—FAILURE TO WARN**

9 96. Plaintiffs re-allege and incorporate by reference the allegations contained in
10 the paragraphs above as if fully set forth herein.

11 97. Allergan manufactured, distributed, and/or sold the BIOCELL breast
12 implants that were implanted in Plaintiff.

13 98. Allergan had a duty to warn Plaintiffs and their physicians about the dangers
14 of the recalled BIOCELL products which it knew, or in the exercise of ordinary care,
15 should have known, at the time the recalled BIOCELL products left Allergan's control.

16 99. The BIOCELL breast implants had potential risks that were known or
17 knowable in light of the scientific and medical knowledge that was generally accepted in
18 the scientific and medical community at the time of the manufacture, distribution, or sale
19 of the implant.

20 100. Allergan failed to warn Plaintiffs and their physicians about the serious risk of
21 using its recalled BIOCELL products, including the greatly increased risk of BIA-ALCL.
22 At the time Plaintiffs received their implants, Allergan was aware of the clear causal
23 connection between its BIOCELL breast implants but did not disclose this information or
24 warn of the significantly greater risk of BIA-ALCL associated with its implants. Allergan
25 obtained this knowledge from performing extensive decades-long clinical studies,
26 reviewing scientific studies and literature, FDA communications, government reports, and
27 from complaints from consumers, among other sources. Rather than disclose the truth,
28

1 Allergan, in violation of federal law, attempted to conceal the true facts by not reporting all
2 adverse events to the FDA and by filing ASRs to avoid public reporting on MAUDE.

3 101. Allergan also failed to warn Plaintiffs and the public by not submitting
4 accurate adverse event reports that patients and physicians rely on to make informed
5 decisions about selecting the type of breast implants.

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

9 103. The potential risks presented a substantial danger to Plaintiffs and ordinary
10 consumers when used or misused in an intended or reasonably foreseeable way.

11 104. Plaintiffs and ordinary consumers would have not recognized the potential
12 for risks.

13 105. Allergan failed to adequately warn or instruct concerning the potential risks
14 of recalled BIOCELL products.

15 106. It was foreseeable to Allergan that failure to adequately warn about the risks
16 of its recalled BIOCELL products would cause irreparable harm to those who had the
17 products implanted in their bodies, including the types of emotional distress suffered by
18 Plaintiff.

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

26 108. Allergan's breach of its duty to warn has caused Plaintiffs damages including
27 surgical costs of removal of the products, ongoing medical monitoring, and other medical
28 expenses.

SECOND CAUSE OF ACTION
NEGLIGENCE

109. Plaintiffs re-allege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

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

111. Allergan breached these duties by failing to provide timely and adequate reports regarding the safety hazards associated with the recalled BIOCELL products, including the close causal connection to BIA-ALCL. Through numerous adverse reports, consumer complaints, scientific research and literature, internal clinical research, and communications from the FDA and international governmental organizations that Allergan monitored, Allergan was aware of the clear connection between the recalled BIOCELL products and BIA-ALCL, and that its textured breast implants posed a significantly greater risk than competing textured breast implants.

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

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

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

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

3 **THIRD CAUSE OF ACTION**
4 **NEGLIGENT RECALL**

5 116. Plaintiffs re-allege and incorporate by reference the allegations contained in
6 the paragraphs above as if fully set forth herein.

7 117. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL
8 products in the United States. That same day, Allergan voluntarily issued a worldwide
9 recall of BIOCELL products.

10 118. In issuing a voluntary recall, Allergan assumed duties to Plaintiffs to exercise
11 reasonable care in issuing and implementing the recall.

12 119. Allergan breached its duties by failing to adequately warn Plaintiffs of the
13 dangers associated with the use of the recalled BIOCELL products and by refusing to pay
14 for the surgical removal of Plaintiffs' implants notwithstanding the clear connection
15 between the recalled BIOCELL products and BIA-ALCL and the continuing risk the
16 implants pose to Plaintiffs' health.

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

19 **FOURTH CAUSE OF ACTION**
20 **BREACH OF THE IMPLIED WARRANTY**
21 **OF MERCHANTABILITY**

22 121. Plaintiffs incorporate the above allegations by reference.

23 122. By operations of law, Allergan, as manufacturer of the recalled BIOCELL
24 products and as the provider of the Limited Warranty, impliedly warranted to Plaintiffs
25 that the implants they were purchasing were of merchantable quality and safe for their
26 ordinary and intended use in the human body as an aesthetic breast enhancement.

27 123. Allergan breached the implied warranty of merchantability in connection with
28 the sale and distribution of the recalled BIOCELL products. At the point of sale, the
recalled BIOCELL products —while appearing normal—contained latent flaws rendering

1 them unsuitable and unsafe for use in the human body.

2 124. Had Plaintiffs known the recalled BIOCELL products are unsafe for use in
3 the human body, they would not have purchased them and had them implanted in their
4 bodies.

5 125. Allergan has refused to provide appropriate warranty relief, as it will not
6 provide surgical fee assistance to patients notwithstanding the substantially increased risk
7 of developing BIA-ALCL. Plaintiffs reasonably expected that their implants would not
8 present a substantial risk of bodily harm at the time of purchase.

9 126. As a direct and proximate result of Allergan's breach of the implied warranty
10 of merchantability, Plaintiffs have sustained damages in an amount to be determined at
11 trial.

12 **FIFTH CAUSE OF ACTION**
13 **VIOLATION OF THE CALIFORNIA**
14 **UNFAIR COMPETITION LAW, CAL. BUS.**
15 **& PROF. CODE §17200, *et seq.* ("UCL")**

16 127. Plaintiffs incorporate the above allegations by reference.

17 128. Plaintiffs bring this claim on behalf of the California Subclass.

18 129. The UCL proscribes acts of unfair competition including "any unlawful,
19 unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading
20 advertising." Cal. Bus. & Prof. Code § 17200.

21 130. Allergan's conduct is unfair in violation of the UCL, because it is immoral,
22 unethical, unscrupulous, oppressive, and substantially injurious.

23 131. Allergan acted in an immoral, unethical, unscrupulous, outrageous,
24 oppressive, and substantially injurious manner, including as follows:

- 25 a. Selling recalled BIOCELL products that it knew to present a substantially
26 greater risk of developing BIA-ALCL than competing textured breast
27 implants;
- 28 b. Concealing the clear connection between its BIOCELL products and
BIA-ALCL from the FDA, consumers, and medical professionals;

1 c. Failing to disclose that the recalled BIOCELL products have a
2 substantially greater risk of developing BIA-ALCL than competing
3 textured breast implants and;

4 d. Minimizing the scope of the risks associated with using the recalled
5 BIOCELL products in communications with the public.

6 132. The gravity of harm resulting from Allergan's unfair conduct outweighs any
7 potential utility. The practice of selling breast implants that present a substantial health
8 risk to consumers harms the public at large and is part of a common and uniform course
9 of wrongful conduct.

10 133. The harm from Allergan's conduct was not reasonably avoidable by
11 consumers because only Allergan was aware of the true facts concerning its BIOCELL
12 implants and BIA-ALCL, and Allergan did not disclose them, despite receiving
13 information establishing a causal connection between the BIOCELL products and BIA-
14 ALCL from clinical testing, medical literature and studies, communications from the FDA
15 and international agencies, and consumer complaints. Plaintiffs did not know of and had
16 no reasonable means of discovering the true risk of using BIOCELL implants.

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

23 135. Plaintiffs suffered injury in fact, including lost money or property, as a result
24 of Allergan's unfair acts. Absent Allergan's unfair conduct, Plaintiffs would not have
25 selected Allergan implants.

26 136. Through its unfair conduct, Allergan acquired money that Plaintiffs once had
27 an ownership interest in either directly or through Plaintiffs' medical professionals.

28 137. Plaintiffs accordingly seek appropriate relief under the UCL, including (a)

1 restitution in full and (b) such orders or judgments as may be necessary to enjoin Allergan
2 from continuing its unfair practices. Plaintiffs also seek reasonable attorneys' fees and
3 costs under applicable law, including California Code of Civil Procedure section 1021.5.

4 **SIXTH CAUSE OF ACTION**
MEDICAL MONITORING

5 138. Plaintiffs incorporate the above allegations by reference.

6 139. As a result of exposure to the recalled BIOCELL products, the need for
7 future monitoring is reasonably certain. Allergan's textured implants significantly increase
8 the risk of BIA-ALCL.

9 140. Medical monitoring is therefore reasonable in order to properly diagnose the
10 symptoms of BIA-ALCL particularly as it can become fatal when not treated in a timely
11 manner.

12 141. Plaintiffs are therefore entitled to have Allergan pay for the costs of ongoing
13 medical monitoring.

14 **PRAYER FOR RELIEF**

15 WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated,
16 request that the Court enter judgment against Defendants as follows:

17 A. An order certifying this action as a class action under Federal Rule of Civil
18 Procedure 23, defining the Class as requested herein, appointing the undersigned as Class
19 Counsel, and finding that Plaintiffs are a proper representative of the Class herein;

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

22 C. Enter an injunction against Allergan and its officers, agents, successors,
23 employees, representatives, assigns, and any and all persons acting in concert with them,
24 to: (1) ensure Allergan's compliance with California Business and Professions Code section
25 17200, *et seq.*; and (2) require them to implement a medical monitoring program for
26 Plaintiffs and class members;

27 D. Retain jurisdiction over this action to ensure Allergan complies with such a
28

1 decree;

- 2 E. Enter other appropriate equitable relief;
- 3 F. Award reasonable attorneys' fees and costs, as provided for by law;
- 4 G. Pre-judgment and post-judgment interest as provided by law; and
- 5 H. Such other and further relief that the Court may deem just and proper.

6 **DEMAND FOR JURY TRIAL**

7 Plaintiffs hereby demand trial by jury of all issues so triable.

8

9

10 AHDOOT & WOLFSON, PC

11 Dated: December 4, 2019

12 /s/ Tina Wolfson
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16 Counsel for Plaintiffs on behalf
17 of themselves and all others similarly situated

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