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February 28, 2018



VIA REGULAR MAIL

The Hon. Glenn A. Grant, J.A.D.
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 R. 4:38A (“Centralized Management of Multicounty Litigation”) Request for Multi-County Litigation Designation for Ethicon Multi-Layered Hernia Mesh

Dear Judge Grant:

The below attorneys and firms submit this letter on behalf of sixty-two Plaintiffs who have cases filed in Bergen County, New Jersey involving one or more Multi-Layered Hernia Mesh products designed, manufactured, marketed, and sold by Defendants, Johnson and Johnson and Ethicon, Inc. (collectively “Defendants”).¹ We write to advocate for a Multi-County Litigation designation in accordance with Rule 4:38A. There are dozens, if not hundreds of additional cases involving Defendants’ Multi-Layered Hernia Mesh, as described below, which will be filed in the near future. In addition to those cases, our current assessment of firms representing Plaintiffs alleging injuries from hernia mesh products suggests that several hundred more cases involving Defendants’ Multi-Layered Hernia Mesh will be filed. Accordingly, MCL designation is appropriate and we respectfully submit that MCL designation before The Honorable Rachelle L. Harz, J.S.C. in Bergen County will conserve resources, reduce cost, eliminate delay, and reduce the likelihood of inconsistent results.

¹ See attached Exhibit A for the complete list of cases.

BACKGROUND

This application addresses the approximately 62 currently pending cases, and any future similar cases filed in the Superior Court alleging that Defendants' Multi Layered Hernia Mesh was defective, and that those defects caused the mesh to fail, resulting in serious injuries and the need for additional medical intervention.

The products referred to throughout this application as "Multi-Layered Hernia Mesh" were all manufactured and sold by Defendants and are all polypropylene-based mesh prosthetics indicated for the repair of hernias, including: Proceed Surgical Mesh, Proceed Ventral Patch, Physiomesh Flexible Composite, Prolene 3D Polypropylene Patch, and Prolene Hernia System. Plaintiffs allege that these products are defective and unsafe for their designed and intended use.

Although Defendants manufacture and sell a wide variety of hernia mesh prosthetics, many of which are made of polypropylene, Defendants' Multi-Layered Hernia Mesh share one important characteristic: all of the subject products feature one or more deviations from an uncoated, two-dimensional polypropylene mesh design, deviations which (1) increase the type and rate of serious complications and (2) were introduced in order to increase sales by making implantation procedures faster, rather than safer or more effective. These Multi-Layered Hernia Mesh also share one or more of the same or similar constituent materials, and are all manufactured and distributed by Defendants.

PROCEED SURGICAL MESH AND PROCEED VENTRAL PATCH

Proceed Surgical Mesh ("Proceed") and Proceed Ventral Patch ("PVP") are hernia mesh products that have been found to *contribute* to adhesion formation by operation of multiple design defects. Defendants knew or should have known that was not an effective adhesion prevention barrier and in fact leads to the formation of adhesions, which can be painful and sometimes life-threatening. Proceed and PVP have an alarmingly high rate of mechanical failure, sometimes described by surgeons as "Proceed rupture".

PHYSIOMESH FLEXIBLE COMPOSITE

The Physiomesh Flexible Composite ("Physiomesh") is marketed as an anti-adhesion barrier mesh, in which the barrier layer that is supposed to prevent scar tissue formation is present on both the side of the mesh which faces the bowel *and* the side which faces the abdominal wall.

Utilizing an anti-adhesion barrier on the side of a polypropylene hernia mesh graft that faces the abdominal wall increases the risk that the graft will not incorporate into the abdominal wall, causing the graft to fold, buckle, and migrate, posing a threat to adjacent organs.

Poliglecaprone is also known to incite an inflammatory response in soft tissue, causing complications. Defendants were aware of this predisposition prior to market launch of the Physiomesh.

In May of 2016, Defendants issued a "Field Safety Notice" relating to the Physiomesh product, to hospitals and medical providers in various countries worldwide. In this Urgent Field Safety Notice, Defendants advise these providers of "a voluntary product recall".

PROLENE 3D POLYPROPYLENE PATCH

The Prolene 3D Polypropylene Patch ("P3D") is a multi-layered, three-dimensional mesh device. This product is often used to repair inguinal hernias and the design contemplates that the mesh acts as a "plug" in the abdominal cavity, while it secures the repair at the anterior abdominal wall. The design of the P3D is problematic. The intense foreign body inflammatory response causes contracture to the tissue and mesh.

PROLENE HERNIA SYSTEM

Prolene Hernia System ("PHS") is a multi-layered, three-dimensional mesh device. Defendants market PHS for both inguinal and ventral hernia repairs. The PHS is intended to minimize the probability of hernia recurrence, but the design results in an intense foreign body inflammatory response which can cause a cascade of injurious complications, including but not limited to profound contracture of the mesh, chronic and debilitating pain, mesh migration and erosion into nearby organs.

COORDINATION IS APPROPRIATE

As set forth in the guidelines, multi-county litigation is warranted when a litigation involves a large number of parties; many claims with common, recurrent issues of law and fact; there is geographical dispersion of parties; there is a high degree of commonality of injury; there is a value interdependence between different claims; there is a degree of remoteness between the court and actual decision makers in the litigation; among other considerations.

This litigation meets the above criteria. There are many common, recurrent issues of law and fact that are associated with this class of products. These products share common Defendants (and likely the same corporate witnesses), designs, materials, manufacturing and production methods, and underlying science. Additionally, there is geographical dispersion of the parties (as these products were sold throughout the nation), a high degree of commonality of injury; and a likely value interdependence among different claims. All of these considerations warrant MCL designation. The same policies and factors which led the Supreme Court to decide on October 12, 2010, that all pending and future Ethicon and J&J pelvic mesh cases should be centralized for management purposes (<https://www.judiciary.state.nj.us/attorneys/mcl/bergen/pelvicmesh.html>), should compel the granting of the instant application.

At least 62 cases have already been filed, and all involve the recurrent legal issues of design defect, failure to warn, breaches of warranties and the possibility of manufacturing defects. There are significant overlapping factual liability issues relating to the selection of the polypropylene and other materials utilized in Defendants' Multi-Layered Hernia Mesh, how it was manufactured and sterilized, the nature of the defect, any delay or failure in recalling the products, failure to comply with good manufacturing practices, and a host of other related factual issues.

Separate discovery demands have been served in many of the cases, including pathology requests necessitating a uniform pathology protocol. MCL designation is appropriate for these cases, and future filed-cases involving Defendants' Multi-Layered Hernia Mesh, as it will allow for efficiencies in discovery that will conserve the resources of the parties and the judicial system.

At the present time, we do not know precisely how many of these products have been implanted in patients in the United States, but publicly available information indicates there are thousands—if not tens of thousands—of these products implanted into US citizens.

BERGEN IS THE MOST APPROPRIATE VENUE

Pursuant to the Mass Tort Guidelines and Criteria for Designation, questions of fairness, the locations of the parties and counsel, and the existing civil and mass tort caseload are considered in determining where to centralize the management of a mass tort case.

Bergen County is the best venue for the consolidation of the Ethicon Multi-Layered Hernia Mesh cases. The previously-filed Ethicon Multi-Layered Hernia Mesh cases are all pending before various judges in Bergen County. Discovery is underway and has been exchanged in several cases. Geographically, the Bergen venue is conveniently located to regional and international airports. Bergen is within driving distance of Defendant Ethicon's headquarters in Somerville, as well as Defendant Johnson & Johnson's headquarters in New Brunswick.

The existing civil and mass tort caseload in the venue is also an important factor in selecting an MCL venue. According to the New Jersey Courts' website, seven MCLs are pending in the Middlesex County Superior Court, five MCLs are centralized in the Atlantic County Superior Court, (including the most recently assigned MCL, the Firefighter Hearing Loss MCL), and seven MCLs are pending in the Bergen County Superior Court. In addition to their non-asbestos MCL docket, Middlesex County also has over four hundred active asbestos cases as well as twenty-seven consumer fraud class actions. In Bergen however, the Stryker Trident Hip Implant Litigation is all but completed, the DePuy ASR Hip Implant litigation announced a global settlement in November 2013, the Stryker Hip/ABG II litigation announced a global settlement in December 2016, and the Pompton Lakes MCL has also recently concluded. The resolution of those matters will reduce the Bergen County MCL caseload significantly.

Additionally, Bergen County Superior Court has gained substantial, relevant knowledge in handling the current and prior pelvic mesh cases, including knowledge regarding these Defendants, the materials, manufacturing and sterilization processes used by mesh manufacturers, and the regulatory processes involved in marketing and recalling such devices.

Judge Rachelle L. Harz, who oversees all MCLs in Bergen County and who has already been assigned 6 of these cases² would be an ideal judge to handle this litigation. Judge Harz has valuable experience, including presiding over the Pelvic Mesh litigation, which involves overlapping science and the same Defendants. Judge Harz has presided over the Pelvic Mesh litigation since it was re-assigned to her in August 2016, and since that time has issued over 300 orders, conducted numerous conferences, and has shown a remarkable understanding of the complex scientific issues of Pelvic Mesh, and their intrinsic interrelationship to the legal issues. Many of these scientific and legal issues will predominate in the Ethicon and J&J Hernia Mesh litigation. Accordingly, by far the most logical and fair procedure for the litigants would be for these cases to remain in Bergen County before Judge Harz.

In light of all the factors discussed above, Plaintiffs respectfully request that the New Jersey Supreme Court designate the Ethicon Multi-Layered Hernia Mesh cases for MCL management in the Bergen County Superior Court before Judge Harz.

Respectfully submitted,

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² Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Dollanmeyer v. Ethicon, Inc., et al, Docket No.: BER-L-774-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; and Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18.

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