CIVIL

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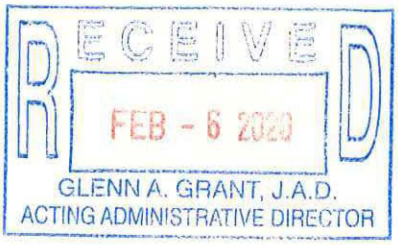
February 5, 2020

Via Overnight Delivery

Hon. Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Administrative Office of the Courts of the State of New Jersey
Richard J. Hughes Justice Complex
25 W. Market Street
Trenton, New Jersey 08625



Re: Application Pursuant to Rule 4:38A to Designate: In re Allergan Biocell Textured Breast Implant Litigation as a Multicounty Litigation for Centralized Management.

Dear Judge Grant:

Plaintiffs respectfully submit this letter application requesting the designation of a Multi-County Litigation ("MCL") for centralized management titled: In re Allergan Biocell Textured Breast Implant Litigation. Plaintiffs request that the MCL be assigned to the Honorable Rachelle L. Harz, J.S.C., in Bergen County, where two of the filed cases are currently pending.

Five cases have currently been filed in New Jersey by Mazie Slater, in Bergen County, Morris County, and Union County. A sixth case has been filed by another law firm in Morris County. Mazie Slater will be filing at least five additional cases in the next few days, and we have been advised that a number of additional cases will soon be filed by other law firms in the Superior Court.

In addition, a federal MDL has already been designated and assigned to the Honorable Brian R. Martinotti, U.S.D.J. in the United States District Court for the District of New Jersey, in Newark, as discussed below.

BACKGROUND

This application addresses six currently pending cases identified in the Schedule of Actions attached as **Exhibit "A"** ("Actions") filed in the Superior Court of New Jersey, and potentially hundreds of additional cases that are expected to be filed in New Jersey. Specifically, these Actions involve claims by women who have been implanted with textured breast expanders and textured breast implants (collectively referenced herein as the "Biocell Products") that were manufactured, marketed and sold by defendants Allergan, Inc., and Allergan USA, Inc., who have their headquarters in Madison, New Jersey and Allergan PLC, with its US headquarters located in Madison, New Jersey (collectively, "Allergan"). The Actions involve claims of failure to warn, breach of express warranty, negligence and punitive damages. The recalled Biocell Products at issue include:

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)

On May 10, 2000, Allergan was granted premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") to market the first segment of the line of Biocell Products. Subsequently, PMA was granted on November 17, 2006 and February 20, 2013, for additional segments of the BIOCELL line. On July 24, 2019, Allergan announced a worldwide recall and discontinuation of marketing of the Biocell Products. The FDA called for the action because Allergan's Biocell Products were associated with and believed to have caused breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL") with a frequency not reported with other textured implants (the "Recall"). Allergan announced that Biocell Products would no longer be sold or distributed in any market as a result of the Recall.

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. BIA-ALCL is treated with surgery to remove the implant and surrounding tissue, and may require treatment including chemotherapy, radiation therapy, and other interventions. The recommended diagnostic testing for BIA-ALCL is invasive. The symptoms of BIA-ALCL may manifest well after the surgical incision has healed, often years after the implant placement, and treatment can be very morbid and damaging, in some cases leading to the need for multiple procedures and operations, and intensive medical and surgical treatment, as well as substantial economic costs. This is all especially devastating for the victims, who in many cases are breast cancer survivors who already underwent mastectomies.

In its July 24, 2019 announcement, the FDA stated that the risk of developing BIA-ALCL with Allergan Biocell Products is about six times that of becoming ill with textured implants from other manufacturers available in the U.S. The FDA noted that more than 80% of known cases of BIA-ALCL 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 in part: "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."

Plaintiffs allege that as a result of Allergan's improper conduct, they were implanted with Biocell Products, have suffered severe injuries including development of BIA-ALCL or the risk of developing this potentially fatal cancer, and are now forced to undergo revision surgeries and other treatment, and incur substantial economic costs as well.

As set forth above, the Judicial Panel on Multidistrict Litigation (JPML) assigned the federal Allergan Biocell textured breast implant cases to the Honorable Brian R. Martinotti, U.S.D.J. in the District of New Jersey. See December 18, 2019 JPML Transfer Order entered in Case No. 2921, In Re: Allergan Biocell Textured Breast Implant Products Liability Litigation attached as **Exhibit "B."** Judge Martinotti conducted the initial case management conference in the newly formed MDL on January 13, 2020 in his courtroom at the United States District Court in Newark, New Jersey. The administrative organization of the MDL has commenced, and the MDL is proceeding.

ARGUMENT

Plaintiffs submit that this litigation meets the criteria required under Directive #8-12 for Centralized Case Management and respectfully request that these cases be consolidated for case management in the Bergen County Superior Court before the Honorable Rachelle L. Harz, J.S.C. Assignment of this MCL to the Bergen County Superior Court will be most efficient and maximize ease of coordination. For example, assignment of the litigation to Bergen County will allow the MDL and MCL Judges to coordinate in person as needed, including joint hearings if deemed beneficial, and allow attorneys traveling to New Jersey from around the United States to attend case management conferences and hearings on the same or consecutive dates with maximum convenience, including staying in one hotel room for both conferences, for example. In addition, Allergan is located in Madison, New Jersey, so assignment of the litigation to Bergen County will also be most convenient for access to witnesses and documents.

I. These Cases Satisfy the Criteria for MCL Case Management

A. The Allergan breast implant litigation involves a large number of parties that are geographically dispersed around the State of New Jersey and the Country.

As with other Multicounty Litigations centralized by this Court, the Allergan Biocell Textured Breast Implant Litigation will involve a large number of parties that are geographically dispersed. The current actions filed in New Jersey by Mazie Slater involve plaintiffs who reside in New Jersey, and there will be cases filed on behalf of plaintiffs from throughout the Country. The current New Jersey Actions are filed in multiple vicinages, including Bergen County, Morris County, and Union County. The parties submit that this geographical diversity makes Centralized Management necessary for the efficient handling of this litigation. In all, we expect hundreds of cases to be filed in New Jersey Superior Court, including on behalf of the many anticipated New Jersey plaintiffs who lack federal diversity jurisdiction. Our firm is currently evaluating numerous cases as are other law firms around the country, and we expect that there will be a steadily increasing number of cases filed in the New Jersey courts.

B. The Allergan breast implant litigation involves many claims with common, recurrent issues of law and fact associated with the Biocell Products that are alleged to cause similar injuries among the plaintiffs.

The Allergan Biocell Textured Breast Implant Litigation cases involve numerous claims with common, recurrent, and complex issues of law and fact. All of these cases involve the Biocell Products, and include similar claims arising from the unreasonably dangerous, defective design and the undisclosed risks of the Biocell Products. The cases therefore involve similar liability issues including the adequacy of the warnings. By necessity, there will be substantial overlapping discovery across these cases. There are also common injuries and damages flowing therefrom including BIA-ALCL, raising common causation issues, and the need for removal and replacement of the implants. It is critical to ensure consistent rulings on the various complex issues that will arise in these numerous cases from the outset. The Defendants have advised in the MDL that they intend to file motions to dismiss based on express and implied preemption, and similar motions are certain to be filed in the Superior Court. It would be most efficient for these motions to be managed and decided by a single Judge to ensure consistent rulings. Once an MCL is designated, all issues will be decided pursuant to New Jersey law. In re Accutane Litig., 235 N.J. 229 (2018). This maximizes the efficiency of rulings on these complex issues, at the trial and appellate levels.

Centralized management will conserve judicial resources and provide all parties with the benefits of coordinated discovery. Centralization is expected to provide a fair and more convenient, cost effective process for all parties, witnesses, counsel and the Court.

C. Centralization will help facilitate coordination with the MDL litigation.

As set forth above, the federal MDL has been assigned to the Honorable Brian R. Martinotti, U.S.D.J. in the District of New Jersey, in Newark, New Jersey. Centralization of these cases will promote effective coordination with the MDL, and thus serves the goal of efficient and inexpensive administration of cases, while maintaining the independence of the New Jersey litigation. For example, Judge Martinotti has scheduled a case management conference once a month for the MDL litigation. Because it is expected that counsel for the parties in the MDL will have substantial overlap with counsel for the parties in the anticipated MCL, case management conferences could be held on the same or consecutive days. That would alleviate unnecessary additional travel and maximize effective coordination with the MDL. Because the MDL is already proceeding, it would be optimal to form and allow the MCL to proceed at a similar pace.

D. Centralized Management is fair and convenient to the parties, witnesses and counsel.

Given the large number of parties, witnesses, and counsel, the cases would benefit from centralized management. Centralized management will minimize duplicative practice and inconsistent discovery rulings. Additionally, because the current Actions (and any future actions) are at the earliest stage, centralization will provide the Court with the ability to manage these cases from the beginning in an efficient and effective manner.

II. All Known Plaintiffs' Counsel Agree that These Cases Should be Assigned to Bergen County for Centralized Management, and that Bergen County is the Most Appropriate Venue for These Cases.

Issues of fairness, geographical location of the parties and attorneys, and the existing civil and mass tort caseload in the vicinage are considered when determining the vicinage to assign a particular mass tort for centralized management. See Mass Torts-Guidelines and Criteria for Designation, at 2 (Oct. 25, 2007).

In light of the number of cases already pending in Northern New Jersey counties with many more to be filed in the coming days and weeks, and that the federal MDL is venued in Newark, New Jersey, it is both logical and efficient for the MCL to be assigned to Judge Harz in Bergen

County. Moreover, because Allergan's principal place of business is located in Morris County, centralization in nearby Bergen County would be the most convenient location for Allergan witnesses and counsel to attend proceedings, and to coordinate court appearances with depositions as discovery proceeds. In addition, though we do not have the exact case numbers, it is our understanding that the pelvic mesh MCL's assigned to the Bergen County Superior Court which previously numbered in excess of 10,000 cases have now been significantly reduced.

We have spoken to known counsel who are in the process of filing these cases, and have attempted to speak with counsel in the Viola case but have not received a response. The counsel we have spoken to are in agreement with this application. Accordingly, it is both logical and fair to the litigants for these cases to proceed in Bergen County for centralized management. A copy has been sent to Defendant's New Jersey counsel in the MDL, who we have reached out to, as well.

CONCLUSION

In light of all the factors and information discussed above, the Plaintiffs respectfully request that pursuant to Rule 4:38A, the Allergan Biocell Textured Breast Implant Litigation be designated as Multicounty Litigation for Centralized Management and be assigned to the Honorable Rachelle L. Harz, J.S.C. in the Bergen County Superior Court, for efficient and effective administration.

By: _____

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Schedule of Actions

E.K. and M.K. v. Allergan, Inc., et als., Docket No. BER-L-472-20;

C.D. v. Allergan, Inc., et als., Docket No. BER-L-870-20;

C.D. and J.D. v. Allergan, Inc., et als., Docket No. UNN-L-281-20;

A.N. and G.P. v. Allergan, Inc., et als., Docket No. UNN-L-282-20;

C.M. v. Allergan, Inc., et als., Docket No. UNN-L-305-20;

Viola v. Allergan PLC, et als., Docket No. MRS-L-252-20

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION

MDL No. 2921

TRANSFER ORDER

Before the Panel: Plaintiffs in two actions move under 28 U.S.C. § 1407 to centralize this litigation in the Central District of California or, alternatively, the Middle District of Tennessee. This litigation currently consists of four actions pending in four districts, as listed on Schedule A.[1] Since the filing of the motion, the Panel has been notified of 25 related federal actions.[2]

All responding parties support or do not oppose centralization, but disagree on the transferee district. The Allergan defendants[3] request centralization in the District of New Jersey. Responding plaintiffs variously propose the Central District of California, the Southern District of New York, the Southern District of Florida, and the District of Kansas.

On the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact, and that centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions arise out of Allergan's announcement on July 24, 2019, of a voluntary worldwide recall of its BIOCELL textured breast implants and tissue expanders. The announcement followed the U.S. Food and Drug Administration's request to initiate the recall based on the risk of breast-implant associated anaplastic large cell lymphoma (BIA-ALCL) associated with the products.[4] All actions share complex factual questions arising from the allegation that Allergan's BIOCELL textured breast implants and tissue expanders significantly increase the risk of developing BIA-ALCL, and that Allergan failed to warn the FDA, patients, and healthcare providers of this risk. The common factual questions include: (1) whether BIOCELL textured breast implants and tissue expanders can cause BIA-ALCL; (2) whether defendants knew or should have known of the risk of BIA-ALCL; (3) whether they provided adequate warnings as to the risk; and (4) the adequacy of defendants' product

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[1] A fifth action on the motion for centralization was voluntarily dismissed during the pendency of the motion.

[2] The related actions are pending in fourteen additional districts. These and any other related actions are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1 and 7.2.

[3] Allergan, Inc., Allergan USA, Inc., and Allergan plc.

[4] According to the FDA, BIA-ALCL is a type of non-Hodgkin's lymphoma, a cancer of the immune system.

design, testing, and manufacturing.[5] Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to class certification and *Daubert* motions; and conserve the resources of the parties, their counsel and the judiciary.

We conclude that the District of New Jersey is an appropriate transferee forum. Allergan USA, Inc., has its headquarters and principal place of business in this district, and represented at oral argument that significant common evidence, including witnesses, will be located there. Further, centralization in the District of New Jersey enables us to assign this litigation to Judge Brian R. Martinotti, an experienced transferee judge with the ability and willingness to manage this litigation. We are confident he will steer this matter on a prudent course.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the District of New Jersey are transferred to the District of New Jersey and, with the consent of that court, assigned to the Honorable Brian R. Martinotti for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Ellen Segal Huvelle
Catherine D. Perry
Matthew F. Kennelly
R. David Proctor
Nathaniel M. Gorton
David C. Norton

[5] We find it unnecessary to include "Anaplastic Large Cell Lymphoma" in the MDL caption, as defendants request. It is clear from the face of this order that the common factual issues in this MDL concern the alleged risk of ALCL – and specifically, BIA-ALCL – associated with the recalled products.

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION MDL No. 2921

SCHEDULE A

Central District of California

A.B., ET AL. v. ALLERGAN, INC., ET AL., C.A. No. 8:19-01651

Central District of Illinois

TAUBEN v. ALLERGAN, INC., ET AL., C.A. No. 2:19-02257

Southern District of New York

DOE 1, ET AL. v. ALLERGAN, INC., ET AL., C.A. No. 7:19-09151

Middle District of Tennessee

ZETTLEMOYER v. ALLERGAN, INC., ET AL., C.A. No. 3:19-00866