UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PLAINTIFFS ALABAMA DOE, ARIZONA DOE, CALIFORNIA DOE, COLORADO DOE, CONNECTICUT DOE, FLORIDA DOE, GEORGIA DOE, HAWAII DOE, ILLINOIS DOE 1, ILLINOIS DOE 2, IOWA DOE, KANSAS DOE, KENTUCKY DOE, LOUISIANA DOE, MICHIGAN DOE, MINNESOTA DOE 1, MINNESOTA DOE 2, MISSOURI DOE, MONTANA DOE, NEVADA DOE, NEW JERSEY DOE 1, NEW JERSEY DOE 2, NEW MEXICO DOE, NEW YORK DOE, NORTH CAROLINA DOE, OHIO DOE, OKLAHOMA DOE, OREGON DOE, PENNSYLVANIA DOE, RHODE ISLAND DOE, SOUTH DAKOTA DOE, TENNESSEE DOE, TEXAS DOE, UTAH DOE, VIRGINIA DOE, WASHINGTON DOE, WISCONSIN DOE, AND WYOMING DOE, individually and on behalf of all others similarly situated, Plaintiffs, v. ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and ALLERGAN plc, Defendants.	Civil Action No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiffs Alabama Doe, Arizona Doe, California Doe, Colorado Doe, Connecticut Doe, Florida Doe, Georgia Doe, Hawaii Doe, Illinois Doe 1, Illinois Doe 2, Iowa Doe, Kansas Doe, Kentucky Doe, Louisiana Doe, Michigan Doe, Minnesota Doe 1, Minnesota Doe 2, Missouri Doe,

Montana Doe, Nevada Doe, New Jersey Doe 1, New Jersey Doe 2, New Mexico Doe, New York Doe, North Carolina Doe, Ohio Doe, Oklahoma, Doe, Oregon Doe, Pennsylvania Doe, Rhode Island Doe, South Dakota Doe, Tennessee Doe, Texas Doe, Utah Doe, Virginia Doe, Washington Doe, Wisconsin Doe, and Wyoming Doe,[1] individually and on behalf of all others similarly situated, through their undersigned counsel, alleges as follows.

NATURE OF THE ACTION

1. Defendant Allergan plc ("Allergan") manufactures and sells BIOCELL saline-filled and silicone-filled breast implants and tissue expanders ("BIOCELL"). On July 24, 2019, Allergan announced a worldwide recall of BIOCELL after the U.S. Food and Drug Administration ("FDA") called for the action following new information that Allergan's BIOCELL implants were tied to a vast majority of cases of breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") not seen with other textured implants. Allergan announced that BIOCELL would no longer be sold or distributed in any market.

2. BIA-ALCL is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread through the body. Even if an individual's risk of developing BIA-ALCL is considered low, this cancer is serious and can lead to death, especially if not treated promptly. BIA-ALCL can be treated with surgery to remove the implant and surrounding scar tissue, and in some patients,

[1] A pseudonym has been used in place of Plaintiffs' real names due to privacy concerns. Plaintiffs may proceed using a pseudonym at this stage of the case because they have a reasonable fear of severe harm in their names being disclosed based upon the facts alleged and nature of this case involving sensitive information. *See Doe v. Megless*, 654 F.3d 404, 408-09 (3d Cir. 2011) (endorsing a non-comprehensive balancing test, which balances "whether a litigant has a reasonable fear of severe harm that outweighs the public's interest in open litigation," and identifying the "refusal to pursue the case at the price of being publicly identified" as an example where courts have permitted plaintiffs to proceed with pseudonyms).

may also require treatment with chemotherapy and radiation therapy. The recommended diagnostic testing for BIA-ALCL is invasive. The Directions for Use ("DFU") for doctors provides in pertinent part: "When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL." The symptoms of BIA-ALCL may occur well after the surgical incision has healed, often years after the implant placement.

3. In its July 24, 2019 announcement, the FDA stated that there are 573 cases of BIA-ALCL worldwide and that 33 people have died, a "significant increase" since the FDA's last update earlier in 2019 -- reflecting 116 new cases and 24 more deaths. The FDA stated that the risk of developing BIA-ALCL with Allergan BIOCELL textured implants is about six times that of becoming ill with textured implants from other manufacturers available in the U.S. The FDA noted that of the 573 cases of BIA-ALCL, 481, or more than 80%, were attributed to Allergan implants, and of the 33 deaths caused by BIA-ALCL, 12 of the 13 patients for whom the implant manufacturer was known had an Allergan implant when they were diagnosed. Dr. Amy Abernethy, principal FDA deputy commissioner stated: "Based on new data, our team concluded that action is necessary at this time to protect the public health." She further stated: "Once the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action." The FDA has identified this recall as a "Class I recall, the most serious type of recall," and warns that "use of these devices may cause serious injury or death."

4. The recalled BIOCELL products are:

> **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 Natrelle Dual-Gel styles LX, MX, and FX.

Allergan Natrelle Komuro breast implants styles KML, KMM, KLL, and KLM.

Allergan Natrelle Ritz Princess breast implants styles RML, RMM, RFL, and RFM.

Allergan Natrelle 150 Full Height and Short Height double lumen implants.

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)

5. On July 30, 2019, Carrie Strom, Senior Vice President, U.S. Medical Aesthetics, Allergan plc, sent the following letter to "Allergan Plastic Surgery Customer[s]":

Dear Allergan Plastic Surgery Customer,

> In follow-up to Allergan's voluntary recall of unused BIOCELL® products, we created the **BIOCELL® Replacement Warranty** for all patients currently implanted with BIOCELL® textured implants.
>
> **For patients in the U.S. who, as a result of the recall announcement on July 24, 2019, choose to replace their BIOCELL® textured devices with smooth devices in consultation with their plastic surgeon, Allergan will provide Allergan smooth device replacements for free.** The program will run for 24 months, until July 24, 2021, and will apply to revision surgeries on or after the date of the recall announcement, July 24, 2019.
>
> The decision to get a breast implant revision is a personal decision between patients and their plastic surgeons, and must be decided based on the appropriate discussion of benefits and risks. **As part of this program, Allergan will not provide surgical fee assistance to revision patients.** This decision is in-line with the FDA's recommendation not to remove textured implants or other types of breast implants in patients who have no symptoms of Breast Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL") due to the low risk of developing BIA-ALCL. Patients who decide to keep their BIOCELL® textured devices will continue to be covered under the NATRELLE® ConfidencePlus® warranty, which includes reimbursement for up to $1,000 in diagnostic fees and up to $7,500 in surgical fees related to diagnosing and treating BIA-ALCL.
>
> Some frequently asked questions about this policy are attached. You may initiate a replacement request under the BIOCELL® Replacement Warranty by talking with your Allergan Plastic Surgery Sales representative or by contacting the Allergan Product Surveillance team prior to surgery at 1-800-624-4261.
>
> Sincerely,
> Carrie Strom
> Senior Vice President, U.S. Medical Aesthetics
> Allergan plc

Allergan's decision as set forth in its July 30, 2019 letter not to provide surgical fee assistance for breast implant revision, but instead to provide only free smooth device replacements and limited reimbursement for diagnostic and surgical fees, is insufficient.

6. In violation of federal law requiring Allergan to report adverse events to the FDA, and to conceal from doctors and the public, the full extent of the risks of BIOCELL products,

Allergan submitted adverse event reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name "Allergan."

7. In October 2019, the FDA recommended labeling changes to breast implants to warn about the risk of BIA-ALCL. This includes a boxed warning and a patient decision checklist contained in an information booklet/brochure.

8. Allergan received a substantial benefit from selling thousands of the recalled BIOCELL products from 2006 through July 24, 2019, at the expense of Plaintiffs and the Class (as defined below) exposed to the risk of developing BIA-ALCL, a serious and deadly disease. Plaintiffs thus bring this action individually and on behalf of others in the United States who have recalled BIOCELL textured breast implants and tissue expanders to seek relief for damages caused by Defendants' conduct at their expense. Plaintiffs and the Class will be forced to expend substantial sums for the removal of the recalled implants, surgical and diagnostic fees, and/or medical monitoring and invasive diagnostic procedures required as a result of their exposure to the risk of contracting BIA-ALCL. Plaintiffs seek relief individually and for the Class to remedy the harms from Defendants' sale of recalled BIOCELL products to Plaintiffs and the Class.

THE PARTIES

I. PLAINTIFFS[2]

Alabama

9. Plaintiff Alabama Doe, identified as such to protect her privacy, was a citizen of the State of Alabama at all times relevant to this action. In approximately April 2015, Plaintiff Alabama Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number MX 410740. In

[2] Each of the Named Plaintiffs is a proposed Class Representative for the state law subclasses in which she resides or had her implant or explant surgery.

approximately April 2016, Plaintiff Alabama Doe was implanted a second time on her left side with Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number MX 410740. Plaintiff Alabama Doe paid approximately $5000.00 for the BIOCELL product, follow-up and implantation procedures. Plaintiff Alabama Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures. Plaintiff Alabama Doe wants the recalled BIOCELL product removed from her body at Defendants' full expense.

Arizona

10. Plaintiff Arizona Doe, identified as such to protect her privacy, was a citizen of the State of Arizona at all times relevant to this action. In approximately April 2016, Plaintiff Arizona Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, reference number FF-410220. At the time of the procedure, Plaintiff Arizona paid approximately $7,000 for the BIOCELL product and the procedure. Plaintiff Arizona Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Arizona Doe wants the recalled BIOCELLproduct removed from her body at Defendants' full expense.

California

11. Plaintiff California Doe, identified as such to protect her privacy, was a citizen of the State of California at all times relevant to this action. In approximately June 2013, Plaintiff California Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference Mumber MF-410525. In approximately December 2019, Plaintiff California Doe had the recalled Allergan product explanted from her body and replaced with non-recalled Allergan product Natrelle Inspira Cohesive Breast Implants, Reference Number SCF-560 (left) and SCF-520 (right). Plaintiff California Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal and replacement, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff California Doe wants the removal of recalled BIOCELL product removed from her body and the replacement with non-recalled Allergan product at Defendants' full expense.

Colorado

12. Plaintiff Colorado Doe, identified as such to protect her privacy, was a citizen of the State of Colorado at all times relevant to this action. In approximately December 2016, Plaintiff Colorado Doe was implanted with a BIOCELL recalled product, Natrelle Inspira Breast Implants, Reference number TRX-375. At the time of the procedure, Plaintiff Colorado Doe lived in Colorado and paid approximately $12,000.00 for the BIOCELL product and the procedure. In approximately October 2019, Plaintiff Colorado Doe had the BIOCELL recalled product explanted and paid approximately $7,500.00 for the explant procedure and replacement with non-recalled, non-Allergan product. Plaintiff Colorado Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject

her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL, as well as the cost of the explant procedure. Plaintiff Colorado Doe wants the removal of the recalled BIOCELL product from her body and the replacement with non-recalled product to be at Defendants' full expense.

Connecticut

13. Plaintiff Connecticut Doe, identified as such to protect her privacy, was a citizen of the State of Connecticut at all times relevant to this action. In approximately November 2016, Plaintiff Connecticut Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number FX-410775. At the time of the procedure, Plaintiff Connecticut Doe lived in Connecticut and paid approximately $1000.00 for the BIOCELL product and the procedure. In approximately November 2019, Plaintiff Connecticut Doe had the BIOCELL recalled product explanted and paid approximately $3,500.00 for the explant procedure and replacement with non-recalled Natrelle Inspira Cohesive Breast Implants, Reference Number SCX-700. Plaintiff Connecticut Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL, as well as the cost of the explant procedure. Plaintiff Connecticut Doe wants the removal of the recalled BIOCELL product from her body and the replacement with non-recalled product to be at Defendants' full expense.

Florida

14. Plaintiff Florida Doe, identified as such to protect her privacy, was a citizen of the State of Florida at all times relevant to this action. In approximately August 2016, Plaintiff Florida Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number MX 410290. At the time of the procedure, Plaintiff Florida Doe lived in Florida and paid approximately $7500.00 for the BIOCELL product and the procedure. In approximately August 2019, Plaintiff Florida Doe had the BIOCELL recalled product explanted and paid approximately $2,400 for the explant procedure. Currently, Plaintiff Florida Doe does not have breast implants. Plaintiff Florida Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL, as well as the cost of the explant procedure.

Georgia

15. Plaintiff Georgia Doe, identified as such to protect her privacy, was a citizen of the State of Georgia at all times relevant to this action. In approximately September 2016, Plaintiff Georgia Doe was implanted with a BIOCELL recalled product, Inspira Breast Implants Reference Number TRLP-280. At the time of the procedure, Plaintiff Georgia Doe lived in Georgia and paid approximately $5,000.00 for the BIOCELL product and the procedure. Plaintiff Georgia Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Georgia Doe wants the recalled BIOCELL© product removed from her body at Defendants' full expense.

Hawaii

16. Plaintiff Hawaii Doe, identified as such to protect her privacy, was a citizen of the State of Hawaii at all times relevant to this action. In approximately July 2013, Plaintiff Hawaii Doe was implanted with a BIOCELL recalled product, Natrelle 468 Saline-filled Breast Implants, Reference Number 468-350, and paid approximately $5,500 for the BIOCELL product and the procedure. Plaintiff Hawaii Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Hawaii Doe wants all costs associated with her original implantation procedure, as well as all medical monitoring and diagnostic procedures moving forward to be at Defendants' full expense.

Illinois

17. Plaintiff Illinois Doe 1, identified as such to protect her privacy, was a citizen of the State of Illinois at all times relevant to this action. In October 2016, Plaintiff Illinois Doe 1 was implanted with a BIOCELL recalled product, Natrelle 410 Cohesive Anatomically Shape Silicone filled breast implant, Reference number FF 410375. At the time of the procedure, Plaintiff Illinois Doe 1 lived in Illinois and paid approximately $15,000 for the BIOCELL product and the procedure. Plaintiff Illinois Doe 1 would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Illinois Doe 1 wants the recalled BIOCELL product removed from her body at Defendants' full expense.

18. Plaintiff Illinois Doe 2, identified as such to protect her privacy, was a citizen of the state of Illinois at all times relevant to this action. In 2013, Plaintiff Illinois Doe 2 was implanted with a BIOCELL recalled product, Natrelle Silicone-Filled Breast Implant Style 120, Reference number 120-340. At the time of the procedure, Plaintiff Illinois Doe 2 lived in Illinois and paid approximately $6,000 for the BIOCELL product and the procedure (including a breast lift). In approximately June 2019, Plaintiff Illinois Doe 2 had the BIOCELL recalled product explanted and paid approximately $10,000 for the explant procedure (including a breast lift). Currently, Plaintiff Illinois Doe 2 does not have breast implants. Plaintiff Illinois Doe 2 would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL and the costs associated with removal, surgical and diagnostic fees and medical monitoring to detect BIA-ALCL, as well as the cost of the explant procedure

Iowa

19. Plaintiff Iowa Doe, identified as such to protect her privacy, was a citizen of the State of Iowa at all times relevant to this action. In approximately September 2016, Plaintiff Iowa Doe was implanted with a BIOCELL recalled product, Natrelle 115 Silicone-filled Breast Implants, Reference number 115-469. Plaintiff Iowa Doe paid approximately $5,200.00 for the BIOCELL product and the procedure. In approximately September 2019, Plaintiff Iowa Doe had the BIOCELL recalled product explanted and paid approximately $4,700.00 for the explant procedure. Plaintiff Iowa Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees,

medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Kansas

20. Plaintiff Kansas Doe, identified as such to protect her privacy, was a citizen of the State of Kansas at all times relevant to this action. In approximately October 2016, Plaintiff Kansas Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference Number FX-410690 on her left side, and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference Number FM-410310 on her right side. Plaintiff Kansas Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Kansas Doe wants the recalled BIOCELL product removed from her body and replaced with non-recalled product at Defendants' full expense.

Kentucky

21. Plaintiff Kentucky Doe, identified as such to protect her privacy, was a citizen of the State of Kentucky at all times relevant to this action. On or about April 1, 2015, Plaintiff Kentucky Doe was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone breast implants, reference number FX-410450. At the time of the procedure, Plaintiff Kentucky Doe lived in Kentucky. Plaintiff Kentucky Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive

diagnostic procedures to detect BIA-ALCL. Plaintiff Kentucky Doe wants the recalled BIOCELL products removed from her body at Defendants' full expense.

Louisiana

22. Plaintiff Louisiana Doe, identified as such to protect her privacy, was a citizen of the State of Louisiana at all times relevant to this action. In approximately January 2015, Plaintiff Louisiana Doe was implanted with two BIOCELL recalled products, Natrelle 168 Saline-Filled breast implant, reference number 168-390. At the time of the procedure, Plaintiff Louisiana Doe lived in Louisiana. Plaintiff Louisiana Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. On or about October 31, 2019, Plaintiff Louisiana Jane Doe had her implants replaced with a different product, for which she paid approximately $5,400 out-of-pocket.

Massachusetts

23. Plaintiff Massachusetts Doe, identified as such to protect her privacy, was a citizen of the State of Massachusetts at all times relevant to this action. On or about February 12, 2015, Plaintiff Massachusetts Jane Doe was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive Anatomically Shaped Saline-Filled breast implants, reference number MX-410445. At the time of the procedure, Plaintiff Massachusetts Doe lived in Massachusetts. Plaintiff Massachusetts Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical

monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Massachusetts Doe wants the recalled BIOCELL products removed from her body at Defendants' full expense.

Michigan

24. Plaintiff Michigan Doe, identified as such to protect her privacy, was a citizen of the State of Michigan at all times relevant to this action. In approximately March 2014, Plaintiff Michigan Jane Doe was implanted with two BIOCELL recalled products, Natrelle Silicone-Filled Breast Implants Model No. 120, Saline-filled breast implant, Reference number 120-500. At the time of the procedure, Plaintiff Michigan Doe lived in Michigan and paid for the BIOCELL products and the procedure. Plaintiff Michigan Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Michigan Doe wants the recalled BIOCELL products removed from her body at Defendants' full expense.

Minnesota

25. Plaintiff Minnesota Doe 1, identified as such to protect her privacy, was a citizen of the State of Minnesota at all times relevant to this action. On or about April 3, 2016, Plaintiff Minnesota Doe 1 was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants, reference numbers FF-410775. At the time of the procedure, Plaintiff Minnesota Doe 1 lived in Minnesota. Plaintiff Minnesota Doe 1 would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical

monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Minnesota Doe 1 wants the recalled BIOCELL products removed from her body at Defendants' full expense.

26. Plaintiff Minnesota Doe 2, identified as such to protect her privacy, was a citizen of the State of Minnesota at all times relevant to this action. On or about June 28, 2018, Plaintiff Minnesota Jane Doe 2 was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants, reference numbers FF-410375. At the time of the procedure, Plaintiff Minnesota Doe 2 lived in Minnesota. Plaintiff Minnesota Doe 2 would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. On or about November 25, 2019, Plaintiff Minnesota Doe 2 had her implants replaced with a different product.

Missouri

27. Plaintiff Missouri Doe, identified as such to protect her privacy, was a citizen of the State of Missouri at all times relevant to this action. In 2005, Plaintiff Missouri Doe had a mastectomy on her right breast and in 2011 had a mastectomy on her left breast. On April 11, 2014 Plaintiff Missouri Doe was implanted with a BIOCELL recalled product, Natrelle 410 silicone-filled breast implants. Plaintiff Missouri Doe has the BIOCELL implants removed on August 30, 2019 at an out-of-pocket cost of approximately $4,300. Plaintiff Missouri Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive

diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Montana

28. Plaintiff Montana Doe, identified as such to protect her privacy, was a citizen of the State of Montana at all times relevant to this action. In 2015, Plaintiff Montana Doe was implanted with two BIOCELL recalled products, Natrelle 410 Highly-Cohesive Anatomically Shaped Silicone-Filled breast implant, reference number FF-410655. Shortly after her implant procedure, Plaintiff Montana Doe developed an infection in her left breast drain tube that required removal of that implant. After multiple weeks of post-removal healing, she received a second implant (also a Natrelle 410 Highly-Cohesive Anatomically Shaped Silicone-Filled breast implant) to replace the first one. The right implant remained from the initial surgery. At the time of the procedure, Plaintiff Montana Doe lived in Montana. Plaintiff Montana Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. On or about December 2, 2019, Plaintiff Montana Doe had her BIOCELL implants removed from her body.

Nevada

29. Plaintiff Nevada Doe, identified as such to protect her privacy, was a citizen of the State of Nevada at all times relevant to this action. In approximately June 2010, Plaintiff Nevada Jane Doe was implanted with two BIOCELL recalled products, Natrelle 120 Silicone-Filled breast implants, reference number 120-340. At the time of the procedure, Plaintiff Nevada Doe lived in Nevada. Plaintiff Nevada Doe would not have had the recalled BIOCELL products implanted had

she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff Nevada Doe wants the recalled BIOCELL products removed from her body at Defendants' full expense

New Jersey

30. Plaintiff New Jersey Doe 1, identified as such to protect her privacy, was a citizen of the State of New Jersey at all times relevant to this action. On or about December 4, 2014, Plaintiff New Jersey Doe 1 was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive breast implants, reference numbers MF410525. At the time of the procedure, Plaintiff New Jersey Doe 1 lived in New Jersey. Plaintiff New Jersey Doe 1 would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. Plaintiff New Jersey Doe 1 wants the recalled BIOCELL products removed from her body at Defendants' full expense.

31. Plaintiff New Jersey Doe 2, identified as such to protect her privacy, was a citizen of the State of New Jersey at all times relevant to this action. On or about May 14, 2014, Plaintiff New Jersey Doe 2 was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive breast implants, reference numbers MF410525. At the time of the procedure, Plaintiff New Jersey Doe lived in New Jersey. Plaintiff New Jersey Doe 2 would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated

with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. On or about August 7, 2019, Plaintiff New Jersey Doe 2 had her implants removed from her body, for which she paid approximately $8,000 out-of-pocket.

New Mexico

32. Plaintiff New Mexico Doe, identified as such to protect her privacy, was a citizen of the State of New Mexico at all times relevant to this action. On or about July 24, 2017, Plaintiff New Mexico Doe was implanted with two BIOCELL recalled products, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants, Reference number MF410335. At the time of the procedure, Plaintiff New Mexico Jane lived in New Mexico. Plaintiff New Mexico Jane Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, together with lost work time for recovery. Plaintiff New Mexico Doe wants the recalled BIOCELL products removed from her body at Defendants' full expense.

New York

33. Plaintiff New York Doe, identified as such to protect her privacy, was a citizen of the State of New York at all times relevant to this action. In approximately August 2015, Plaintiff New York Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference number MX 410420. Plaintiff New York Doe paid approximately $10,000.00 for the BIOCELL product and the procedure. In approximately August 2019, Plaintiff New York Doe had the BIOCELL recalled product explanted and paid approximately $6,000.00 for the explant procedure and replacement with non-recalled

Smooth Shell Surface Natrelle Saline-Filled Breast Implants, Reference Number 68-420. Plaintiff New York Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

North Carolina

34. Plaintiff North Carolina Doe, identified as such to protect her privacy, was a citizen of the State of North Carolina at all times relevant to this action. On or about August 3, 2015, Plaintiff North Carolina Doe was implanted with two BIOCELL recalled products, Natrelle 410 Saline-filled breast implants, reference number FX-410410. At the time of the procedure, Plaintiff North Carolina Doe lived in North Carolina. Plaintiff North Carolina Doe would not have had the recalled BIOCELL products implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical, and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL. On or about October 18, 2019, Plaintiff North Carolina Doe had her implants replaced with a different product, for which she paid approximately $4,466 out-of-pocket. As a result of the explant procedure Plaintiff North Carolina Doe sustained additional scarring beyond what she experienced at the time of her initial implant procedure

Ohio

35. Plaintiff Ohio Doe, identified as such to protect her privacy, was a citizen of the State of Ohio at all times relevant to this action. In approximately October 2013, Plaintiff Ohio Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically

Shaped Silicone-filled breast implants, Reference number MF-410470. Plaintiff Ohio Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Ohio Doe wants the recalled BIOCELL product removed from her body and replaced with non-recalled product at Defendants' full expense.

Oklahoma

36. Plaintiff Oklahoma Doe, identified as such to protect her privacy, was a citizen of the State of Oklahoma at all times relevant to this action. In 1998 Plaintiff Oklahoma Doe was diagnosed with breast cancer and underwent a double-mastectomy and reconstruction. On June 20, 2017 Plaintiff Oklahoma Doe was implanted with a BIOCELL recalled product, Natrelle Silicone-filled breast implants. Plaintiff Oklahoma Doe paid approximately $6,000.00 for the BIOCELL product and the procedure. Plaintiff Oklahoma Doe intends to have the recalled implants removed, but does not yet have a date set for the removal procedure. Plaintiff Oklahoma Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Oregon

37. Plaintiff Oregon Doe identified as such to protect her privacy, was a citizen of the State of Oregon at all times relevant to this action. On March 25, 2008 Plaintiff Oregon Doe was

implanted with a BIOCELL recalled product, Natrelle 115 Silicone-filled breast implants. Plaintiff Oregon Doe intends to have the recalled implants removed, but does not yet have a date set for the removal procedure. Plaintiff Oregon Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Pennsylvania

38. Plaintiff Pennsylvania Doe, identified as such to protect her privacy, was a citizen of the State of Pennsylvania at all times relevant to this action. In June 2012, Plaintiff Pennsylvania Doe was implanted with a BIOCELL recalled product, Natrelle 115 Silicone-filled breast implants, reference number 115-354. At the time of the procedure, Plaintiff Pennsylvania Doe lived in Pennsylvania and paid approximately $9,300 for the BIOCELL product and the procedure. Plaintiff Pennsylvania Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Pennsylvania Doe wants the recalled BIOCELL product removed from her body at Defendants' full expense.

Rhode Island

39. Plaintiff Rhode Island Doe identified as such to protect her privacy, was a citizen of the State of Rhode Island at all times relevant to this action. In 2013 Plaintiff Rhode Island Doe underwent a double-mastectomy and reconstruction. Plaintiff Rhode Island Doe was implanted

with a BIOCELL recalled product, Natrelle 410 Silicone-filled breast implants, reference number MF-410580. Due to complications, the right implant had to be removed and replaced with the same style implant on December 10, 2015. Plaintiff Rhode Island Doe intends to have the recalled implants removed and the removal procedure is currently scheduled for December 20, 2019. Plaintiff Rhode Island Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

South Dakota

40. Plaintiff South Dakota Doe identified as such to protect her privacy, was a citizen of the State of South Dakota at all times relevant to this action. On February 27, 2019 Plaintiff South Dakota Doe underwent a double-mastectomy and reconstruction. Plaintiff South Dakota Doe was implanted with a BIOCELL recalled product, Natrelle 410 Silicone-filled breast implants. Plaintiff South Dakota Doe had the BIOCELL implants removed on September 11, 2019. Plaintiff South Dakota Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Tennessee

41. Plaintiff Tennessee Doe, identified as such to protect her privacy, was a citizen of the State of Tennessee at all times relevant to this action. On April 4, 2017 Plaintiff Tennessee

Doe was implanted with a BIOCELL recalled product, Natrelle 410 Silicone-filled breast implants. Plaintiff Tennessee Doe intends to have the recalled implants removed, but does not yet have a date set for the removal procedure. Plaintiff Tennessee Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Texas

42. Plaintiff Texas Doe, identified as such to protect her privacy, was a citizen of the State of Texas at all times relevant to this action. In July 2017, Plaintiff Texas Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, reference number FM-410395. At the time of the procedure, Plaintiff Texas Doe lived in Texas and traveled to Florida where she paid approximately $13,500 for the BIOCELL product and the procedure. Plaintiff Texas Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Texas Doe wants the recalled BIOCELL product removed from her body at Defendants' full expense.

Utah

43. Plaintiff Utah Doe, identified as such to protect her privacy, was a citizen of the State of Utah at all times relevant to this action. On January 11, 2017 Plaintiff Utah Doe was

implanted with a BIOCELL recalled product, Natrelle Inspira TRF-220 textured round gel breast implants. Plaintiff Utah Doe intends to have the recalled implants removed, but does not yet have a date set for the removal procedure. Plaintiff Utah Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Virginia

44. Plaintiff Virginia Doe, identified as such to protect her privacy, was a citizen of the State of Virginia at all times relevant to this action. In 2014, Plaintiff Virginia Doe was diagnosed with breast cancer. In January 2015, Plaintiff Virginia Doe underwent a mastectomy and reconstruction in her left breast including implantation of an expander. In or about April 2015 Plaintiff Virginia Doe was implanted with a BIOCELL recalled product, Natrelle 410 Silicone-filled breast implants. Plaintiff Virginia Doe had the BIOCELL implants removed on October 31, 2019 at a cost to her of approximately $8,000. Plaintiff Virginia Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures.

Washington

45. Plaintiff Washington Doe, identified as such to protect her privacy, was a citizen of the State of Washington at all times relevant to this action. In approximately December 2013,

Plaintiff Washington Doe was implanted with a BIOCELL recalled product, Natrelle 120 Silicone-filled Breast Implants, Reference Number 120-260, and paid approximately $10,500 for the BIOCELL product and the procedure. Plaintiff Washington Doe would not have had the recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL. Plaintiff Washington Doe wants the recalled BIOCELL product removed from her body and replaced with non-recalled at Defendants' full expense.

Wisconsin

46. Plaintiff Wisconsin Doe, identified as such to protect her privacy, was a citizen of the State of Wisconsin at all times relevant to this action. In approximately August 2014, Plaintiff Wisconsin Doe was implanted with a BIOCELL recalled product, Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-filled breast implants, Reference Number FF-410335. In approximately October 2019, Plaintiff Wisconsin Doe had the BIOCELL recalled product explanted and paid approximately $6500.00 for the explant procedure and replacement with non-recalled Allergan product. Plaintiff Wisconsin Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA- ALCL, as well as the cost of the explant procedure. Plaintiff Wisconsin Doe wants the removal of the recalled BIOCELL product from her body and the replacement with non-recalled Allergan product to be at Defendants' full expense.

Wyoming

47. Plaintiff Wyoming Doe, identified as such to protect her privacy, was a citizen of the State of Wyoming at all times relevant to this action. In approximately March 2016, Plaintiff Wyoming Doe was implanted with a BIOCELL© recalled product, Natrelle Inspira Breast Implants Reference number TRX-800. Owing to implant movement, Plaintiff Wyoming Doe was re-implanted with her Natrelle Inspira Breast Implants Reference number TRX-800 in approximately November 2018. Plaintiff Wyoming Doe paid approximately $2,100.00 for the BIOCELL product, the implantation and corrective re-implantation procedures. Plaintiff Wyoming Doe would not have had recalled BIOCELL product implanted had she known prior to the procedure that implantation with BIOCELL would subject her to the risk of contracting BIA-ALCL, as well as the costs associated with removal, surgical and diagnostic fees, medical monitoring, and invasive diagnostic procedures to detect BIA-ALCL, as well as the cost of the explant and implant replacement procedures. Plaintiff Wyoming Doe wants the recalled BIOCELL© product removed from her body at Defendants' full expense.

II. DEFENDANTS

48. Defendant Allergan plc is a publicly-traded corporation whose headquarters are in Dublin, Ireland. Allergan's administrative headquarters in the United States are located in the States of New Jersey and California.

49. Defendant Allergan, Inc., formerly known as Inamed Corporation ("Inamed"), and prior to that known as McGhan Medical Corporation ("McGhan"), 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.

50. Defendant Allergan USA, Inc. 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.

51. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, and reference to "Allergan," "Defendant" or "Defendants" herein refers to each and every Defendant individually and collectively.

JURISDICTION AND VENUE

52. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

53. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in New Jersey and within this District. Defendants have sufficient minimum contacts with New Jersey and intentionally avail themselves of the consumers and markets within New Jersey through the promotion and sale of their products, including now-recalled BIOCELL.

54. 109. Venue is proper in this District on account of the MDL consolidation pursuant to 28 U.S.C. § 1407 and because one Defendant resides in this District, 28 U.S.C. § 1391(b)(1); "a substantial part of the events or omissions giving rise to the claim occurred" in this District, 28 U.S.C. § 1391(b)(2); and Defendants are subject to the personal jurisdiction of this Court, 28 U.S.C. § 1391(b)(3).

FACTUAL ALLEGATIONS

I. Breast Implants and ALCL.

55. A breast implant is a prosthetic product used to change the size, shape, and contour of a woman's breast. There are three general types of breast implant products, defined by their

filler material: saline solution, silicone gel, and composite filler. Breast implants are available in various sizes and can have either a smooth or textured shell.

56. Approximately 300,000 total breast implants are placed per year in the U.S. From 2000 to 2016, the number of breast augmentations in the United States rose 37%, and reconstructions after mastectomy rose 39%.

57. In 2011, a summary of published studies, evidence, and reports was published that identified 27 cases of ALCL, and concluded that there was an association between breast implants and ALCL. In January 2011, the FDA released a report on BIA-ALCL, listing as its primary finding the following: "[b]ased on the published case studies and epidemiological research, the FDA believes that there is a possible association between breast implants and ALCL." The FDA further noted that, while it was not prepared to associate a particular type of breast implant with BIA-ALCL, "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."

58. The natural occurrence of ALCL is 1/300,000. However, the FDA recently cited studies that place the estimated current risk of BIA-ALCL in women with textured implants to be between 1:3,817 and 1:30,000. This is consistent with risks reported in Europe. A December 2016 update from Australia's Therapeutic Goods Administration ("TGA") reported a risk of 1:1,000 to 1:10,000 for textured implants.

59. In March 2015, an analysis identified 173 cases of ALCL. That same month, the French National Cancer Institute announced, "There is a clearly established link between the occurrence of this disease and the presence of a breast implant."

60. On May 19, 2016, the World Health Organization ("WHO") gave the disease an official designation as "BIA-ALCL" and classified it as a distinct clinical entity, separate from other categories of ALCL.

61. In November 2016, Australia's TGA convened an expert advisory panel to discuss the association between breast implants and ALCL and provide ongoing advice.

62. On March 21, 2017, the FDA released a safety communication updating the current understanding of BIA-ALCL. In the Updated Safety Alert, the FDA recognized the WHO's designation that BIA-ALCL can occur after a patient receives breast implants, and stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

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

64. A September 2017 update from the FDA reported that the agency had received a total of 414 medical device reports ("MDRs") related to breast implants and ALCL, including nine deaths.

65. On May 9, 2018, Australia's TGA reported 72 cases of ALCL in Australian patients.

II. Allergan's Repeated Attempts to Conceal the Risks of ALCL Associated with its Breast Implants.

66. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). Upon enactment of the MDA, the FDA deemed saline-filled breast implants as Class II devices, to be reviewed through a premarket notification process. The devices could be publicly sold so long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. § 360e(d)(2). In 1988, in response

to growing safety concerns, the FDA re-classified both saline-filled and silicone gel-filled breast implants as Class III devices requiring premarket approval ("PMA").

67. In April 1991, upon final publication of new regulations, the FDA began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone gel-filled breast implants. Through its PMA process, the FDA engages in scientific evaluations of the safety and effectiveness of Class III medical devices. The FDA considers Class III devices to create the greatest risk to human safety, necessitating the implementation of special controls, including the requirement to obtain PMA under 21 U.S.C. § 360 prior to marketing the product to the public.

68. A PMA application must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement Application must provide:

a. Proposed indications for use;

b. Device description including the manufacturing process;

c. Any marketing history;

d. Summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk;

e. Each of the functional components or ingredients of the device;

f. Methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. Any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably known to the manufacturer from any source, including information derived from investigations other than those proposed in the application from commercial marketing experience.

69. Allergan's Natrelle® silicone-filled breast implants are Class III medical devices receiving pre-market approval by the FDA in November 2006.

70. As conditions of the 2006 approval, the FDA required Allergan to conduct six post-approval studies to characterize the long-term performance and safety of the devices. The post-approval studies for Allergan's Natrelle® Silicone-Filled breast implants included:

a. Core Post-Approval Studies (Core Studies) – To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.

b. Large Post-Approval Studies (Large Studies) – To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10 years.

c. Device Failure Studies (Failure Studies) – To further characterize the modes and causes of failure of explanted devices over a 10-year period.

d. Focus Group Studies – To improve the format and content of the patient labeling.

e. Annual Physician Informed Decision Survey (Informed Decision Study) – To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.

f. Adjunct Studies – To provide performance and safety information about silicone gel-filled breast implants for the period when implants could only be used for reconstruction and replacement of existing implants.

71. The PMA provided that "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

72. After receiving premarket approval for a Class III device, manufacturers are subject to a continuous obligation to comply with Medical Device Reporting pursuant to 21 U.S.C. § 360i(a)(1) and 21 C.F.R. § 803.50(a). Significant to this action, manufacturers are required to file adverse event reports with the FDA.

73. The primary responsibility for timely and accurately communicating complete, accurate, and current safety and efficacy information related to medical devices, such as Allergan's Natrelle® Silicone-Filled breast implants, rests with the manufacturer.

74. This primary reporting obligation instills in the manufacturer a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

75. According to the FDA, the purpose of filing the reports is to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments.[3]

76. These reports can be accessed on the FDA's Manufacturer and User Facility Device Experience ("MAUDE"). Running a search on MAUDE as of the date of this Complaint generates over 300 BIA-ALCL cases and approximately 1,400 injury reports.

77. In order to conceal the true number of adverse event reports, Allergan reported adverse event reports with incorrect manufacturer names, including "Santa Barbra" and "Costa Rica," instead of under the name Allergan. As a result, consumers, healthcare professionals, and the FDA were unable to detect trends in Allergan's products, depriving the market of the necessary information to make an informed decision about whether Allergan's products were safe and effective.

78. Equally as troubling, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure" until

[3] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM (last visited December 19, 2019).

2017.[4] This was done through filing "Alternative Summary Reports" ("ASR") for multiple adverse event reports all at one time, instead of filing an adverse event report for each individual adverse event. The ASRs require less detail and are not publicly available through the MAUDE website.

79. In 2017, the FDA no longer permitted the filing of ASRs.[5] Prior to 2017, there were, on average, fewer than 200 breast implant injuries reported a year. In 2017, this number skyrocketed to 4,567 adverse events, and nearly doubled to 8,242 in the first half of 2018.

80. Due to Allergan's reporting practices, medical professionals and consumers relying on the public reports would be unable to draw an accurate conclusion about the safety of a particular medical device.

81. Indeed, Allergan reported a case of possible BIA-ALCL through a non-public ASR.[6]

82. Under state laws, including those states represented by the Plaintiffs, which do not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

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[4] *See* https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface (last visited December 19, 2019).

[5] *See* https://www.medtechdive.com/news/fda-ends-alternative-reporting-program-pledges-to-make-maude-user-friendly/557465/ (last visited December 19, 2019).

[6] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.cfm?MDRFOI__ID=7521708 (last visited December 19, 2019) ("[A] possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (alcl), a type of non-hodgkin[]s lymphoma.").

83. Time is of the essence when monitoring and reporting adverse events, especially those indicating an association between a medical product and breast cancer, ALCL and/or BIA-ALCL, as required by federal regulations, as well as by those states represented by the Plaintiffs.

84. Delayed reporting prevents the healthcare community and the public from timely learning of risks which inevitably play a part in their decision-making, including by both physicians and consumers, regarding treatments and procedures, and thereby exposes countless additional women to potential harm.

85. Allergan failed to report adverse events from the post-market approval studies commissioned as part of the implant's PMA approval that would have led to reports suggesting the devices' contribution to serious injury.

86. Had Defendants not intentionally failed to comply with their clearly-established post-market surveillance obligations, Plaintiffs and the Class would have decided against implantation.

87. Under applicable state law, which does not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to exercise reasonable care in adequately warning Plaintiffs, Class members, and/or implanting medical professionals about the dangers of Allergan's Natrelle® Silicone-Filled breast implants, and about all adverse events of which Allergan became aware, and further, had a post-market duty to identify, monitor, and report all adverse events and all risks associated with the product.

88. Despite having knowledge and possession of evidence showing that the use of Allergan's textured breast implants was dangerous and likely to place consumers' health at serious risk, as detailed further below, Allergan refused or recklessly failed to identify, disclose, and warn

of the health hazards and risks associated with the product, and about all adverse events that were known to Allergan.

89. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was required to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

90. From 2006 through the date of Plaintiffs' implants, Allergan continually acquired new information regarding the strong association between its Natrelle® and BIOCELL implants and the development of BIA-ALCL; an association that was significantly higher than any other textured breast implant.

91. Based on the newly acquired information, Allergan had an obligation to unilaterally make changes to the directions for use ("DFU") for its Natrelle® and BIOCELL implants to add or strengthen the warnings about the causal association between the product and the development of BIA-ALCL.

92. Rather than strengthen the information about the link between its product and BIA-ALCL, Allergan instead actively concealed its acquired knowledge of the causal link through its manipulation of adverse event reports and other public reports as described above.

93. Additionally, under applicable state laws, which do not impose duties or requirements materially different from those imposed by federal law, Allergan had a duty to revise its product labeling after becoming aware of otherwise undisclosed dangers in its Natrelle® and BIOCELL breast implant products. Allergan refused and recklessly and intentionally failed to do so.

94. Under applicable state laws, which do not impose duties or requirements materially different from those imposed by federal law, Allergan was required at all material times to promptly report any information suggesting that one of its products may have contributed to a serious injury, or had malfunctioned, and the malfunction would be likely to contribute to a serious injury if it were to recur.

95. Allergan's insufficient follow-up rates and inadequate data, as detailed above, establish and confirm Allergan's reckless and intentional disregard for the safety of hundreds of thousands of women in the United States.

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

97. Notwithstanding Allergan's failures to comply with post-approval requirements, including the failures described above, Allergan continued to distribute its Natrelle® and BIOCELL breast implants commercially. As expressly provided in the PMA, such distribution was a violation of federal law.

98. Had Allergan substantially complied with the PMA, rather than flagrantly, recklessly, and intentionally underperforming the post-approval requirements as alleged above, Allergan's disclosures would have led to much wider knowledge of the risks associated with Allergan's products. In addition, Allergan's physician and patient labeling would have materially changed over time, and patients including Plaintiffs, and medical providers including Plaintiffs' physicians, would not have purchased or implanted Allergan's products.

CLASS ALLEGATIONS

99. Plaintiffs bring this action individually and as a class action, pursuant to FED. R. CIV. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Class consists of the following:

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

Or, in the alternative,

> **State [Name of State] Subclasses:** All persons in [name of State] who have been implanted with BIOCELL saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.

100. Together, the Nationwide Class and the State Subclasses shall be collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers and directors; and the Judge(s) assigned to this case.

101. Plaintiffs reserve the right to redefine the Class before class certification.

102. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

103. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. Plaintiffs are informed and believe that the proposed Class contains at least thousands of individuals in whom recalled BIOCELL products were implanted from 2006 through July 24, 2019. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Defendants' records.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were unjustly enriched by the sale of BIOCELL recalled products;

ii. Whether Defendants were negligent in selling BIOCELL recalled products;

iii. Whether Defendants failed to warn consumers regarding the risks of the BIOCELL recalled products;

iv. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

v. The appropriate nature of class-wide equitable relief; and

vi. The appropriate measurement of restitution and/or measure of damages to Plaintiffs and members of the Class.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class who were implanted with recalled BIOCELL products.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. The injury suffered by each Class

member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

CAUSES OF ACTION

COUNT 1
STRICT LIABILITY-FAILURE TO WARN
On Behalf of the Class

104. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

105. Under the common law or relevant state statutory provisions, Defendants had a duty to warn Plaintiffs and the Class members regarding the true risks associated with BIOCELL implants through submitting accurate adverse event reports as well as amending its warnings contained within the product DFUs.

106. Defendants failed to provide adequate warnings regarding the risks of BIA-ALCL.

107. For many of the Plaintiffs, Allergan did not include any warning within its Directions for Use ("DFU") at the time of the surgery.[7]

[7] https://web.archive.org/web/20131108204233/http://www.allergan.com/assets/pdf/L034-03_Silicone_DFU.pdf. (last reviewed December 19, 2019)

108. For other products, Allergan included the inadequate warning within its DFU. For example, the Natrelle 410 implants warned that[8]:

> Anaplastic Large Cell Lymphoma
>
> ▪ Based on information reported to FDA and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants may have a very small but increased risk of developing ALCL in the fluid or scar capsule adjacent to the implant.
>
> ▪ ALCL has been reported globally in patients with an implant history that includes Allergan's and other manufacturers' breast implants.

However, the above warning failed to relay Allergan's actual knowledge of the clear causal connection between its BIOCELL implants and BIA-ALCL, an association that was significantly greater than the risk posed by "other manufacturers' breast implants."

109. Beginning in 2006, Defendants continually acquired new information regarding the true risks with BIOCELL implants and their clear causal connection to BIA-ALCL but failed to warn Plaintiffs, Class members, and their physicians by not submitting accurate adverse action reports and failing to unilaterally strengthen their warnings. Defendants' failure to submit accurate adverse event reports made their warning inadequate and the implants defective.

110. Pursuant to 21 C.F.R. § 814.39(d)(1)-(2), Allergan was required to unilaterally make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association" in order to "reflect newly acquired information."

[8] https://www.allergan.com/miscellaneous-pages/allergan-pdf-files/l3717_410_dfu, pg. 21 (last reviewed December 19, 2019).

111. Despite Allergan's obligation to unilaterally strengthen its warning regarding the newly acquired knowledge of the link between BIOCELL implants and BIA-ALCL, it instead chose to actively conceal this knowledge and causal association through its manipulation of adverse event reports and other reporting data.

112. Had Allergan properly reported those adverse events, the FDA would have required it to add warnings to the label or otherwise disseminate the additional adverse event information to the implanting doctors at a minimum, and would have required the BIOCELL implants to be recalled sooner. This is confirmed by the FDA's 2019 request that BIOCELL implants be recalled and removed from the market once Allergan disclosed the true causal association between the implants and BIA-ALCL.

113. Moreover, if implanting physicians had been provided with the appropriate warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would have chosen to use an alternative product that did not present such a high risk of BIA-ALCL.

114. Defendants' breach of their duty to warn have caused Plaintiffs and Class members damages in the form of surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

115. Plaintiffs and Class members would not have purchased, chosen, and/or paid for all or part of the BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

116. This defect proximately caused Plaintiffs' injuries. When the BIOCELL implants are surgically placed in the body, the textured surface disrupts the body's normal healing process

and was thought to result in scar tissue that was less firm than that produced by smooth-walled implants. However, it is believed that the BIOCELL implants' textured surface creates an implant-induced chronic inflammation that results in injury to the structure of cells in and around the implant.[9] Plaintiffs and Class members have sustained such cellular damage as a result of the BIOCELL implants, and a currently unknown number of such Class members will go on to develop BIA-ALCL as a result of this damage and neoplastic transformation.

117. Plaintiffs and Class members have also been injured by undergoing a surgery and implantation of a medical device and invasive diagnostic procedures, and in some cases an explant procedure, that they would not have had done if they were made aware of the true risks posed by the BIOCELL implants.

118. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT 2
NEGLIGENCE
On Behalf of the Class

119. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

120. Under the common law or relevant state statutory provisions, Defendants owed Plaintiffs and Class Members a duty of care and to warn of any risks associated with the recalled BIOCELL implants. Defendants knew or should have known of the true risks with BIOCELL implants but failed to warn Plaintiffs, Class members, and their physicians by not submitting accurate adverse action reports. By submitting misleading adverse event reports, and concealing

[9] George EV, Pharm J, Houston C, *et al.*, Breast implant-associated ALK-negative anaplastic large cell lymphoma: a case report and discussion of possible pathogenesis. Int J Clin Exp Pathol. 2013;6; Bizjak M, Selmi C, Praprotnik S, et al., Silicone implants and lymphoma: the role of inflammation. J Autoimmun. 2015;65:64–73.

the risks associated with the recalled BIOCELL implants, Defendants negligently violated their duty of care to Plaintiffs and Class Members and their doctors.

121. Defendants' breach of duty caused Plaintiffs and Class members damages in the form of surgical costs of removal of the products and/or the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products.

122. Plaintiffs and Class members would not have purchased, chosen, and/or paid for all or part of the BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

123. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT 3
NEGLIGENT RECALL
On Behalf of the Class

124. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

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

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

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

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

COUNT 4
UNJUST ENRICHMENT
On Behalf of the Class (In the Alternative)

129. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

130. Plaintiffs and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing recalled BIOCELL implants from 2006 through July 24, 2019. Plaintiffs and Class members would not have purchased, chosen and/or paid for all or part of BIOCELL had they known that they would be exposed to the risk of developing BIA-ALCL, while Defendants refuse to compensate them for the surgical costs of removal of the products and/or compensate them sufficiently for the surgical and diagnostic fees and medical monitoring and invasive diagnostic procedures associated with retention of the products. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiffs and the Class.

131. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiffs and the Class members who endure being exposed to the risk of developing a serious and deadly disease.

132. Defendants' retention of the benefit conferred upon them by Plaintiffs and the Class would be unjust and inequitable.

133. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT 5
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
On Behalf of the Class

134. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

135. By operation of law, Defendants, as manufacturers of the recalled BIOCELL implants and as the providers of a limited warranty for recalled BIOCELL implants, impliedly

warranted to Plaintiffs and the Class that the Defective Implants were of merchantable quality and safe for their ordinary and intended use in the human body.

136. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of recalled BIOCELL implants. At the point of sale, the while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

137. Had Plaintiffs and the Class known the recalled BIOCELL implants are unsafe for use in the human body, they would not have purchased them and had them implanted.

138. Defendants have refused to provide appropriate warranty relief notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiffs and the Class reasonably expected, at the time of purchase, that the recalled BIOCELL implants would not present a substantial risk of bodily harm.

139. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT 6
MEDICAL MONITORING
On Behalf of the Class

140. Plaintiffs and the Class incorporate by reference all preceding paragraphs.

141. Due to Defendants' actions and inactions in violation of federal law, medical monitoring is, to a reasonable degree of medical certainty, necessary to diagnose the warning signs of BIA-ALCL properly.

142. Plaintiffs and the Class are thus entitled to have Defendants pay for the costs of ongoing medical monitoring.

COUNT 7
ARIZONA
Arizona Consumer Fraud Act
A.R.S. §§ 44-1521, *et. seq.*
On Behalf of the Arizona Subclass

143. Plaintiffs incorporate by reference all preceding paragraphs.

144. Plaintiff Arizona Doe brings this cause of action on behalf of herself and on behalf of the members of the Arizona Subclass.

145. The Arizona Consumer Fraud Act prohibits "[t]he act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged." A.R.S. § 44-1522.

146. Defendants engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated the Arizona Consumer Fraud Act.

147. Defendants participated in unfair or deceptive trade practices that violated the Arizona Consumer Fraud Ac as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

148. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of

any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

149. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

150. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

151. Defendants knew or should have known that their conduct violated the Arizona Consumer Fraud Act.

152. Had Plaintiff Arizona Doe and the Arizona Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

153. Defendants owed Plaintiff Arizona Doe and the Arizona Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff Arizona Doe and the Alabama Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff Arizona Doe and the Arizona Subclass Members that contradicted these representations.

154. Plaintiff Arizona Doe and the Arizona Subclass Members suffered monetary damages as a result of Defendants' conduct.

155. Defendants' violations present a continuing risk to Plaintiff Arizona Doe and the Arizona Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

156. Defendants are liable to Plaintiff Arizona Doe and the Arizona Subclass Members for their damages, punitive damages, attorneys' fees costs.

COUNT 8
CALIFORNIA
California Unfair Competition Law
Cal. Civil Code §§ 17200, et. seq.
On Behalf of the California Subclass

157. Plaintiffs incorporate by reference all preceding paragraphs.

158. Plaintiff California Doe brings this cause of action on her behalf and on behalf of the members of the California Subclass.

159. California Business & Professions Code § 17200 prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

160. The acts and practices of Defendants as alleged herein constitute "unfair" business acts and practices under the UCL in that Defendants conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

161. Defendants have, in the course of their business and the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

162. These acts also constitute "fraudulent" business acts and practices under the UCL in that Defendants' conduct is false, misleading, and has a tendency to deceive the Class and the general public.

163. Plaintiff California Doe and California Class Members have suffered injury in fact and have lost money as a result of Defendants' fraudulent business acts or practices.

164. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiff California Doe and California Class Members in that Defendants have systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

165. Pursuant to Business and Professions Code §§ 17200 and 17203, Plaintiff Doe _ and California Class Members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

166. Because of their reliance on Defendants' omissions concerning the BIOCELL implants, Plaintiff California Doe and California Subclass Members suffered an ascertainable loss of money, property, and/or value and were harmed and suffered actual damages.

167. Plaintiff California Doe and California Subclass Members are reasonable consumers who did not expect the risks inherent with the BIOCELL implants.

168. Defendants' conduct in concealing and failing to disclose the is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

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

a. Selling recalled BIOCELL products that it knew to present a substantially greater risk of developing BIA-ALCL than competing textured breast implants;

b. Concealing the clear connection between its BIOCELL products and BIA-ALCL from the FDA, consumers, and medical professionals;

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

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

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

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

172. There were reasonably available alternatives that would further Allergan's business interest of satisfying and retaining its customers while maintaining profitability, such as: (1) completely and accurately disclosing adverse events to the public; (2) acknowledging the significantly greater risk of BIA-ALCL with its recalled BIOCELL products and paying for

surgery to remove the implants for patients with recalled implants; and (3) disclosing the true extent of the risk of BIA-ALCL to prospective purchasers.

173. Plaintiff California Doe suffered injury in fact, including lost money or property, as a result of Allergan's unfair acts. Absent Allergan's unfair conduct, Plaintiff California Doe would not have selected Allergan implants.

174. Through its unfair conduct, Allergan acquired money that Plaintiff California Doe once had an ownership interest in either directly or through Plaintiff California Doe's medical professionals.

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

COUNT 9
COLORADO
Colorado Consumer Protection Act
Colo. Rev. Stat. §§ 6-1-101, *et. seq.*
On Behalf of the Colorado Subclass

176. Plaintiffs incorporate by reference all preceding paragraphs.

177. Plaintiff Colorado Doe brings this cause of action on behalf of herself and on behalf of the members of the Colorado Subclass.

178. The Colorado Consumer Protection Act prohibits unfair or deceptive acts or practices, including, "fail[ing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction." Colo.

Rev. Stat. § 6-1-105(u). Defendants engaged in deceptive acts or practices that violated the Colorado Consumer Protection Act.

179. Defendants participated in unfair or deceptive trade practices that violated the Colorado Consumer Protection Act as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

180. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

181. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

182. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

183. Defendants knew or should have known that their conduct violated the Colorado Consumer Protection Act.

184. Had Plaintiff Colorado Doe and the Colorado Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL

implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

185. Defendants owed Plaintiff Colorado Doe and the Colorado Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff Colorado Doe and the Colorado Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff Colorado Doe and the Colorado Subclass Members that contradicted these representations.

186. Plaintiff Colorado Doe and the Colorado Subclass Members suffered monetary damages as a result of Defendants' conduct.

187. Defendants' violations present a continuing risk to Plaintiff Colorado Doe and the Colorado Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

188. Defendants are liable to Plaintiff Colorado Doe and the Colorado Subclass Members for actual damages sustained.

COUNT 10
CONNECTICUT
Connecticut Unfair Trade Practices Act
Conn. Gen. Stat. §§ 42-110a, *et. seq.*
On Behalf of the Connecticut Subclass

189. Plaintiffs incorporate by reference all preceding paragraphs.

190. Plaintiff Connecticut Doe brings this cause of action on behalf of herself and on behalf of the members of the Connecticut Subclass.

191. The Connecticut Consumer Protection Act prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110(b)(a).

192. Defendants participated in unfair or deceptive trade practices that violated the Connecticut Unfair Trade Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

193. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

194. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

195. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

196. Defendants knew or should have known that their conduct violated the Connecticut Unfair Trade Practices Act.

197. Had Plaintiff Connecticut Doe and the Connecticut Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL

implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

198. Defendants owed Plaintiff Connecticut Doe and the Connecticut Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff Connecticut Doe and the Connecticut Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff Connecticut Doe and the Connecticut Subclass Members that contradicted these representations.

199. Plaintiff Connecticut Doe and the Connecticut Subclass Members suffered monetary damages as a result of Defendants' conduct.

200. Defendants' violations present a continuing risk to Plaintiff Connecticut Doe and the Connecticut Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

201. Defendants are liable to Plaintiff Connecticut Doe and the Connecticut Subclass Members for actual damages, punitive damages, equitable relief, attorneys' fees and costs. Conn. Gen. Stat. § 42-110g(a), (d).

202. A copy of this complaint is being mailed to the Connecticut Attorney General and the Connecticut Commissioner of Consumer Protection. Conn. Gen. Stat. § 42-110g(d).

COUNT 11
FLORIDA
Florida Deceptive Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq.*,
On Behalf of the Florida Subclass

203. Plaintiffs incorporate by reference all preceding paragraphs.

204. Plaintiff Florida Doe brings this cause of action on her behalf and on behalf of the members of the Florida Subclass.

205. Defendants' business acts and practices alleged herein constitute unfair, unconscionable and/or deceptive methods, acts or practices under the Florida Deceptive and Unfair Trade Practices Act, § 501.201, *et seq*., Florida Statutes ("FDUTPA").

206. At all relevant times, Plaintiff Florida Doe and the Florida Subclass Members were "consumers" within the meaning of the FDUTPA. F.S.A. § 501.203(7).

207. Defendants' conduct, as set forth herein, occurred in the conduct of "trade or commerce" within the meaning of the FDUTPA. F.S.A. § 501.203(8).

208. Defendants' omissions and practices described herein were likely to, and did in fact, deceive and mislead members of the public, including Plaintiff Florida Doe and the Florida Subclass Members, acting reasonably under the circumstances, to their detriment. By failing to he true risks of the BIOCELL implants and failing to comply with federal law, Defendant violated FDUTPA.

209. Defendants failed to reveal facts that were material to Plaintiff Florida Doe and the Florida Subclass Members' decisions to purchase and implant the BIOCELL implants, and Defendants intended that Plaintiff Florida Doe and the Florida Subclass Members would rely upon the omissions.

210. Defendants' actions impact the public interest because Plaintiff Florida Doe and the Florida Subclass Members were injured in exactly the same way as hundreds or thousands of others purchasing and implanting the recalled BIOCELL implants as a result of and pursuant to Defendants' generalized course of deception.

211. Had Plaintiff Florida Doe and the Florida Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants.

212. The foregoing acts, omissions and practices proximately caused Plaintiff Florida Doe and the Florida Subclass Members to suffer actual damages with they are entitled to recover such damages, together with attorneys' fees and costs of suit.

COUNT 12
HAWAII
Hawaii Unfair and Deceptive Trade Practices Act,
Haw. Rev. Stat. § 480-2 *et seq*.,
On Behalf of the Hawaii Subclass

213. Plaintiffs incorporate by reference all preceding paragraphs.

214. Plaintiff Hawaii Doe brings this cause of action on behalf of herself and on behalf of the members of the Hawaii Subclass.

215. The Hawaii Unfair and Deceptive Trade Practices Act prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Haw. Rev. Stat. § 480-2(a).

216. Defendants participated in unfair or deceptive trade practices that violated the Hawaii Unfair and Deceptive Trade Practices Act as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

217. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of

any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

218. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

219. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

220. Defendants knew or should have known that their conduct violated the Hawaii Unfair and Deceptive Trade Practices Act.

221. Had Plaintiff Hawaii Doe and the Hawaii Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

222. Defendants owed Plaintiff Hawaii Doe and the Hawaii Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff Hawaii Doe and the Hawaii Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff Hawaii Doe and the Hawaii Subclass Members that contradicted these representations.

223. Plaintiff Hawaii Doe and the Hawaii Subclass Members suffered monetary damages as a result of Defendants' conduct.

224. Defendants' violations present a continuing risk to Plaintiff Hawaii Doe and the Hawaii Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

225. Defendants are liable to Plaintiff Hawaii Doe and the Hawaii Subclass Members for actual damages, treble damages, equitable relief, attorneys' fees and costs. Haw. Rev. Stat. § 480-13.

COUNT 13
ILLINOIS
Illinois Consumer Fraud Act
815 ILCS § 505/1, *et. seq.*
On Behalf of the Illinois Subclass

226. Plaintiffs incorporate by reference all preceding paragraphs.

227. Plaintiffs Illinois Doe1 and Illinois Doe2 bring this cause of action on their behalf and on behalf of the members of the Illinois Subclass.

228. Defendants engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the products purchased by Plaintiffs and Illinois Subclass Members, in violation of 815 ILCS § 505/2, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law. These injuries outweigh any benefits to consumers or to competition.

229. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

230. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Illinois Subclass members.

231. Plaintiffs and Illinois Subclass members would not have purchased, chosen, and/or paid for all or part of BIOCELL had they known that they would be exposed to the risk of

developing BIA-ALCL.

232. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Illinois Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

233. Plaintiffs and Illinois Subclass members seek relief under 815 ILCS § 505/10a, including, but not limited to injunctive relief, damages, restitution, punitive damages and attorneys' fees and costs.

234. A copy of this complaint is being sent to the Illinois Attorney General. 815 ILCS § 505/10d.

COUNT 14
IOWA
Iowa Consumer Frauds Act
Iowa Code §§ 714H, 714.16
On Behalf of the Iowa Subclass

235. Plaintiffs incorporate by reference all preceding paragraphs.

236. Plaintiff Iowa Doe brings this cause of action on behalf of herself and on behalf of the members of the Iowa Subclass.

237. The Iowa Consumer Frauds Act prohibits "practice or act the person knows or reasonably should know is an unfair practice, deception, fraud, false pretense, or false promise, or the misrepresentation, concealment, suppression, or omission of a material fact, with the intent that others rely upon the unfair practice, deception, fraud, false pretense, false promise, misrepresentation, concealment, suppression, or omission in connection with the advertisement,

sale, or lease of consumer merchandise, or the solicitation of contributions for charitable purposes." Iowa Code § 714H.3.

238. Defendants participated in unfair or deceptive trade practices that violated the Iowa Consumer Frauds Act as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

239. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

240. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

241. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

242. Defendants knew or should have known that their conduct violated the Iowa Consumer Frauds Act.

243. Had Plaintiff Iowa Doe and the Iowa Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

244. Defendants owed Plaintiff Iowa Doe and the Iowa Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff Iowa Doe and the Iowa Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff Iowa Doe and the Iowa Subclass Members that contradicted these representations.

245. Plaintiff Iowa Doe and the Iowa Subclass Members suffered monetary damages and ascertainable losses as a result of Defendants' conduct.

246. Defendants' violations present a continuing risk to Plaintiff Iowa Doe and the Iowa Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

247. Defendants are liable to Plaintiff Iowa Doe and the Iowa Subclass Members for actual damages, treble damages, equitable relief, attorneys' fees and costs. Iowa Code § 714H.5.

248. A copy of this complaint is being sent to the Iowa Attorney General. Iowa Code § 714H.6.

COUNT 15
KANSAS
Kansas Consumer Protection Act
Kan. Stat. Ann. §§ 50-623, *et seq.*
On Behalf of the Kansas Subclass

249. Plaintiffs incorporate by reference all preceding paragraphs.

250. Plaintiff Kansas Doe brings this cause of action on her behalf and on behalf of the members of the Kansas Subclass.

251. A key policy purpose of the Kansas Consumer Protection Act, which is to be

"construed liberally," is "to protect consumers from suppliers who commit deceptive and unconscionable practices." Kan. Stat. Ann. § 50-623.

252. The Kansas Consumer Protection Act prohibits suppliers from engaging in deceptive acts and practices "in connection with a consumer transaction," which include, among other things, (1) representations made knowingly or with reason to know that "[p]roperty or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have," (2) representations made knowingly or with reason to know that "property or services are of particular standard, quality, grade, style or model, if they are of another which differs materially from the representation," (3) "the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact," and (4) "the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact." Kan. Stat. Ann. § 50-626(b)(1-3).

253. The BIOCELL implants purchased by Plaintiff and Kansas Subclass Members are "property" as defined by Kan. Stat. Ann. § 50-624(j).

254. Defendants are "suppliers" as defined by Kan. Stat. Ann. § 50-624(l).

255. Defendants engaged in deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Kansas Subclass Members, in violation of Kan. Stat. Ann. §§ 50-623, *et seq.*, including by misrepresenting the true quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants, and failing to comply with federal law.

256. The above deceptive acts or practices by Defendants were conducted in connection with "consumer transactions" as defined by Kan. Stat. Ann. § 50-624(c).

257. The above unlawful deceptive acts or practices by Defendants were immoral,

unethical, oppressive, and unscrupulous.

258. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Kansas Subclass members.

259. Plaintiff and Kansas Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

260. As a direct and proximate result of Defendants' deceptive acts or practices, Plaintiff and Kansas Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

261. Plaintiff and Kansas Subclass members seek relief under by Kan. Stat. Ann. § 50-634, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 16
KENTUCKY
Kentucky Consumer Protection Act
Kentucky Revised Statutes Annotated §§ 367.110, *et seq.*
On Behalf of the Kentucky Subclass

262. Plaintiffs incorporate by reference all preceding paragraphs.

263. Plaintiff Kentucky Doe brings this cause of action on her behalf and on behalf of the members of the Kentucky Subclass.

264. The Kentucky Consumer Protection Act was passed after its legislature found that "the public health, welfare and interest require a strong and effective consumer protection program to protect the public interest and the well-being of both the consumer public and the ethical sellers

of goods and services" and declared unlawful "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce."

265. Defendants engaged in unfair, false, misleading, or deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Kentucky Subclass Members, in violation of Ky. Rev. Stat. Ann. § 367.170, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

266. The above unfair, false, misleading, or deceptive acts or practices by Defendants were conducted in "trade" or "commerce," as defined by Ky. Rev. Stat. Ann. § 367.110(2).

267. The above unfair, false, misleading, or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

268. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Kentucky Subclass members.

269. Plaintiffs and Kentucky Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

270. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Kentucky Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

271. Plaintiffs and Kentucky Subclass members seek relief under Ky. Rev. Stat. Ann. § 367.220, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 17
LOUISIANA
Louisiana Unfair Trade Practices and Consumer Protection Law
La. Rev. Stat. Ann. §§ 51:1401 *et seq.*
On Behalf of the Louisiana Subclass

272. Plaintiffs incorporate by reference all preceding paragraphs.

273. Plaintiff Louisiana Doe brings this cause of action on her behalf and on behalf of the members of the Louisiana Subclass.

274. The Louisiana Unfair Trade Practices and Consumer Protection Law makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." La. Rev. Stat. Ann. §§ 51:1405(A).

275. Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Louisiana Subclass Members, in violation of La. Rev. Stat. Ann. § 51:1405A, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

276. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "trade" or "commerce," as defined by La. Rev. Stat. Ann. §§ 51:1402(10).

277. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

278. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Louisiana Subclass members.

279. Plaintiffs and Louisiana Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

280. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Louisiana Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

281. Plaintiffs and Louisiana Subclass members seek relief under La. Rev. Stat. Ann. §51:1409, including, but not limited to damages, treble damages and attorneys' fees and costs.

COUNT 18
MICHIGAN
Michigan Consumer Protection Act
Mich. Comp. Laws §§ 445.901 *et seq.*
On Behalf of the Michigan Subclass

282. Plaintiffs incorporate by reference all preceding paragraphs.

283. Plaintiff Michigan Doe brings this cause of action on her behalf and on behalf of the members of the Michigan Subclass.

284. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.…" Mich. Comp. Laws § 445.903(1). GM engaged in unfair, unconscionable, or deceptive methods, acts or practices prohibited by the Michigan CPA, including: "(c) Representing that goods or services have… characteristics… that they do not have.…;" "(e) Representing that goods or services are of a particular standard… if they are of another;" "(i) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" "(s)

Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;" "(bb) Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;" and "(cc) Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." Mich. Comp. Laws § 445.903(1).

285. Defendants engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Michigan Subclass Members, in violation of Mich. Comp. Laws § 445.903, including by misrepresenting the true quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants, and failing to comply with federal law.

286. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "[t]rade or commerce," as defined by Mich. Comp. Laws § 445.902(1)(g).

287. The above unfair and deceptive practices and acts by Defendants were material misrepresentations of a presently existing or past fact.

288. The representations by Defendants regarding the quality of the BIOCELL implants was false.

289. Defendants knew the representations were false or made it recklessly as a positive assertion without knowledge of its truth.

290. Defendants intended that persons rely on the above misrepresentation regarding the quality of the BIOCELL implants.

291. Plaintiffs and Michigan Subclass members acted in reliance on Defendants'

representations.

292. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

293. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Michigan Subclass members.

294. Plaintiffs and Michigan Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

295. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Michigan Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

296. Plaintiffs and Michigan Subclass members seek relief under Mich. Comp. Laws § 445.911, including, but not limited to injunctive relief, damages, attorneys' fees and costs.

COUNT 19
MINNESOTA
Minnesota Consumer Fraud Act, Minnesota Unlawful Trade Practices Act, and Minnesota Uniform Deceptive Trade Practices Act
Minn. Stat. §§ 325F.69; 325D.13; and 325D.44, respectively
On Behalf of the Minnesota Subclass

297. Plaintiffs incorporate by reference all preceding paragraphs.

298. Plaintiffs Minnesota Doe 1 and Minnesota Doe 2 bring this cause of action on their behalf and on behalf of the members of the Minnesota Subclass.

299. The MPCFA makes unlawful "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice,

with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby." Minn. Stat. § 325F.69(1). The MPCFA further provides that "any person injured by a violation of [the MPCFA] may bring a civil action and recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney's fees, and receive other equitable relief as determined by the court." Minn. Stat. § 8.31(3a).

300. Defendants engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Minnesota Subclass Members, in violation of Minn. Stat. §§ 325F.69; 325D.13; and 325D.44, including by misrepresenting the true quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants, and failing to comply with federal law.

301. The above unfair and deceptive practices and acts by Defendants involved the "sale" of "merchandise," as defined by Minn. Stat. § 325F.68.

302. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

303. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Minnesota Subclass members.

304. Plaintiffs and Minnesota Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

305. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Minnesota Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of

the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

306. Plaintiffs and Minnesota Subclass members seek relief under Minn. Stat. § 8.31, subd. 3a; and § 325D.45, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 20
MISSOURI
Missouri Merchandising Practices Act
Mo. Rev. Stat. § 407.010, *et seq.*
On Behalf of the Missouri Subclass

307. Plaintiffs incorporate by reference all preceding paragraphs.

308. Plaintiff Missouri Doe brings this cause of action on her behalf and on behalf of the members of the Missouri Subclass.

309. The Missouri Merchandising Practices Act ("MMPA") was created to protect Missouri consumers from deceptive and unfair business practices.

310. The MMPA makes it unlawful to engage in any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. § 407.020.1.

311. Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Louisiana Subclass Members, in violation of Mo. Rev. Stat. § 407.010, *et seq*., including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

312. The above unfair methods of competition and unfair or deceptive acts or practices

by Defendants were conducted in "trade" or "commerce," as defined by of Mo. Rev. Stat. § 407.010(7).

313. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

314. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Missouri Subclass members.

315. Plaintiff and Missouri Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

316. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Missouri Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

317. Plaintiffs and Missouri Subclass members seek relief under the MMPA, Mo. Rev. Stat. § 407.010, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT 21
MONTANA
Montana Unfair Trade Practices and Consumer Protection Act of 1973
Mont. Code Ann. §§ 30-14-101, *et seq.*
On Behalf of the Montana Subclass

318. Plaintiffs incorporate by reference all preceding paragraphs.

319. Plaintiff Montana Doe brings this cause of action on her behalf and on behalf of the members of the Montana Subclass.

320. The Montana Unfair Trade Practices and Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103.

321. Defendants engaged in unlawful methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Montana Subclass Members, in violation of Mont. Code Ann. §§ 30-14-103, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

322. The above unfair or deceptive acts or practices by Defendants were conducted in "trade" or "commerce," as defined by *id.,* § 30-14-102(8).

323. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

324. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Montana Subclass members.

325. Plaintiffs and Montana Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

326. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Montana Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

327. Plaintiffs and Montana Subclass members seek relief under Mont. Code Ann. § 30-14-133, including, but not limited to injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 22
NEVADA
Nevada Deceptive Trade Practices Act
Nev. Rev. Stat. §§598.0903 *et seq.*
On Behalf of the Nevada Subclass

328. Plaintiffs incorporate by reference all preceding paragraphs.

329. Plaintiff Nevada Doe brings this cause of action on her behalf and on behalf of the members of the Nevada Subclass.

330. The Nevada Deceptive Trade Practices Act, among other things, makes it unlawful to make "a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith" and represent "that goods or services for sale or lease are of a particular standard, quality or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model." Nev. Rev. Stat. § 598.0915.

331. Defendants engaged in deceptive trade practices in the course of their business, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Nevada Subclass Members, in violation of Nev. Rev. Stat. § 598.0915, including by making statements or representations that were false or misleading regarding the quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

332. The above unfair and deceptive practices and acts by Defendants were immoral,

unethical, oppressive, and unscrupulous.

333. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Nevada Subclass members.

334. Plaintiffs and Nevada Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

335. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Nevada Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

336. Plaintiffs and Nevada Subclass members seek relief under Nev. Rev. Stat. § 41.600, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 23
NEW JERSEY
New Jersey Consumer Fraud Act
N.J. Stat. Ann. §§ 56:8-1, *et seq*.
On Behalf of the New Jersey Subclass

337. Plaintiffs incorporate by reference all preceding paragraphs.

338. Plaintiffs New Jersey Doe 1 and New Jersey Doe 2 bring this cause of action on their behalf and on behalf of the members of the New Jersey Subclass.

339. The New Jersey Consumer Fraud Act ("NJCFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission

of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with

340. Defendants engaged in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and New Jersey Subclass Members, in violation of N.J. Stat. Ann. §§ 56:8-2, including by making statements or representations that were false or misleading regarding the quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

341. The above unfair and deceptive practices and acts by Defendants were material misrepresentations of a presently existing or past fact.

342. Defendants knew or believed that the above unfair and deceptive practices and acts were material misrepresentations.

343. Defendants intended that other persons rely on the above unfair and deceptive practices and acts by Defendants were material misrepresentations of a presently existing or past fact, and their reliance was reasonable.

344. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

345. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the New Jersey Subclass members.

346. Plaintiffs and New Jersey Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

347. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and New Jersey Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

348. Plaintiffs and New Jersey Subclass members seek relief under N.J. Stat. Ann. §§ 56:8-2.11 and 56:8-19, including, but not limited to a refund of all moneys acquired by Defendants for the BIOCELL implants, injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 24
NEW MEXICO
New Mexico Unfair Practices Act
N.M. Stat. Ann. §§ 57-12-1, *et seq.*
On Behalf of the New Mexico Subclass

349. Plaintiffs incorporate by reference all preceding paragraphs.

350. Plaintiff New Mexico Doe brings this cause of action on her behalf and on behalf of the members of the New Mexico Subclass.

351. The New Mexico Unfair Trade Practices Act, N.M. STAT. ANN. §§ 57-12-1, et seq. ("New Mexico UTPA") makes unlawful any "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce." N.M. STAT. ANN. § 57:12-3. Trade or commerce includes the "sale or distribution of any services." N.M. STAT. ANN. § 57-12-2(C).

352. Defendants engaged in unfair or deceptive trade practices and unconscionable trade practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and New Mexico Subclass Members, in violation of N.M. Stat. Ann. § 57-12-3, including

by making statements or representations that were false or misleading regarding the quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

353. The above unfair or deceptive acts or practices by Defendants were conducted in or affecting "commerce," as defined by *id.,* § 57-12-2(C).

354. The above unfair or deceptive trade practices and unconscionable trade practices by Defendants were immoral, unethical, oppressive, and unscrupulous, and the type that may, tend to, or does deceive or mislead any person.

355. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the New Mexico Subclass members.

356. Plaintiffs and New Mexico Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

357. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and New Mexico Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

358. By engaging in the practices discussed above, including, but not limited to, Defendant's undisclosed defects, Defendant has violated N.M. Stat. Ann. § 57-12-2.

359. Plaintiffs and New Mexico Subclass members seek relief under N.M. Stat. Ann. § 57-12-10, including, but not limited to injunctive relief, damages, and attorneys' fees and costs.

COUNT 25
NEW YORK
N.Y. Gen. Bus. Law § 349
On Behalf of the New York Subclass

360. Plaintiffs incorporate by reference all preceding paragraphs.

361. Plaintiff New York Doe brings this cause of action on behalf of herself and on behalf of the members of the New York Subclass.

362. Plaintiff New York Doe and the New York Subclass Members are "persons" within the meaning of New York General Business Law ("New York GBL"). N.Y. GEN. BUS. LAW § 349(h).

363. Defendants are a "person," "firm," "corporation," or "association" within the meaning of N.Y. GEN. BUS. LAW § 349.

364. New York's General Business Law § 349 makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. GEN. BUS. LAW § 349. Defendants' conduct, as described in this Complaint, constitutes "deceptive acts or practices" within the meaning of the New York GBL. All of Defendants' deceptive acts and practices, which were intended to mislead consumers in a material way in the process of purchasing BIOCELL implants, constitute conduct directed at consumers and "consumer-oriented." Further, Plaintiff New York Doe and the New York Subclass Members suffered injury as a result of the deceptive acts or practice.

365. Defendants' actions, as set forth above, occurred in the conduct of business, trade or commerce.

366. Defendants participated in unfair or deceptive trade practices that violated the New York GBL as described below and alleged throughout the Complaint. By concealing the true risks

of the BIOCELL implants and failing to comply with federal law, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale of the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

367. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

368. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

369. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

370. Defendants knew or should have known that their conduct violated the New York GBL.

371. Had Plaintiff New York Doe and the New York Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

372. Defendants owed Plaintiff New York Doe and the New York Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Plaintiff New York Doe and the New York Subclass

Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while purposefully withholding material facts from Plaintiff New York Doe and the New York Subclass Members that contradicted these representations.

373. Plaintiff New York Doe and the New York Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendants' conduct, Plaintiff New York Doe and the New York Subclass Members were harmed and suffered actual damages.

374. Defendants' violations present a continuing risk to Plaintiff New York Doe and the New York Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

375. Pursuant to N.Y. GEN. BUS. LAW § 349(h), Plaintiff New York Doe and the New York Subclass Members seek actual damages or $50, whichever is greater, in addition to discretionary three times actual damages up to $1,000 for Defendants' willful and knowing violation of N.Y. GEN. BUS. LAW § 349. Plaintiff New York Doe and the New York Subclass Members members also seek attorneys' fees, an order enjoining Defendants' deceptive conduct, and any other just and proper relief available under the New York GBL.

COUNT 26
NORTH CAROLINA
North Carolina Unfair and Deceptive Trade Practices Act
N.C. Gen. Stat. §§ 75-1.1 *et seq.*
On Behalf of the North Carolina Subclass

376. Plaintiffs incorporate by reference all preceding paragraphs.

377. Plaintiff North Carolina Doe brings this cause of action on her behalf and on behalf of the members of the North Carolina Subclass.

378. North Carolina's Unfair and Deceptive Trade Practices Act, N.C. GEN. STAT. §§ 75-1.1, et seq. ("NCUDTPA"), prohibits a person from engaging in "[u]nfair methods of

competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce[.]" The NCUDTPA provides a private right of action for any person injured "by reason of any act or thing done by any other person, firm or corporation in violation of" the NCUDTPA. N.C. Gen. Stat. § 75-16.

379. Defendants engaged in unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and North Carolina Subclass Members, in violation of N.C. Gen. Stat. § 75-1.1(a), including by making false representations or concealing the true risks of the BIOCELL implants and failing to comply with federal law.

380. The above unfair or deceptive acts or practices by Defendants were conducted in or affecting "commerce," as defined by *id.,* § 75-1.1(b).

381. The above unfair or deceptive acts or practices by Defendants were reasonably calculated to deceive class members and other consumers, and made with intent to deceive.

382. The above unfair or deceptive acts or practices by Defendants did in fact deceive class members and other consumers, causing them damage.

383. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

384. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the North Carolina Subclass members.

385. Plaintiffs and North Carolina Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

386. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and North Carolina Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

387. Plaintiffs and North Carolina Subclass members seek relief under N.C. Gen. Stat. §§ 75-16 and 75-16.1, including, but not limited to injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 27
OKLAHOMA
Oklahoma Consumer Protection Act
Okla. Stat. tit. 15, § 751, *et seq.*
On Behalf of the Oklahoma Subclass

388. Plaintiffs incorporate by reference all preceding paragraphs.

389. Plaintiff Oklahoma Doe brings this cause of action on her behalf and on behalf of the members of the Oklahoma Subclass.

390. The Oklahoma Consumer Protection Act makes it unlawful to make a misrepresentation, omission or other practice that has deceived or could reasonably be expected to deceive or mislead a person to the detriment of that person," or engage in "any practice which offends established public policy or if the practice is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." Okla. Stat. tit. 15, § 752.

391. Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Oklahoma Subclass Members, in violation of Okla. Stat. tit. 15, § 752, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

392. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted as part of a "consumer transaction," as defined by Okla. Stat. tit. 15, § 752.

393. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

394. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Oklahoma Subclass members.

395. Plaintiffs and Oklahoma Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

396. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiffs and Oklahoma Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

397. Plaintiffs and Oklahoma Subclass members seek relief under Okla. Stat. tit. 15, § 75, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 28
OREGON
Oregon Unlawful Trade Practices Law
Or. Rev. Stat. §§ 646.605, *et seq.*
On Behalf of the Oregon Subclass

398. Plaintiffs incorporate by reference all preceding paragraphs.

399. Plaintiff Oregon Doe brings this cause of action on her behalf and on behalf of the

members of the Oregon Subclass.

400. Oregon make it unlawful to for any person to employ "any unconscionable tactic in connection with selling, renting or disposing of real estate, goods or services, or collecting or enforcing an obligation." Or. Rev. Stat. § 646.607(1).

401. Defendants engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Oregon Subclass Members, in violation of Or. Rev. Stat. §§ 646.605, *et seq*., including by misrepresenting the true quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants, and failing to comply with federal law.

402. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "[t]rade" and/or "commerce," as defined by Or. Rev. Stat. § 646.605(8).

403. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

404. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Oregon Subclass members.

405. Plaintiff and Oregon Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

406. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Oregon Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention

of the products.

407. Plaintiffs and Oregon Subclass members seek relief under Or. Rev. Stat. § 646.638, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT 29
PENNSYLVANIA
Pennsylvania Unfair Trade Practices and Consumer Protection Law
73 P.S. §§ 201-1, et. seq.
On Behalf of the Pennsylvania Subclass

408. Plaintiffs incorporate by reference all preceding paragraphs.

409. Plaintiff Pennsylvania Doe brings this cause of action on behalf of herself and on behalf of the members of the Pennsylvania Subclass.

410. Plaintiff Pennsylvania Doe and the Pennsylvania Subclass Members purchased their BIOCELL implants primarily for personal, family or household purposes within the meaning of 73 P.S. § 201-9.2.

411. All of the acts complained of herein were perpetrated by Defendants in the course of trade or commerce within the meaning of 73 P.S. § 201-2(3).

412. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits unfair or deceptive acts or practices, including, "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding." 73 P.S. § 201-2(4). Defendants engaged in unlawful trade practices, and unfair or deceptive acts or practices that violated Pennsylvania CPL.

413. Defendants participated in unfair or deceptive trade practices that violated the Pennsylvania CPL as described below and alleged throughout the Complaint. By concealing the true risks of the BIOCELL implants and failing to comply with federal law, Defendants knowingly

and intentionally misrepresented and omitted material facts in connection with the sale the BIOCELL implants. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the BIOCELL implants in the course of their business.

414. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the BIOCELL implants.

415. Defendants' unfair and deceptive acts or practices repeatedly occurred in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

416. Defendants knew that the risks inherent in the BIOCELL implants made them not suitable for their intended use.

417. Defendants knew or should have known that their conduct violated the Pennsylvania CPL.

418. Had Pennsylvania Doe and the Pennsylvania Subclass Members known the truth about the BIOCELL implants, they would not have purchased and implanted the BIOCELL implants. Plaintiffs did not receive the benefit of their bargain as a result of Defendants' misconduct.

419. Defendants owed Pennsylvania Doe and the Pennsylvania Subclass Members a duty to disclose the truth about the BIOCELL implants because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the BIOCELL implants; (b) intentionally concealed the foregoing from Pennsylvania Doe and the Pennsylvania Subclass Members; and/or (c) made incomplete representations regarding the BIOCELL implants, while

purposefully withholding material facts from Pennsylvania Doe and the Pennsylvania Subclass Members that contradicted these representations.

420. Plaintiff Pennsylvania Doe and the Pennsylvania Subclass Members suffered injury in fact to a legally protected interest. As a result of Defendants' conduct, Plaintiff Pennsylvania Doe and the Pennsylvania Subclass Members were harmed and suffered actual damages.

421. Defendants' violations present a continuing risk to Plaintiff Pennsylvania Doe and the Pennsylvania Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

422. Defendants are liable to Pennsylvania Doe and the Pennsylvania Subclass Members for treble their actual damages or $100, whichever is greater, and attorneys' fees and costs under 73 P.S. § 201-9.2(a). Plaintiff Pennsylvania Doe and the Pennsylvania Subclass Members are also entitled to an award of punitive damages given that Defendant's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

COUNT 30
RHODE ISLAND
Rhode Island Unfair Trade Practice and Consumer Protection Act
R.I. Gen. Laws §§ 6-13.1-1, *et seq*.
On Behalf of the Rhode Island Subclass

423. Plaintiffs incorporate by reference all preceding paragraphs.

424. Plaintiff Rhode Island Doe brings this cause of action on her behalf and on behalf of the members of the Rhode Island Subclass.

425. The Rhode Island Unfair Trade Practice and Consumer Protection Act ("Rhode Island Act") identifies several types of "unfair" and/or "deceptive trade practices, but also incorporates by reference "the Federal Trade Commission's and federal courts' interpretations of section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1)," rather than set forth

specific definitions of those operative terms. R.I. Gen. Laws § 6-13.1-2.

426. Rhode Island has adopted a three-part test to determine whether an act is "deceptive": (1) a representation, omission, or practice, that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3), the representation, omission, or practice is material," meaning the representation is important to the consumer and likely to affect their decisions with respect to the product.

427. Defendants engaged in unlawful, unfair, and deceptive acts and practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Rhode Island Subclass Members, in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq*., including by misrepresenting the true quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants, and failing to comply with federal law.

428. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "[t]rade" and/or "commerce," as defined by R.I. Gen. Laws § 6-13.1-1(5).

429. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

430. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Rhode Island Subclass members.

431. Defendants' actions were material to Plaintiff and Rhode Island Subclass members, who relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

432. As a direct and proximate result of Defendants' deceptive acts and practices,

Plaintiff and Rhode Island Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

433. Plaintiffs and Rhode Island Subclass members seek relief under R.I. Gen. Laws §§ 6-13.1-5.2, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, punitive damages, and attorneys' fees and costs.

COUNT 31
SOUTH DAKOTA
South Dakota Deceptive Trade Practices and Consumer Protection Law
S.D. Codified Laws §§ 37-24-1, *et seq.*
On Behalf of the South Dakota Subclass

434. Plaintiffs incorporate by reference all preceding paragraphs.

435. Plaintiff South Dakota Doe brings this cause of action on her behalf and on behalf of the members of the South Dakota Subclass.

436. The South Dakota Deceptive Trade Practices and Consumer Protection Law, among other things, makes it unlawful to "[k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise, regardless of whether any person has in fact been misled, deceived, or damaged thereby." S.D. Codified Laws § 37-24-6(1).

437. Defendants engaged in deceptive trade practices in the course of their business, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and South Dakota Subclass Members, in violation of S.D. Codified Laws §§ 37-24-1, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the

BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

438. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

439. Defendants' actions were negligent, knowing and willful, and/or intentional, wanton and reckless with respect to the rights of Plaintiff and the South Dakota Subclass members.

440. Plaintiff and South Dakota Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

441. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and South Dakota Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

442. Plaintiff and South Dakota Subclass members seek relief under S.D. Codified Laws §§ 37-24-1, *et seq*., including, but not limited to injunctive relief, compensatory damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 32
TENNESSEE
Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
On Behalf of the Tennessee Subclass

443. Plaintiffs incorporate by reference all preceding paragraphs.

444. Plaintiff Tennessee Doe brings this cause of action on her behalf and on behalf of

the members of the Tennessee Subclass.

445. The Tennessee Consumer Protection Act ("TNCPA") was enacted to "protect consumers…from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce in part or wholly within [Tennessee]." Tenn. Code Ann. § 47-18-102(2).

446. The TNCPA makes unlawful, among other things, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have" and "[r]epresenting that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another." Tenn. Code Ann. § 47-18-104.

447. Defendants engaged in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Tennessee Subclass Members, in violation of Tenn. Code Ann. §§ 47-18-101, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

448. Defendants intended that other persons rely on the above unfair and deceptive practices and acts by Defendants were material misrepresentations of a presently existing or past fact, and their reliance was reasonable.

449. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

450. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Tennessee Subclass members.

451. Plaintiff and Tennessee Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

452. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Tennessee Subclass members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

453. Plaintiff and Tennessee Subclass members seek relief under Tenn. Code § 47-18-108-109, including, but not limited to injunctive relief, compensatory damages, statutory damages, punitive damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 33
UTAH
Utah Consumer Sales Practices Act
Utah Code Ann. §§ 13-11-1, *et seq.*
On Behalf of the Utah Subclass

454. Plaintiffs incorporate by reference all preceding paragraphs.

455. Plaintiff Utah Doe brings this cause of action on her behalf and on behalf of the members of the Utah Subclass.

456. The Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq*. makes it unlawful to, among other things, "knowingly or intentionally" "indicate[] that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits, if it has not" or "that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not." Utah Code Ann. § 13-11-4.

457. A "Consumer transaction" means a sale, lease, assignment, award by chance, or

other written or oral transfer or disposition of goods, services, or other property, both tangible and intangible (except securities and insurance) to, or apparently to, a person for…primarily personal, family, or household purposes." Utah Code Ann. § 13-11-3.

458. Defendants engaged in unfair or deceptive trade practices and unconscionable trade practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Utah Subclass Members, in violation of Utah Code Ann. §§ 13-11-1, *et seq*., including by making statements or representations that were false or misleading regarding the quality of the BIOCELL implants, concealing the true risks of the BIOCELL implants and failing to comply with federal law.

459. The above unfair or deceptive trade practices and unconscionable trade practices by Defendants were immoral, unethical, oppressive, and unscrupulous, and the type that may, tend to, or does deceive or mislead any person.

460. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Utah Subclass members.

461. Plaintiffs and Utah Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

462. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Utah Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

463. By engaging in the practices discussed above, including, but not limited to,

Defendant's undisclosed defects, Defendant has violated Utah Code Ann. §§ 13-11-1, *et seq*.

464. Plaintiff and Utah Subclass members seek relief under Utah Code Ann. § 13-11-17 and -19, including, but not limited to injunctive relief, compensatory damages, statutory damages, civil penalties and attorneys' fees and costs.

COUNT 34
VIRGINIA
Virginia Consumer Protection Act
Va. Code Ann. §§ 59.1-196, *et seq.*
On Behalf of the Virginia Subclass

465. Plaintiffs incorporate by reference all preceding paragraphs.

466. Plaintiff Virginia Doe brings this cause of action on her behalf and on behalf of the members of the North Carolina Subclass.

467. Virginia Consumer Protection Act, Va. Code Ann. §§ 59.1-196, *et seq*. ("VCPA") was enacted to "promote fair and ethical standards of dealings between suppliers and the consuming public."

468. The VCPA makes unlawful, among other things, any "deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction." Va. Code Ann. § 59.1-200.

469. Defendants engaged in unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Virginia Subclass Members, in violation of Va. Code Ann. §§ 59.1-196, including by making false representations or concealing the true risks of the BIOCELL implants and failing to comply with federal law.

470. The above unfair or deceptive acts or practices by Defendants were conducted as part of a "consumer transaction" as defined by Va. Code Ann. § 59.1-198.

471. The above unfair or deceptive acts or practices by Defendants were reasonably calculated to deceive class members and other consumers, and made with intent to deceive.

472. The above unfair or deceptive acts or practices by Defendants did in fact deceive class members and other consumers, causing them damage.

473. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

474. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Virginia Subclass members.

475. Plaintiff and Virginia Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

476. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Virginia Subclass Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

477. Plaintiffs and Virginia Subclass members seek relief under Va. Code Ann. §§ 59.1-196, *et seq*., including, but not limited to injunctive relief, compensatory damages, statutory damages, treble damages, civil penalties and attorneys' fees and costs.

COUNT 35
WASHINGTON
Washington Consumer Protection Act
Wash. Rev. Code § 19.86.020, et. seq.
On Behalf of the Washington Subclass

478. Plaintiffs incorporate by reference all preceding paragraphs.

479. Plaintiff Washington Doe brings this cause of action on her behalf and on behalf of

the members of the Washington Subclass.

480. The Washington Consumer Protection Act makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020.

481. Defendants engaged in unfair methods of competition and unfair or deceptive acts or practices, with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Washington Subclass Members, in violation of Wash. Rev. Code §§ 19.86.010, *et seq.*, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

482. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted as part of "trade" or "commerce" as defined by Wash. Rev. Code § 19.86.010.

483. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

484. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Washington Subclass members.

485. Plaintiffs and Washington Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants had they known that they would be exposed to the risk of developing BIA-ALCL.

486. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and Washington Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees

and medical monitoring associated with retention of the products.

487. Plaintiffs and Washington Subclass members seek relief under Wash. Rev. Code §§ 19.86.090, including, but not limited to injunctive relief, restitution, statutory damages, compensatory damages, civil penalties and attorneys' fees and costs.

COUNT 36
WISCONSIN
Wisconsin False Advertising Act
Wis. Stat. § 100.18
On Behalf of the Wisconsin Subclass

488. Plaintiffs incorporate by reference all preceding paragraphs.

489. Plaintiff Wisconsin Doe brings this cause of action on her behalf and on behalf of the members of the Wisconsin Subclass.

490. Wisconsin law prohibits companies from making "untrue, deceptive, or misleading" statements in any "notice, handbill, poster, bill, circular, pamphlet, letter, sign, placard, card, [or] label" in selling merchandise. Wis. Stat. § 100.18(1).

491. Defendants made "untrue, deceptive or misleading" statement with respect to the sale and advertisement of the BIOCELL implants purchased by Plaintiff and Wisconsin Subclass Members, including by concealing the true risks of the BIOCELL implants and failing to comply with federal law.

492. The above untrue, deceptive, or misleading acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

493. Defendants' actions were negligent, knowing and willful, and/or wanton and reckless with respect to the rights of Plaintiffs and the Wisconsin Subclass members.

494. Plaintiffs and Wisconsin Subclass members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of BIOCELL implants

had they known that they would be exposed to the risk of developing BIA-ALCL.

495. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff and Wisconsin Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with removal of the products and/or the surgical and diagnostic fees and medical monitoring associated with retention of the products.

496. Plaintiff and Wisconsin subclass members have suffered pecuniary loss and seek damages, including double damages, costs, and attorneys' fees. Wis. Stat. § 108.18(11)(b).

PRAYER FOR RELIEF

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

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and Subclasses defined above, and designate Plaintiffs as the class representative and Plaintiffs' counsel as counsel for the Nationwide Class and Subclasses;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Class Members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiffs and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiffs and the Class demand a trial by jury on all issues so triable.

Dated: December 20, 2019

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