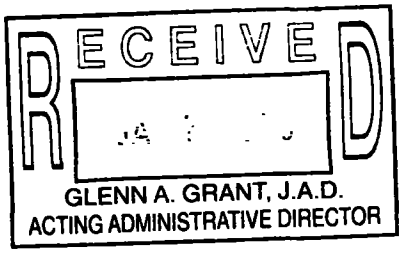

McCARTER &ENGLISH
ATTORNEYS AT LAW

January 25, 2019

VIA HAND 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
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Re: Dec. 3, 2018 Application for Multicounty Litigation Designation for Proceed and Prolene Hernia System Mesh Products

Dear Judge Grant:

This Firm, along with Riker Danzig Scherer Hyland & Perretti LLP and Butler Snow LLP, represents Defendants Ethicon, Inc. ("Ethicon") and Johnson & Johnson (collectively "Defendants") in certain cases involving Proceed Surgical Mesh, Proceed Ventral Patch and Prolene Hernia System products currently pending in New Jersey. These cases -- once again -- are the subject of a Rule 4:38A Multi-County Litigation ("MCL") application, dated December 3, 2018, which is currently pending before the Administrative Office of the Courts ("AOC"). The AOC issued a Notice to the Bar on December 26, 2018, requesting comments or objections.[1] This letter is submitted pursuant to that notice and in response to Plaintiffs' application.

This is Plaintiffs' second attempt to manufacture an MCL for cases involving a broad array of different hernia mesh products. In February 2018, Plaintiffs' counsel filed an application seeking to establish an MCL for five different mesh products. In response to that application, Defendants did not oppose the creation of an MCL for cases involving PHYSIOMESH™ Flexible Composite Mesh ("Physiomesh"), as there was already a federal multidistrict litigation ("MDL") involving such cases, which remains pending in the United States District Court for the Northern District of Georgia. Defendants did oppose, however, the creation of a single, unwieldy MCL for all five distinct products, which would necessarily involve complex and unworkable discovery issues, making coordination inefficient and unfairly prejudicial. On July 17, 2018, the Supreme Court created an MCL for cases involving Physiomesh only, and assigned the MCL to Atlantic County for centralized case management by Superior Court Judge Nelson C. Johnson.

For the reasons set forth in Defendants' May 11, 2018 response to Plaintiffs' initial MCL application, and stated herein, Defendants again oppose the creation of an

[1] The AOC's notice indicates that Plaintiffs' application requests assignment of the proposed MCL to Middlesex County; however, Plaintiffs' application did not request any particular MCL venue.

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MCL for cases involving hernia mesh products other than Physiomesh. The hernia mesh products subject to this application are each materially different with respect to their development, design, and materials, and are not suitable for MCL designation. State and federal courts have routinely reminded litigants that coordination or centralization of litigation "should be the last solution after considered review of all other options." See, e.g., In re: Linear Gadolinium-Based Contrast Agents Products Liability Litig., Case MDL No. 2868, Oct. 10, 2018 Order Denying Transfer (J.P.M.L) (quoting In re: Best Buy Co., Inc., Cal. Song-Beverly Credit Card Act Litig., 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011)). Creating a second MCL for these divergent products would serve only to invite more individuals and law firms to file lawsuits in New Jersey – regardless of the merit (or lack thereof) of their claims. Plaintiffs' proposal will make New Jersey a magnet for the meritless, as many plaintiffs will attempt to ride the wave of coordinated litigation managed by others. Such a consequence has become a reality in practice that cannot be ignored, and respectfully, should be taken into consideration by the Court.

In the alternative, in the event the Court is inclined to establish another MCL, Defendants respectfully submit that it should be limited to cases involving Proceed Surgical Mesh and the Proceed Ventral Patch only – but not create an MCL for Prolene Hernia System, which in no way meets the standards for an MCL. Cases involving these two Proceed products represent the overwhelming majority of the cases that are the subject of the Plaintiffs' current application. The benefits of any coordination would be better managed separate from, but alongside, the Physiomesh MCL in Atlantic County.

PROCEDURAL HISTORY

I. Plaintiffs' Initial Law Division Filings in Bergen County

Beginning in late 2017, Plaintiffs (largely represented by the same small number of law firms supporting this application) began filing complaints in New Jersey Superior Court, Bergen County, alleging product liability claims related to hernia mesh products manufactured by Ethicon. At that time, none of the Plaintiffs resided in Bergen County, nor did any Plaintiff's counsel have an office in Bergen County. Indeed, the overwhelming majority of Plaintiffs lived outside of New Jersey and received the implant outside of New Jersey.

On January 11, 2018, the Lomurro Firm, which represents a significant number of the Plaintiffs, wrote to Bergen County Civil Presiding Judge Robert L. Polifroni asking for a case management conference to discuss consolidation or an MCL created for all hernia mesh cases then-pending in Bergen County. (See Ex. A: Plaintiffs' 1/11/18 Letter to Judge Polifroni). Defendants opposed that request. (See Ex. B: Defendants' 1/26/18 Letter to Judge Polifroni).

Judge Polifroni flatly rejected Plaintiffs' "informal" attempt to achieve MCL designation in Bergen County and reminded the Lomurro Firm of New Jersey's MCL application process. (See Ex. C: Judge Polifroni's January 25, 2018 letter to Plaintiffs' Counsel). In his letter, Judge Polifroni explained that "[d]ecisions by counsel to select a county of venue, and then request to have the matters consolidated and handled by one judge outside of the MCL format, will not be validated by this Court." (Id.) Judge Polifroni further noted that "unless the individual plaintiffs live in Bergen County, it seems reasonable the most convenient venue would be the corporate location of the defendants, which appears to be outside of Bergen County." (Id.) (emphasis added).

Despite the Court's suggestion, Plaintiffs' counsel continued to file lawsuits in Bergen County, even though that venue has no connection to the parties or the circumstances underlying the complaints.

II. Plaintiffs' First MCL Application

On February 28, 2018, Plaintiffs filed a Rule 4:38A Multicounty Litigation Application with the AOC, seeking the creation of an MCL for five different hernia mesh products manufactured by Ethicon, including a product that, at that time, was not even at issue in any case pending in New Jersey. Specifically, Plaintiffs sought MCL designation for the following products: (1) Physiomesh; (2) PROCEED® Surgical Mesh; (3) PROCEED® Ventral Patch; (4) Prolene Hernia System; and (5) Prolene 3D Patch. Additionally, Plaintiffs requested that the proposed MCL be assigned to The Honorable Rachelle L. Harz in Bergen County.

The AOC issued a Notice requesting comments or objections to Plaintiffs' counsel's MCL application by May 14, 2018. (See Apr. 11, 2018 Notice to the Bar by Glen A. Grant, J.A.D., available at https://www.njcourts.gov/notices/2018/n180412a.pdf?cacheID=QaWMX7I). Defendants timely responded to Plaintiffs' MCL application. In their response, Defendants did not oppose the creation of an MCL for cases involving only Physiomesh, as such an MCL would mirror the federal multidistrict litigation pending in the United States District Court for the Northern District of Georgia and would promote judicial efficiency. Defendants did oppose creation of a broader MCL involving so many different products, as it would create complex and unworkable discovery issues, making coordination inefficient and unfairly prejudicial. The same remains true today.

On July 17, 2018, the Supreme Court created an MCL for cases involving Physiomesh only, and denied Plaintiffs' request to include the Proceed and Prolene cases. The Court assigned the Physiomesh MCL to Atlantic County for centralized case management by Superior Court Judge Nelson C. Johnson. (See Ex. D: Order of Supreme Court of New Jersey, dated July 17, 2018). Specifically, the Supreme Court ordered that "all pending and future New Jersey state court actions against Johnson & Johnson and Ethicon, Inc. alleging injuries as a result of use of

Physiomesh Flexible Composite Mesh . . . shall be transferred from the county of venue to the Superior Court, Law Division, Atlantic County." (See id.) Atlantic County Superior Court Judge John C. Porto is currently presiding over the Physiomesh MCL. As of the date of this letter, Judge Porto has entered four (4) case management orders in the Physiomesh MCL.

III. Judge Harz Transfers Proceed and Prolene Cases to Middlesex County

After the Physiomesh MCL was created, cases involving the other hernia mesh products remained in Bergen County – a venue having no connection to Plaintiffs, their claims, or Defendants. Accordingly, on September 6, 2018, Defendants filed motions to transfer all Bergen County Ethicon hernia mesh cases to Somerset County, where Ethicon, the company responsible for the design, manufacture, marketing, sale, and distribution of those products, is located.

On September 28, 2018, Judge Harz granted Defendants' motions to transfer venue, and ordered that "all cases filed by the plaintiffs against the defendants pertaining to personal injury product liability claims concerning hernia mesh other than Physiomesh" be transferred to Middlesex County. (See Ex. E: Transcript of Motion and Opinion, dated Sept. 28, 2018, at 27:1-4). Judge Harz stated that "Bergen County is not a proper venue" and that "these cases have absolutely no nexus to Bergen County." (Id. at 36:18, 38:18-19). Specifically, Judge Harz held:

> Plaintiff has failed to establish that venue is proper in Bergen County. Ethicon headquarters are in Somerville, Somerset County. That is where the . . . majority of Ethicon's activities and New Jersey business is conducted and where Ethicon's business activities are targeted in this State. Likewise Johnson & Johnson's principle New Jersey office is in Middlesex County which is where the majority of its business is conducted in this State.
>
> Accordingly, pursuant to Rul[e] 4:3-2, and the principles articulated in Crepy [v. Reckitt Benckiser, LLC, 448 N.J. Super. 419 (Law Div. 2016)], as well as the proposed amendment clarifying the rule consistent with Crepy venue is not properly laid in Bergen County.

(Id. at 32:18-33:5).

Judge Harz further observed, "Plaintiff's arguments seeking out this Court amounts to an admission of for[u]m shopping that courts should discourage" and recognized that Plaintiffs were raising "identical" arguments to those raised in their first MCL

application "which was rejected by the Supreme Court." (Id. at 34:9-14). The judge reasoned:

> In sum, these cases have absolutely no nexus to Bergen County. While this Court appreciates the compliments that plaintiffs have provided in their papers indicating that they have confidence that I would be able to handle these hernia mesh cases, that's not how assignment judges or our court system makes decisions regarding venue. To do so would be tantamount to judge shopping.
>
> Our system does not allow the parties to pick a venue or a judge because they believe a particular judge would be well-suited for particular case or case type.

(Id. at 38:18-39:4). Judge Harz further reasoned that Middlesex County had the resources and experience to handle these matters as individual cases. (Id. at 36:22-37:2). Judge Harz entered an Order on October 9, 2018, which denied as moot Plaintiffs' motion to consolidate all Proceed and Prolene hernia mesh cases. (See Ex. F: Oct. 9, 2018 Order).

Since the entry of Judge Harz's Order, Plaintiffs have filed complaints involving Ethicon hernia mesh products other than Physiomesh in Middlesex County.

BACKGROUND

The products involved in the cases implicated by Plaintiffs' second MCL application are distinct products with distinct regulatory histories and product development timelines. By way of background, there are multiple different types of hernias, each characterized largely by their anatomical location and presentation and which can require different treatment.[2] Three of the most common hernias include inguinal, ventral, and umbilical.[3] For many years, surgeons have repaired hernias using medical devices made of mesh. There are over one million hernia repair surgeries

[2] A hernia is a hole in the muscular layer of the abdominal wall, through which pre-peritoneal or intra-abdominal contents can protrude. This protrusion results in a bulge, which is often associated with abdominal discomfort and cosmetic deformity. An untreated hernia can also lead to further medical complications.

[3] An inguinal hernia is a defect in the abdominal wall that occurs through an area of weakening of the muscle layers of the lower abdominal wall. A ventral hernia is a defect in the abdominal wall (usually midline) that occurs along the scar formed by prior abdominal surgery. An umbilical hernia is a hernia that develops at the umbilicus through a weakened layer of the abdominal wall.

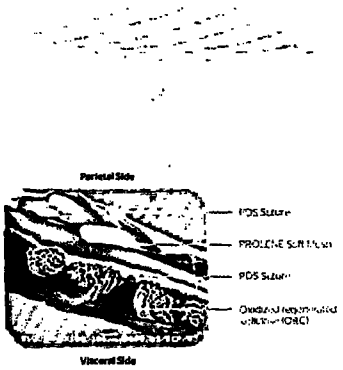
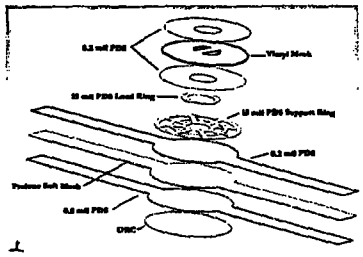
performed each year in the United States alone. By the year 2000, fewer than 10% of hernia repair surgeries for groin hernias did not utilize a mesh product.[4] The mesh in many, but not all, of these devices is made from sterile, polypropylene-based materials. Depending on the surgeon's repair technique, the mesh is typically placed either under or over the hernia and held in place utilizing one of several methods. The mesh acts as "scaffolding" for new growth of the patient's own tissue, which eventually incorporates the mesh into the surrounding area to provide the needed support.

For more than 50 years, Ethicon, Inc. has manufactured and sold a number of distinct hernia mesh devices. In 2010, Ethicon launched Physiomesh, a mesh device comprised of Prolene fibers laminated between Monocryl and polydioxanone films. The Monocryl layers dissolve and allow for a gradual in-growth of tissue into the mesh. Ethicon voluntarily withdrew Physiomesh from the market in 2016. In 2017, a federal MDL was created for cases alleging claims exclusively related to Physiomesh. That MDL is assigned to Judge Richard Story in the United States District Court for the Northern District of Georgia.

At the time of Plaintiffs' first application for MCL designation, there were approximately 62 cases filed in the Bergen County Superior Court alleging product liability claims related to five different products. Plaintiffs' current application seeks an MCL designation for three different products: (1) PROCEED® Surgical Mesh; (2) PROCEED® Ventral Patch; and (3) Prolene Hernia System. The following chart provides a brief description of the products identified by Plaintiffs in their application:

Device	Type of Mesh	Year Launched	Status
Prolene Hernia System	3D with onlay and underlay patch, non-absorbable	1997	Currently marketed

[4]https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/HerniaSurgicalMesh/default.htm.

Device	Type of Mesh	Year Launched	Status
PROCEED® Surgical Mesh	Flat, partially absorbable 	2004	Currently marketed
PROCEED® Ventral Patch	3D patch, partially absorbable 	2008	Currently marketed

Each of these products is materially different with respect to development, design, materials, method of manufacture, place of manufacture, primary uses, method of placement, and labeling, even though they share some components. Some of the products were manufactured in Germany, while others were manufactured in the United States. The products were conceived and designed at different times over several decades with different individuals involved.

Plaintiffs' attempt to portray dozens of actions involving different products as presenting common issues misleadingly ignores the true differences between the products and the allegations of the complaints. At the outset, Plaintiffs generically label all three products as being "multi-layered" and assert the devices have similar designs and compositions. In fact, each of the products has a different design and components, and these differences are material to Plaintiffs' claims.

Although Plaintiffs generally describe all of the products as multi-layered hernia mesh products, Prolene Hernia System, in fact, is not multi-layered. And while both Proceed Ventral Patch and Proceed Surgical Mesh are partially absorbable, Prolene Hernia System is not absorbable. Additionally the products have different uses: Proceed Surgical Mesh and Proceed Ventral Patch are tissue-separating devices typically used on the inside of the abdominal wall, whereas Prolene Hernia System is typically used for inguinal repairs. Proceed Surgical Mesh is also very different from both the Proceed Ventral Patch and Prolene Hernia System in that Proceed Surgical Mesh is flat, but the other products are three-dimensional and intended to be applied, not just over, but through a hernia defect.

Those differences are not only significant in how the products are used, they are significant in how Plaintiffs themselves portray these products. Indeed, Plaintiffs rely on those very differences to allege that the design of each product makes it more dangerous than other products. In actions related to the Proceed Ventral Patch, for example, Plaintiffs claim that the product has characteristics that make it more dangerous than Proceed Surgical Mesh. In particular, they allege that "Defendants were aware that ***adding Vicryl and other additional layers to the Proceed Surgical Mesh to create Proceed Ventral Patch, would increase the intensity and duration of inflammation and foreign body response (FBR)***, thus increasing fibrinous exudate." (See Ex. G: Bednarcyk Compl., at ¶ 35, emphasis added).

At the same time, Plaintiffs also claim that components found in both the Proceed products, but not Prolene Hernia System, render those products uniquely more dangerous than products without those components. For example, Plaintiffs claim that Oxidized Regenerated Cellulose, included in the composition of both Proceed products but not the Prolene product, "had pores which were too large to prevent adhesion formation" and that "increased adhesion formation would result in increased mesh shrinkage." (See Ex. H: Wetch Compl., at ¶¶ 23-26; Ex. G: Bednarcyk Compl., at ¶¶ 29-31). Plaintiffs further allege that "Defendants were aware that the ORC layer in the Proceed was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the Proceed to market." (See Ex. H: Wetch Compl., at ¶ 42; Ex. G: Bednarcyk Compl., at ¶ 49).

Conversely, Plaintiffs allege that the design of the Prolene Hernia System made it more unsafe than any other products. In this regard, Plaintiffs claim the Prolene product is different from any other product used: "The Prolene Hernia System has a

unique design, which incorporates two distinct layers of polypropylene connected by a central polypropylene tube. ***This design is not used in any other hernia repair product sold in the United States.***" (See, e.g., Ex. I: Wilson Compl., at ¶ 31, emphasis added). Plaintiffs further allege that the unique design of Prolene Hernia System increases the risk of injury and makes treatment more difficult: "the multi-layer polypropylene mesh occupied two inguinal compartments instead of one, increasing the intense inflammatory and chronic foreign body response; . . . When an implanted Prolene Hernia System fails, the complications are harder to treat. Further, its eventual explantation results in large amounts of tissue loss due to the Prolene Hernia System's occupying of two inguinal compartments." (See, e.g., id. at ¶¶ 32-33).

Plaintiffs' application thus ignores their own misguided characterization of these products, but also glosses over the fact that all three of the products at issue were introduced at different times over the course of over a decade. Prolene Hernia System was introduced in 1997; Proceed Surgical Mesh was introduced in 2004; and Proceed Ventral Patch in 2008. The information available to Ethicon and surgeons at each of those times was different, a consideration that directly impacts issues such as design defect, adequacy of warnings, and the application of the learned intermediary doctrine.

The different histories of the products also mean that there will likely be significant variations in the witnesses having relevant knowledge regarding the products. Witnesses involved in the development of Prolene Hernia System prior to its launch in 1997 would be different from those involved with Proceed Surgical Mesh and Proceed Ventral Patch products introduced 7 and 11 years later. The likelihood of having different witnesses is vastly increased by the fact the different products were produced in different countries.

It is important to consider the nature, composition, history, and development of these particular products alongside the specific allegations raised by Plaintiffs, which make clear that MCL designation is inappropriate under these circumstances.

ARGUMENT

I. The Court Should Deny Plaintiffs' Application Because the Cases Do Not Meet the Criteria for an MCL Designation.

The Court should deny Plaintiffs' application to establish an MCL for any or all of the three hernia mesh products included in their application and permit the cases to proceed individually in their current venue, which has the judicial resources and support staff to handle these actions. Creating an MCL under these circumstances would lead to a flood of litigation by foreign plaintiffs raising meritless claims and seeking to take advantage of New Jersey's centralized litigation process; it would not further the goals and policy of Rule 4:38A and AOC Directive #08-12.

In determining whether centralization of cases is warranted, the Court applies the factors contained in AOC Directive #08-12. Specifically, they include whether the cases possess, among other things, the following characteristics: Many claims with common recurrent issues of law and fact "that are associated with **a single product**"; a large number of parties; and a high degree of commonality among injuries or damages among plaintiffs. See AOC Directive #08-12, at 1-2 (emphasis added). The Court also should consider administrative factors including, but not limited to: whether there is a risk that centralization will unreasonably delay the progress, increase the expense, or complicate the processing of any action; whether centralized management is fair and convenient to the parties, witnesses, and counsel; whether coordinated discovery would be advantageous; and whether there are related matters pending in federal court or in other state courts that require coordination with a single New Jersey judge. Id.

Here, the administrative factors are particularly relevant to the determination that MCL designation is unwarranted for these products. Unlike Physiomesh, there are no federal court MDLs involving these products, and Plaintiffs have not demonstrated that there are a significant number of cases that are being filed across the country which would, in turn, support the position that there is a legitimate need for an MCL in New Jersey. There is also a significant risk that centralization will unreasonably delay the progress and complicate the processing of these actions that are currently pending in the Superior Court. Accordingly, the administrative factors are not met.

In addition, there are distinct issues of law and fact within and among the cases involving these different products that make an MCL inappropriate. Specifically, as noted above, different doctors use each mesh product differently, and for different purposes with respect to their overall treatment of hernias. As such, each individual case is uniquely different from another case, despite the fact that they may involve the same product.

Moreover, the creation of the proposed MCL would attract meritless cases. The Proceed Surgical Mesh, Proceed Ventral Patch, and Prolene Hernia Mesh products are proven products that have been on the market for many years, remain on the market, and are recommended and implanted by physicians to this day. The reality is that all hernia repair surgeries, including those using mesh, can lead to complications. The mere fact that there are patients with these devices that have experienced complications does not establish that these devices are defective. Indeed, like all widely sold medical products used to treat medical conditions, patients can experience complications in the absence of any defect in the product.

Rather than advertising for Physiomesh products only, the subject of the federal MDL, Plaintiffs' attorneys across the country have cast a wide net, publishing general advertisements related to "Hernia Mesh" or "Hernia Surgical Mesh." In all

likelihood, clients responded who may have thought they had Physiomesh but who, in fact, received other products. Alternatively, due to the vague and general use of the term "hernia mesh," the lawyers received inquiries from anyone who was ever implanted with hernia mesh. Thus, the allegations involving these cases are highly attenuated.

The following are samples of advertisements posted on publicly available social media pages that depict Plaintiffs' counsel's conduct in using broad language to attract plaintiffs with meritless claims:[5]

[5] See https://www.facebook.com/pages/category/Lawyer---Law-Firm/Hernia-Mesh-Defects-374846209633625/.

It is evident that mere creation of an MCL will attract more complaints by plaintiffs nationwide seeking to take advantage of litigating in an MCL, which allows plaintiffs and their counsel to "park" cases with no factual or legal basis for recovery and do little to no work on those cases, in hopes of collecting from a global settlement in the future. In fact, there is evidence of a very concerning and growing trend of litigation funding companies and marketing firms targeting individuals treating with medical devices to lure them into undergoing unnecessary surgery so that those individuals will be more lucrative Plaintiffs in a coordinated MCL or MDL against medical device companies.[6]

In the Accutane litigation, this State saw firsthand how the establishment of an MCL can result in a flood of meritless claims. After the creation of the Accutane MCL, there was a significant increase in the number of cases filed, growing to approximately 7,800 cases. However, nearly all of those cases were either dismissed via dispositive motions or voluntarily dismissed by the plaintiffs. The same will hold true here in the event an MCL is created and a wave of copycat Plaintiffs file baseless lawsuits without any legally cognizable injuries.

Similarly, jurisdictions across the country have experienced the same outcomes when they establish a centralized management or multidistrict litigation. For example, in the Baycol litigation, initially there were a moderate number of cases alleging that the medication caused patients a higher risk of rhabdomyolysis. After the MDL was established in the United States District Court for the District of Minnesota, tens of thousands of cases were filed, alleging complications other than rhabdomyolysis that clogged the courts. Ultimately, the parties resolved only the cases involving rhabdomyolysis.

Additionally, after the Chinese-manufactured drywall products liability MDL was created, plaintiffs started bringing lawsuits against American drywall manufacturers, making similar arguments. Plaintiffs bringing claims against American drywall manufacturers sought centralization of four actions pursuant to 28 U.S.C. § 1407. There, Plaintiffs' motion promised "thousands" of cases. The United States Judicial Panel on Multidistrict Litigation denied the plaintiffs' motion, finding that the plaintiffs "have not convinced us that any efficiencies would outweigh the multiple individualized issues, including ones of liability and causation, that these actions appear to present." (Ex. J: Order Denying Transfer, In re: American-Manufactured Drywall Prod. Liab. Litig., June 8, 2010). After the denial, no meaningful litigation developed.[7]

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[6] See, e.g., Matthew Goldstein, How Profiteers Lure Women into Often-Unneeded Surgery, N.Y. Times, Apr. 14, 2018, available at https://www.nytimes.com/2018/04/14/business/vaginal-mesh-surgery-lawsuits-financing.html.

[7] In addition, many lawsuits filed after an MDL is established are later subject to dismissal on procedural grounds for failing to provide fundamental information about the plaintiffs' claims. For example, in the Abilify MDL, hundreds of plaintiffs who filed lawsuits after the establishment of the

In sum, establishing an MCL here for these hernia mesh products that are still on the market will result in a flood of litigation that will unreasonably delay the progress and complicate the processing of the actions already pending in the Superior Court. This is not only bad for Defendants headquartered in this State, but it is also very harmful to the Court system because of the time and expense of an MCL, including the toll on New Jersey citizens forced to sit on juries in cases involving out-of-state plaintiffs. Accutane, Baycol, and the Drywall litigations are just some examples that demonstrate how significant judicial resources will be expended to resolve baseless lawsuits filed solely because the opportunity was provided through an MCL or MDL. Here, there is no need to upend the current state of the litigation. There are only a few firms representing Plaintiffs and the parties will be able to work well together regarding these actions. Accordingly, Plaintiffs' application should be denied.

II. In the Alternative, Any MCL Created Should be Limited to Cases Involving Proceed Surgical Mesh and Proceed Ventral Patch Products.

In the event the Court is inclined to establish another MCL – which it should not – the resulting MCL should be limited to cases involving Proceed Surgical Mesh and Proceed Ventral Patch products. It should not include the Prolene Hernia System.

As set forth in detail above, there are significant differences between all three products, which become even more significant when comparing the Proceed products with the Prolene Hernia System. Most notably, unlike the Proceed products, the Prolene Hernia System is not multi-layered, it is not absorbable and is typically used for inguinal repairs. Plaintiffs also claim that components found in both Proceed products, but not the Prolene Hernia System, such as Oxidized Regenerated Cellulose, render those products uniquely more dangerous. Plaintiffs further allege that the unique design of the Prolene product makes it more unsafe than other products and that it increases the risk of injury and makes treatment more difficult. (See, e.g., Ex. I: Wilson Compl., at ¶¶ 31, 32). Moreover, the Proceed products were introduced more recently, within a few years of each other in 2004 and 2008, while the Prolene Hernia System was introduced more than 20 years ago in 1997.

Plaintiffs' application staunchly fails to satisfy the criteria for establishing an independent MCL for cases involving the Prolene Hernia System. Out of all of the complaints involving hernia mesh products referenced in Plaintiffs' application, cases involving the Prolene Hernia System make up less than 25% -- approximately 49 out of 205 cases. All of the other cases involve a Proceed product. (See Pls.' Ex. A: Case Listing). Moreover, the number of complaints filed involving the Prolene

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MDL failed to provide requested plaintiff profile forms. The forms requested basic information such as the plaintiff's date of birth, when they used the drug, and the name of their prescribing physician. See Nathan Hale, Drugmakers Aim to Bump Delinquent Plaintiffs in Abilify MDL, Law360, Jan. 16, 2019, available at https://www.law360.com/florida/articles/1119387/drugmakers-aim-to-bump-delinquent-plaintiffs-in-abilify-mdl

Hernia System has lagged behind the filings of cases involving the Proceed products, which supports rejecting the creation of an MCL for this particular product.

Plaintiffs indicated in their first MCL application in February 2018 that "several hundred more cases" will be filed with respect to Ethicon's hernia mesh products. Yet, that has not been true for cases involving the Prolene Hernia System. Indeed, in February 2018 there were 7 cases involving the Prolene Hernia System that were the subject of Plaintiffs' prior application. Almost one year later, only 42 additional cases have been filed – a far cry from the "several hundred" plaintiffs promised.

Moreover, the jurisdiction in which the Prolene Hernia System cases are currently venued has adequate staffing and judicial resources to handle the existing and potential case load for the relatively modest number of cases involving the Prolene Hernia System on an individual basis. Indeed, that is one of the stated reasons why the cases involving hernia mesh products were transferred to that vicinage. (See Ex. E: Transcript of Motion and Opinion, dated Sept. 28, 2018, at 36:22-37:2).

Therefore, while Defendants submit that the Court should not establish another MCL, in the event it is inclined to do so, it should be limited to cases involving the Proceed products only.

III. Potential MCL Venues

AOC and court rules set forth certain factors that should be considered in determining which venue an MCL should be assigned. Specifically, the MCL Guidelines and Criteria for Designation, as promulgated by Directive #08-12 and in accordance with Rule 4:38A, provide that "[i]ssues of fairness, geographical location of parties and attorneys, and the existing civil and multicounty litigation caseload in the vicinage" are factors to be considered in determining where to assign an MCL.

In making its determination between the three MCL venues available in New Jersey, the following should be taken into consideration:

- Atlantic County – As noted in Plaintiffs' application, the Physiomesh MCL is already pending in Atlantic County before Judge Porto. In the event another MCL is created, the Court and the parties would benefit from coordination with the Physiomesh MCL in this venue. In addition, Atlantic County has the least number of active MCLs pending at this time.

- Bergen County – Bergen County is a large vicinage in Northern New Jersey that has the judicial resources and staffing needed to handle an MCL. Plaintiffs intentionally sought out Bergen County with the intention that Judge Harz would preside over an MCL. Nevertheless, Judge Polifroni advised Plaintiffs that Bergen County was not the most suitable venue and Judge

Harz appropriately transferred all cases involving Ethicon's hernia mesh products to Middlesex County.

- Middlesex County – Middlesex County is currently home to the most active and complex MCLs pending at this time.

Defendants defer to the Court with respect to the location of an MCL – if one is created – and offer the above information to assist the Court in making its determination.

CONCLUSION

In conclusion, Defendants oppose the creation of any MCL for cases involving hernia mesh products other than Physiomesh. There is no question that creation of an MCL for these products would only serve to trigger the mass filing of baseless lawsuits by out-of-state litigants looking to take advantage of coordinated litigation that would drain the resources of the judiciary and the State. As such, this Court should deny Plaintiffs' request to establish an MCL for the Proceed Surgical Mesh, Proceed Ventral Patch, and Prolene Hernia System products. If, however, the Court is inclined to create another MCL, it should be limited to cases involving Proceed products (Proceed Surgical Mesh and Proceed Ventral Patch), as those products were conceived and designed within a few years of one another and are far more numerous than cases involving the Prolene Hernia System.

Respectfully submitted,

David R. Kott

cc: Joshua Kincannon, Esq. (via regular mail and email)
Kelsey Stokes, Esq. (via regular mail and email)
Adam Evans, Esq. (via regular mail and email)
Robert Price, Esq. (via regular mail and email)
Michael Daly, Esq. (via regular mail and email)
Tobias Millrood, Esq. (via regular mail and email)
James Barry, Esq. (via regular mail and email)
Robert Kinsman, Esq. (via regular mail and email)
Kelly S. Crawford, Esq. (via email)

EXHIBIT A

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NJ ATTORNEY ID NUMBER 19831978

January 11, 2018

VIA REGULAR MAIL
Hon. Robert L. Polifroni, P.J. Cv.
Bergen County Superior Court
Bergen County Justice Center
10 Main St.
Hackensack, NJ 07601

Re: **In re Ethicon Hernia Mesh Litigation**

Dear Judge Polifroni:

Our office, in conjunction with several other firms, has filed 16 product liability cases in Bergen County against Ethicon, Inc. and Johnson & Johnson. The complaints assert that various hernia mesh products manufactured, marketed, and sold by these defendants are defective. All lawsuits involve the same defendants, and all involve the failure of one or more of their hernia mesh products. We anticipate filing well over one hundred such lawsuits in the near future.

To date, the 16 cases have been assigned to 9 different Judges: Judge Thurber (4 cases), Judge Perez-Friscia (3 cases), Judge O'Dwyer (3 cases), Judge DeLuca (1 case), Judge De La Cruz (1 case), Judge Farrington (1 case), Judge Powers (1 case), Judge Padovano (1 case), and Judge Harz (1 case). A list of the cases is attached. Defendants have filed timely answers on two of the 16 cases. Discovery has not yet begun.

Due to the nature and breadth of this litigation, we feel that it would be most efficient to schedule a case management conference with all counsel to discuss the consolidation of these cases for discovery or an MCL application.

I am sending a copy of this letter to defense counsel, and to all attorneys who have indicated they have or may be filing a similar claim. I am confident that all counsel will work together to efficiently and expeditiously handle these cases.

Your Honor's kind consideration of this request will be most appreciated.

Respectfully submitted,

ABBOTT S. BROWN, ESQ.

ASB/slm
Encl
cc: Hon. Estela M. De La Cruz (via regular mail w/encl)
Hon. James J. Deluca (via regular mail w/encl)
Hon. Christine A. Farrington (via regular mail w/encl)
Hon. Rachelle L. Harz (via regular mail w/encl)
Hon. John D. O'Dwyer (via regular mail w/encl)
Hon. Gregg A. Padovano (via regular mail w/encl)
Hon. Lisa Perez-Friscia (via regular mail w/encl)
Hon. Charles E. Powers (via regular mail w/encl)
Hon. Mary F. Thurber (via regular mail w/encl)
Kelly S. Crawford, Esq. (via regular mail w/encl)
Kelsey Stokes, Esq. (via electronic mail w/encl)
Adam Evans, Esq. (via electronic mail w/encl)
Robert Price, Esq. (via electronic mail w/encl)
Michael Daly, Esq. (via electronic mail w/encl)

PENDING ETHICON HERNIA MESH CASES - as of January 11, 2018

DOCKET NUMBER	PLAINTIFF	JUDGE
BER-L-7065-17	JASON COTTLE	JUDGE JAMES J. DELUCA
BER-L-7836-17	RICHARD BASSETT	JUDGE JOHN D. O'DWYER
BER-L-8037-17	ILENE GOLD	JUDGE JOHN D. O'DWYER
BER-L-8276-17	KENNETH NOAKES	JUDGE CHRISTINE A. FARRINGTON
BER-L-8572-17	SUSIE FOWLER	JUDGE RACHELLE L. HARZ
BER-L-8827-17	CHARLES GRIFFIN	JUDGE MARY F. THURBER
BER-L-8829-17	CHRISTINA LINNENBRINK	JUDGE MARY F. THURBER
BER-L-8998-17	CASSANDRA CAMPBELL	JUDGE LISA PEREZ-FRISCIA
BER-L-9127-17	MARVIN MARTIN	JUDGE MARY F. THURBER
BER-L-9130-17	JOHN RUIZ	JUDGE MARY F. THURBER
BER-L-9133-17	WALTER TREBOLO, JR.	JUDGE JOHN D. O'DWYER
BER-L-9151-17	BRENDA GATELEY	JUDGE ESTELA M. DE LA CRUZ
BER-L-184-18	SHONNA REDDING	JUDGE CHARLES E. POWERS
BER-L-197-18	MELISSA RICE	JUDGE LISA PEREZ-FRISCIA
BER-L-198-18	NORMAN BEAN	JUDGE LISA PEREZ-FRISCIA
BER-L-207-18	ALAN ALUMBAUGH	JUDGE GREGG A. PADOVANO

EXHIBIT B

COPY

McCARTER &ENGLISH
ATTORNEYS AT LAW

January 26, 2018

VIA HAND DELIVERY

Hon. Robert L. Polifroni, P.J. Cv.
Bergen County Superior Court
Bergen County Courthouse
10 Main Street, 3rd Floor Rotunda
Hackensack, NJ 07601

Re: Ethicon Hernia Mesh Litigation

Dear Judge Polifroni:

David R. Kott
Partner
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WASHINGTON, DC

This Firm, along with our co-counsel Riker Danzig Scherer Hyland & Perretti LLP and Butler Snow LLP, represent Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter collectively "Ethicon") in sixteen recently filed actions in Bergen County related to hernia mesh products.[1] We are in receipt of plaintiffs' counsel, Abbot S. Brown, Esq.'s letter to the Court requesting a case management conference with all counsel involved in these actions. We write to clarify and respond to some of the statements contained in that letter.

Ethicon manufactures more than a dozen different mesh products indicated for the treatment of hernia. Plaintiffs implicitly suggest that any case involving any hernia mesh product manufactured by Ethicon would be appropriate for consolidation. However, there are many important differences among these products, including differences in design, materials, method of manufacture, place of manufacture, and indications. The products were developed, and manufactured at different times and different locations over decades. Indeed, plaintiffs acknowledge that the sixteen filed cases involve at least three distinct hernia mesh products. Some of the cases assert claims related to Ethicon Physiomesh™ (which was withdrawn from the market in 2016), whereas the majority of the other cases involve claims related to different products, namely the Proceed Ventral Patch and Proceed (which are currently marketed). Both on discovery and the merits, there will not be sufficient common factual and legal issues arising out of the same series of occurrences required for consolidation.

Specifically, it would be wholly improper under New Jersey law and Rule 4:38-1, as well as Rule 4:38A and Directive #08-12, to consolidate cases involving different hernia mesh products, i.e. non-Physiomesh™ and Physiomesh™ cases. Accordingly, Ethicon objects to any attempt by plaintiffs to consolidate all cases involving any Ethicon hernia mesh product, and will oppose any application seeking such relief. Similarly, it would also be improper under New Jersey law and the Court

[1] While not changing our analysis, for completeness there are other additional cases not referenced in Plaintiffs' letter. Two cases are venued in Bergen County, and one of the plaintiffs in those cases is from Essex County and the other is an out of state plaintiff. There are five other cases pending in Monmouth County, Middlesex County, Atlantic County (2) and Ocean County. Of those seven cases, three are Physiomesh.

Rules to consolidate all of the cases involving the various non-Physiomesh™ products, and Ethicon likewise will object to and oppose any such application as well.

With respect to the cases involving Ethicon Physiomesh™ products, we do not believe consolidation or an MCL application is ripe for discussion. To date, only two of the cases referred to by Mr. Brown in his letter have been filed alleging claims involving an Ethicon Physiomesh™ product: Martin v. Ethicon, Inc. et al., Docket No. BER-L-9127-17 and Ruiz v. Ethicon, Inc., et al., Docket No. BER-L-9128-17. Both of those cases are pending before Judge Thurber. Respectfully, we do not believe that the filing of these two cases warrants a discussion of an MCL application at this time. Indeed, it is inconceivable that the Supreme Court would grant an MCL application based on the filing of two cases.

Moreover, plaintiffs' counsel's request is also premature because Ethicon is still in the process of reviewing the various Complaints filed in these actions to determine whether venue is proper in Bergen County, or whether venue would be more convenient in another New Jersey vicinage. In fact, not a single plaintiff in any of the sixteen filed actions is a resident of Bergen County; indeed, not a single plaintiff is a resident of New Jersey. It is likely that the issues related to venue could be the subject of a motion in the near future. Accordingly, it would be inefficient to engage in consolidation discussions regarding cases that could be transferred to a different venue.

We will be prepared to discuss these matters with Your Honor in the event that Your Honor decides to conduct a conference. Please do not hesitate to contact us if the Court has any questions.

Respectfully submitted,

David R. Kott

cc: Hon. Estela M. De La Cruz (via regular mail)
Hon. James J. Deluca (via regular mail)
Hon. Christine A. Farrington (via regular mail)
Hon. Rachelle L. Harz (via regular mail)
Hon. John D. O'Dwyer (via regular mail)
Hon. Gregg A. Padovano (via regular mail)
Hon. Lisa Perez-Friscia (via regular mail)
Hon. Charles E. Powers (via regular mail)
Hon. Mary F. Thurber (via regular mail)
Abbott S. Brown, Esq. (via regular mail and email)
Kelsey Stokes, Esq. (via regular mail and email)
Adam Evans, Esq. (via regular mail and email)
Robert Price, Esq. (via regular mail and email)
Michael Daly, Esq. (via regular mail and email)

EXHIBIT C

SUPERIOR COURT OF NEW JERSEY

ROBERT L. POLIFRONI, P.J.Cv.
CIVIL DIVISION

BERGEN COUNTY JUSTICE CENTER
10 MAIN STREET
HACKENSACK, NEW JERSEY 07601-7689
(201) 527-2690

January 25, 2018

Abbott S. Brown, Esq.
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Freehold, NJ 07728

RE: Ethicon Hernia Mesh Litigation

Dear Mr. Brown:

This will acknowledge receipt of your correspondence dated January 11, 2018.

As counsel are aware, the New Jersey Supreme Court has developed a specific procedure regarding the type of cases you describe. Specifically, at the earliest available opportunity, counsel are to seek to have the matters designated as Multi-County Litigation (MCL). It appears counsel acknowledge the issues at the heart of the litigation are best handled by one judge, in one county. However, that goal will not be achieved informally.

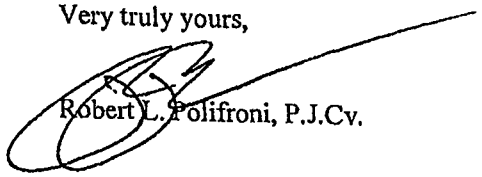
You request a "global" case management conference to discuss the consolidation of these matters for discovery or an MCL application. Respectfully, counsel's only option is the latter. Decisions by counsel to select a county of venue, and then request to have the matters consolidated and handled by one judge outside the MCL format, will not be validated by this court. Indeed, unless the individual plaintiffs live in Bergen County, it seems reasonable the most convenient venue would be the corporate location of the defendants, which appears to be outside Bergen County.

Respectfully, the court will not accommodate counsel's efforts to secure case management by one designated judge in one particular county without seeking an MCL designation in situations where such designation is clearly appropriate. There is no need to conduct a case management conference. Therefore, your request is denied. The cases will be handled by the individual judges assigned via the standard docket number system, pending any Supreme Court decision on an MCL designation.

This letter does not serve to comment on the discretion of the Assignment Judge to address issues involving venue, either via a conference or sua sponte.

Please be guided accordingly.

Very truly yours,



Robert L. Polifroni, P.J.Cv.

RLP/len

cc: Hon. Bonnie J. Mizdol, A.J.S.C.
Hon. Estela M. De La Cruz, J.S.C.
Hon. James J. DeLuca, J.S.C.
Hon. Christine A. Farrington, J.S.C.
Hon. Rachelle L. Harz, J.S.C.
Hon. John D. O'Dwyer, J.S.C.
Hon. Gregg A. Padovano, J.S.C.
Hon. Lisa Perez Friscia, J.S.C.
Hon. Charles E. Powers, Jr., J.S.C.
Hon. Mary F. Thurber, J.S.C.
Kathleen Stylianou, Civil Division Manager
Kelly S. Crawford, Esq.
Kelsey Stokes, Esq.
Adam Evans, Esq.
Robert Price, Esq.
Michael Daly, Esq.

EXHIBIT D

NOTICE TO THE BAR

MULTICOUNTY LITIGATION – PHYSIOMESH FLEXIBLE COMPOSITE MESH LITIGATION

A previous Notice to the Bar requested comments on an application for multicounty litigation (MCL) designation of New Jersey state-court litigation alleging injuries resulting from use of certain hernia mesh products. This Notice is to advise that the Supreme Court, after considering the application and the comments received, has determined to designate only the cases involving allegations of injuries from use of **Physiomesh Flexible Composite Mesh** as multicounty litigation. The Court has assigned this MCL to Atlantic County for centralized case management by Superior Court Judge Nelson C. Johnson.

Published with this Notice is the Supreme Court's July 17, 2018 Order. This Order is posted in the Multicounty Litigation Center http://www.njcourts.gov/attorneys/mcl/index/html on the Judiciary's website (www.njcourts.gov). Judge Johnson's Initial Case Management Order will be posted in the Multicounty Litigation Center once issued.

Questions concerning this matter may be directed to Taironda E. Phoenix, Esq., Assistant Director for Civil Practice, Administrative Office of the Courts, Hughes Justice Complex, P. O. Box 981, Trenton, New Jersey 08625-0981; telephone: (609) 815-2900 ext. 54901; e-mail address: taironda.phoenix@njcourts.gov.

Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts

Dated: August 15, 2018

SUPREME COURT OF NEW JERSEY

On application made pursuant to Rule 4:38A and the Multicounty Litigation Guidelines promulgated by Directive # 08-12 in accordance with that Rule, it is hereby ORDERED that all pending and future New Jersey state court actions against Johnson & Johnson and Ethicon, Inc., alleging injuries as a result of use of Physiomesh Flexible Composite Mesh be designated as multicounty litigation ("MCL") for centralized management purposes; and

It is FURTHER ORDERED that any and all such complaints that have been filed in the various counties and that are under or are awaiting case management and/or discovery shall be transferred from the county of venue to the Superior Court, Law Division, Atlantic County and that, pursuant to N.J. Const. (1947), Art.VI, sec.2, par.3, the provisions of Rule 4:3-2 governing venue in the Superior Court are supplemented and relaxed so that all future such complaints, no matter where they might be venued, shall be filed in Atlantic County; and

It is FURTHER ORDERED that Superior Court Judge Nelson C. Johnson shall oversee management and trial issues for such cases and may, in his discretion, return such cases to the original county of venue for disposition, and

It is FURTHER ORDERED that no Mediator or Master may be appointed in this litigation without the express prior approval of the Chief Justice.

For the Court

Chief Justice

Dated: July 17, 2018

Civil

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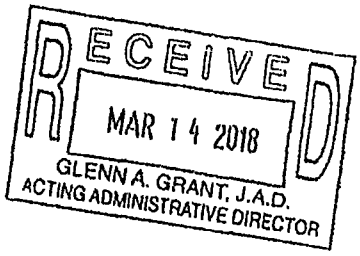
February 28, 2018



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 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 cases[2] 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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ADAM EVANS, ESQ.

[2] Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Dollaumeyer 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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ROBERT L. KINSMAN, ESQ.

LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 35202
rprice@levinlaw.com

ROBERT E. PRICE, ESQ.

JSK/slm
Encl
Cc: Kelly S. Crawford, Esq. (via regular mail)
David R. Kott, Esq. (via regular mail)
G. Brian Jackson, Esq. (via regular mail)
Fred E. Bourn, III, Esq. (via regular mail)

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EXHIBIT A

Plaintiff	Docket No.	Assigned Judge	Firm
Aaron, Daniel	BER-L-870-18	Rachelle L. Harz	Locks Law Firm
Adams, Donna	BER-L-728-18	Mary F. Thurber	Hollis Law Firm/Lomurro Law Firm
Alexander, Diane	BER-L-1241-18	Robert C. Wilson	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Alumbaugh, Alan	BER-L-207-18	Gregg A. Padovano	Hollis Law Firm/Lomurro Law Firm
Alvarado, Danny	BER-L-1479-18	Christine A. Farrington	Lomurro Law Firm
Anawaty, Viola	BER-L-1516-18	Walter F. Skrod	Hollis Law Firm/Lomurro Law Firm
Bassett, Richard	BER-L-7836-17	John D. O'Dwyer	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Bean, Norman	BER-L-198-18	Lisa Perez-Friscia	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Campbell, Cassandra	BER-L-8998-17	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Capshaw, Clifton	BER-L-1530-18	Mary F. Thurber	Krause & Kinsman/Lomurro Law Firm
Clark, Jeneen	BER-L-691-18	Charles E. Powers	Hollis Law Firm/Lomurro Law Firm
Cottle, Jason	BER-L-7065-17	James J. DeLuca	Hollis Law Firm/Lomurro Law Firm
Crossland, Stephanie	BER-L-729-18	Mary F. Thurber	Hollis Law Firm/Lomurro Law Firm
Denney, Robert	BER-L-732-18	John D. O'Dwyer	Hollis Law Firm/Lomurro Law Firm
Dias, Alexsandro	BER-L-1471-18	Rachelle L. Harz	Hollis Law Firm/Lomurro Law Firm
Diloreto, Edward	BER-L-1018-18	Walter F. Skrod	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Dollanmeyer, Terry	BER-L-774-18	Rachelle L. Harz	Hollis Law Firm/Lomurro Law Firm
Fielding, Chad	BER-L-693-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Fontenot, Emily	BER-L-1513-18	Gregg A. Padovano	Hollis Law Firm/Lomurro Law Firm
Fowler, Susie	BER-L-8572-17	Rachelle L. Harz	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Gaddis, Troy	BER-L-658-18	James J. DeLuca	Hollis Law Firm & Holman Schiavone/Lomurro Law Firm
Galvez, Michael	BER-L-1393-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Gateley, Brenda	BER-L-9151-17	Estela M. De La Cruz	Hollis Law Firm/Lomurro Law Firm
Gibson, Renee	BER-L-1110-18	Gregg A. Padovano	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Gold, Ilene	BER-L-8037-17	John D. O'Dwyer	Pogust, Braslow & Millrood
Griffin, Charles	BER-L-8827-17	Mary F. Thurber	Hollis Law Firm/Lomurro Law Firm
Hart, Dennis	BER-L-1349-18	Estela M. De La Cruz	Hollis Law Firm/Lomurro Law Firm
Hollimon, Thomas	BER-L-694-17	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Jarrell, Sara	BER-L-775-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Jennings, Jerry	BER-L-777-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Johnson, Steven	BER-L-778-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Kennedy, Bryan	BER-L-779-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Krampen-Yerry, Denise	BER-L-1466-18	James J. DeLuca	Krause & Kinsman/Lomurro Law Firm
Lang, Christine	BER-L-1067-18	Rachelle L. Harz	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Lindly, James	BER-L-1402-18	Robert L. Polifroni	Krause & Kinsman/Lomurro Law Firm
Linnenbrink, Christina	BER-L-8829-17	Mary F. Thurber	Hollis Law Firm/Lomurro Law Firm
Lotridge, Robin	BER-L-1467-18	Rachelle L. Harz	Hollis Law Firm/Lomurro Law Firm
Maestas, Joseph	BER-L-1456-18	Estela M. De La Cruz	Hollis Law Firm/Lomurro Law Firm
Martin, Marvin	BER-L-9127-17	Mary F. Thurber	Ogborn Mihm, LLP/Lomurro Law Firm
McKinney, Earl	BER-L-780-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm

Miller, Tracee	BER-L-695-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Moore, Tammy	BER-L-697-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Morgan, Karrie	BER-L-781-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Mountjoy, James	BER-L-1480-18	Christine A. Farrington	Lomurro Law Firm
Noakes, Kenneth	BER-L-8276-17	Christine A. Farrington	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Pikulsky, Jamie Pikulsky, Jeffrey	BER-L-1052-18	Estela M. De La Cruz	Levin Law/Lomurro Law Firm
Redding, Shonna	BER-L-184-18	Charles E. Powers	Hollis Law Firm/Lomurro Law Firm
Reynolds, Burton	BER-L-279-18	Christine A. Farrington	Hollis Law Firm/Lomurro Law Firm
Rice, Melissa	BER-L-197-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Robins, Janice	BER-L-809-18	Gregg A. Padovano	Hollis Law Firm/Lomurro Law Firm
Rodriguez, Kelly	BER-L-699-18	Lisa Perez-Friscia	Hollis Law Firm/Lomurro Law Firm
Ruiz, John	BER-L-9130-17	Mary F. Thurber	Hollis Law Firm/Lomurro Law Firm
Schaeffer, Elena	BER-L-914-18	Walter F. Skrod	Hollis Law Firm/Lomurro Law Firm
Schriner, Yesenia	BER-L-1222-18	Walter F. Skrod	Hollis Law Firm/Lomurro Law Firm
Senkel, William	BER-L-1433-18	John D. O'Dwyer	Hollis Law Firm/Lomurro Law Firm
Shackelford, Cecelia	BER-L-1200-18	Lisa Perez-Friscia	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Smith, Diane	BER-L-652-18	Estela M. De La Cruz	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Sollis, Jamie	BER-L-703-18	Robert L. Polifroni	Hollis Law Firm/Lomurro Law Firm
Szaroleta, Christopher	BER-L-1458-18	James J. DeLuca	Hollis Law Firm/Lomurro Law Firm
Trebolo, Jr., Walter	BER-L-9133-17	John D. O'Dwyer	Hollis Law Firm/Lomurro Law Firm
Usey, Christina	BER-L-1244-18	Robert C. Wilson	Fleming, Nolen & Jez, LLP/Lomurro Law Firm
Westerbeck, Mike	BER-L-733-18	John D. O'Dwyer	Hollis Law Firm/Lomurro Law Firm

EXHIBIT E

SUPERIOR COURT OF NEW JERSEY
BERGEN COUNTY
LAW DIVISION, CIVIL PART
DOCKET NO. BER-L-8037-17
APP. DIV. NO.

ILENE GOLD, ET AL.

Plaintiff,

vs.

JOHNSON & JOHNSON AND ETHICON,

Defendants.

TRANSCRIPT
of
MOTION

Place: Bergen Co. Courthouse
10 Main Street
Hackensack, NJ 07601

Date: September 28, 2018

BEFORE:

HONORABLE RACHELLE LEA HARZ, J.S.C.

TRANSCRIPT ORDERED BY:

DAVID R. KOTT, ESQ. (McCarter & English, LLP., 100 Mulberry Street, Four Gateway Center, PO Box 652, Newark, New Jersey 07102)

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THE COURT: This is BER-L-8037-17, we just have it under, HERNIA MESH VS. ETHICON AND JOHNSON & JOHNSON. Fair statement, that's how the caption should read right now?
MR. KINCANNON: The caption -- I think we filed -- well, there are -- there are 109 of these motions.
THE COURT: Right.
MR. KINCANNON: The first one filed was COTTLE (phonetic).
THE COURT: Uh-huh.
MR. KINCANNON: That's the first filed case. So, that's what we had done and look to file our omnibus objection under. We ended up filing it under all of them. So, I know it's --
THE COURT: Okay. But for purposes of today we'll use Docket Number 8037-17, but every one understands what it encompasses.
MR. KINCANNON: Perfect. Thank you, Your Honor.
THE COURT: Okay. Thank you. So, let's have appearances by plaintiff's counsel.
MR. KINCANNON: Good morning, Your Honor. I'm Josh Kincannon from the Lomurro law firm.
MR. BARRY: James Barry, Your Honor, from the

Locks law firm.
MR. KOTT: David Kott, K-O-T-T, from McCarter and English, LLP.
MS. CRAWFORD: Kelly Crawford, Riker, Danzig, Scherer, Hyland, and Perretti also for the defendant.
THE COURT: Thank you. Does anyone else here wish to put their appearances on the record?
MS. STOKES: Yes, Your Honor. My name is Kelsey Stokes from Fleming, Nolen, and Jez out of Houston.
MR. EVANS: Adam Evans from the Hollis law firm out in Prairie Village, Kansas.
THE COURT: From where?
MR. EVANS: Prairie Village, Kansas.
THE COURT: Wow. How did you get here? It was a long way.
MR. EVANS: United.
MS. PATERSON: Good morning, Your Honor. Jean Patterson from McCarter English.
THE COURT: Hi. How are you?
MR. ROJAO: Good morning Your Honor. Chris Rojao from McCarter and English.
THE COURT: Thank you. Anyone else? I have read all the papers and I've -- I've thoroughly read them and thought about this issue. I think it's

important to state that I am acting today as Judge Mizdol's -- Mizdol's designee.

Judge Mizdol signed an order on September 24th, 2018 indicating this matter having been open to the court by defendant seeking change of venue from Bergen County to Somerset County. And upon notice to plaintiffs pursuant to Rule 4:3-3(a) and for good cause shown it's on this 24th day of September, 2018 order the Honorable Rachelle Lea Harz, J.S.C. is hereby appointed designee of the assignment judge to hear and determine the application for change of venue in accordance with Rule 4:3-3(a) signed by the Honorable Bonnie J. Mizdol assignment judge of the Superior Court here in Bergen County.

So, I sit here with unique (Indiscernible) privileged rare opportunity to hear a motion to change venue as the assignment judge.

Before we start oral argument, and I recognize it's the motion of defense counsel, can I just ask plaintiff's counsel, after having read all your papers, it would appear as though your position is that any county in New Jersey would be appropriate. Because based upon your understanding of the law and the court rules since Ethicon does business, according to your definition of doing business, in every county

then you could file these cases in Cape May. You could file it any county in New Jersey. If I understand the premise of your argument.

MR. KINCANNON: Yes. Your Honor, looking at the venue rule on the rule about where they're actually conducting business if we look at that and look at these defendants and try and analyze whether they're actually doing business in any of these counties sufficient to satisfy that -- that phrase in the venue rule, I think it's manifest that they are.

And I think we can touch on the policy of that, right, the reason that it says that you have to actually being doing business there is so that the defendant has some reasonable foreseeability that if they make those contacts with that venue that it's foreseeable that they may be hailed into court there.

THE COURT: Isn't that a jurisdictional argument that you just made?

MR. KINCANNON: Well, --

THE COURT: You know, hailing into court, contacts, that -- that's -- that's a jurisdictional motion.

MR. KINCANNON: But generally speaking with regard to the phrase, actually doing business there, cases cited by defendant, CREPY, BUCKLU (phonetic), and

others, describe the reason behind saying, actually doing business there, as opposed to just principle place of business. And that's because if they are doing business there, it's reasonable to expect that they may be hailed into the court there.

So, for venue purposes we laid venue here because these are giant companies that do business throughout the State of New Jersey. Venue is proper here. This is a Fortune 500 company with 250 subsidiaries. They sell products all over the world, all over the country, all over the State, and in Bergen County. Ethicon sells 440 different medical devices. They sell them in New Jersey. They sell them in Bergen County. Bergen County is the most populist county in the State. We have the largest hospital in the State here.

Johnson & Johnson makes band-aids and Tylenol. There's no -- if you look at their papers, nowhere in their papers does the following sentence exist, Johnson & Johnson and Ethicon do not do business in Bergen County.

THE COURT: But they conceded that.

MR. KINCANNON: So, if they're doing business here, then venue is proper here.

THE COURT: But so, an answer to my question

venue could be proper anywhere in the State of New Jersey.

MR. KINCANNON: I would think so. Yes, Your Honor.

THE COURT: So, -- okay. So, then you chose Bergen County, and I thank you for the compliment, you -- you indicated in your papers that I had handled pelvic mesh and you thought that I personally had familiarity with the product and, therefore, it seemed like a good fit.

MR. KINCANNON: Well, Your Honor, correct. We get to pick -- the State -- we pick -- well, the court picks the State really. The defendant's location where we can sue or we could sue in federal court as a one-off in plaintiff's home jurisdiction.

If we look at that, I think it answers your question in part. If we bring -- if a one-off case in a federal court, we're now forced with litigating this entire thing along and educating a judiciary that probably has no experience with polypropylene pelvic mesh --

THE COURT: You lost me on that. Why would you just bring one case in federal court?

MR. KINCANNON: Well, I'm saying we have plaintiffs from out-of-state. So, those plaintiffs

they have two choices.
THE COURT: Oh, oh, so --
MR. KINCANNON: You can file in defendant's backyard here in New Jersey or we could file in federal court, but federal court really is not practically availing. And especially in light of what's really the elephant --
THE COURT: Ok-- okay. I understand now. Okay. Because there's no MDL for these products.
MR. KINCANNON: That's correct.
THE COURT: Okay.
MR. KINCANNON: And so, I think we would be remiss to ignore the fact that this Court has handled polypropylene pelvic mesh cases against these same defendants for years. It's a different product, but there is substantial overlap. This is extruded woven polyethylene mesh that is put into the abdomen, that's what this mesh is.
We would be remiss as attorneys if we did not consider the fact that this Court and Your Honor is probably one of the top five courts in the entire world in terms of the knowledge of polypropylene pelvic mesh and these two defendants.
So, bringing it here in Bergen recognizes the tremendous convenience and efficiencies that will be

achieved by being here.
THE COURT: But that same argument was rejected by Judge Grant and he gave physiomesh to Atlantic. I mean, I understand what you are saying, but that's not how venue is picked or how selection of counties are picked. I mean, that, in essence, is almost like judge shopping.
Because -- well, let's look at a perfect example Judge Higby (phonetic) at pelvic mesh in Atlantic County, right, and she was extraordinarily knowledgeable about pelvic mesh. She was elevated to Appellate Division and then all those cases came Judge Martinotti who nothing about pelvic mesh. And then he had it for two years and then he went to the federal court and then I took over the docket and at the time I knew nothing about pelvic mesh.
So, while I understand you're indicating the Court has this knowledge that is not a factor in determining where cases go because where judges go is a moving element and there's no guarantee that a judge won't be transferred to a different county, or have a different assignment, or retire for that matter, or go to the Appellate Division, or go to federal court.
So, while that's an understandable idea in practicality it doesn't work that way, but that's not

how cases are assigned or designated. That's not how venue is chosen or how it -- an MCL assignment is chosen.

MR. KINCANNON: I understand. And I agree Your Honor, but I believe that if they do business, as -- as we've talked about earlier, in every county in New Jersey, then plaintiff is permitted to choose and plaintiff is permitted some modicum of deference in their choice and if we agree that they can be brought in any county, this was plaintiff's choice. And so, they do business here, venue is proper, there is no viable argument of inconvenience.

Let's look at the other alternative, right, they would have you send this to Somerset. That's forum shopping, Your Honor. That would be sending us to a court that would -- it would create a substantial amount of delay. And the convenience that they allude to it's really kind of a red herring.

They talk about documents and witnesses being available there, but as a practical matter that's not how this plays out. No witnesses will be produced at the offices of Ethicon for plaintiff's counsel to depose. Depositions have been taken in the Ethicon hernia mesh litigation in the MDL the same witnesses we'll seek to depose. None of those depositions

occurred in Somerset County.

THE COURT: Are you involved in the MDL?

MR. KINCANNON: I am not involved in the MDL. We have a cases -- I lost my train of thought.

THE COURT: I'm sorry.

MR. KINCANNON: That's okay. About Somerset County --

THE COURT: You were talking about the convenience.

MR. KINCANNON: Oh, --

THE COURT: The convenience factors.

MR. KINCANNON: -- the convenience, right. So, the convenience of the parties and the delay that would be inherent in the transfer of this that is a -- it's a judiciary that is not as sizeable or as used to complex administration as -- as this Court is. And -- and this Court has been able to resolve and move dockets along.

These are all things that we may consider, but the bottom line is that venue is proper here. And the alternative sending it to Somerset County, that's -- where they would have it, that's defendant's backyard. They've got 2,400 employees there. They've got untold thousands of people that tangentially derive a benefit from those defendants and those employees in

that county.
So, if venue --
THE COURT: So, you're concerned about the resources of -- of a particular county.
MR. KINCANNON: And -- and I'm concerned about the jury pool. And if venue is proper here and there's a court here that -- and defendants are presents litigating thousands of polypropylene pelvic mesh cases in this court currently, it just seems to us that it would be -- we wouldn't be doing our jobs if we didn't recognize that there is overlap with experts, with the discovery, with the protective order we're negotiating I'm working off the TBM protective order draft.
All of these things that have already been, in some cases, litigated before Your Honor and -- and we know defendants can live with them because they're moving forward under those orders. And we've -- are looking to see if we can live with them too. We can move this litigation very expeditiously because so much of the work has been done here already.
To reinvent that wheel is simply unnecessary because venue is proper here. And there's no real showing of inconvenience on the part of defendants.
THE COURT: Why don't I hear from the moving

party.
MR. KINCANNON: Thank you, Your Honor.
THE COURT: (Indiscernible).
MR. KOTT: Thank you, Your Honor. This our motion to transfer venue from Bergen to Somerset County. And I think there are three issues before the Court. The first issue, which I'll address first, is whether for the convenience of the parties venue should be transferred.
Here is what's in the record on that. And what I'm going to now give comes from the complaints filed by the plaintiffs.
None of the plaintiffs reside in Bergen County. Of the 109 motions that are pending 107 live in some other State. One plaintiff lives in Essex, one plaintiff lives in Monmouth. So, that's where the plaintiffs are from.
None of the events giving rise to the litigation occurred in Bergen County. There are no witnesses in Bergen County, there's no evidence in Bergen County. Plaintiffs acknowledge in the complaint that Ethicon is located in Somerset County and that the other defendant Johnson & Johnson is located in Middlesex County.
I recognize that the Court gives deference to

the plaintiff's choice. However, the Appellate Division has said as has the Supreme Court that when the plaintiffs are not from the county of venue, their choice of venue is entitled to less deference. And that's what the Supreme Court has said.

Plaintiffs in their papers rely on two cases. One is DI DONATO (phonetic), that's an Appellate Division decision where the Appellate Division actually granted leave to appeal on a motion to transfer venue. In DI DONATO the plaintiff was rendered a quadriplegic. He lived in Middlesex County.

THE COURT: He couldn't travel.

MR. KOTT: He couldn't travel.

THE COURT: I read that.

MR. KOTT: His -- his eyewitnesses -- eyewitnesses to the accident were from Bergen County. And the Court did all of the measuring and sent the Middlesex County quadriplegic to Camden County.

The other case the plaintiffs relies is OTINGER (phonetic), which is a decision of Judge Doin (phonetic), on a motion like this motion to transfer from Bergen to Somerset County. The defendants were in Somerset County. Judge Doin --

THE COURT: They were government officials.

MR. KOTT: They were. However, both in DI

DONATO and OTINGER the Court said that ordinarily and the Court will require is the venue be where the governmental agency is, but nevertheless we're going to go through the analysis of where it's convenient to be because we can choose to not follow that aspect of the court rule. So, both in DI DONATO and in OTINGER the Court went through the analysis and Judge Doin concluded that because the defendants were in Somerset the case should be litigated in Somerset.

Here is what the plaintiffs say. The plaintiffs say that it would be convenient to litigate here because it's close to major airports, because it's within the driving distance of both Ethicon and Somerset and J&J in Middlesex, and because Your Honor had the pelvic mesh MCL.

Ordinarily you decide a case and then it goes to the Appellate court and you get affirmed or reversed. This is unique, you already have the Supreme Court telling you what to do on this. And what I mean by that is those three arguments were exact arguments the plaintiffs made in their MCL designation under physiomesh MCL, close to the airports, driving distance to Somerset and Middlesex, we have a judge here who has extensive experience with mesh products and Ethicon. And the Supreme Court said, we're not going to assign

the cases to Bergen County.
The plaintiffs also do not address in their papers Judge Polifroni's January 25th, 2018 letter in which he noted that in his words, "the most convenient" venue for this -- these lawsuits is where the corporate defendants have their principle offices. And then he said, which is not in Bergen County. So, this Court should grant the motion to transfer to a more convenient venue.
Second issue, is venue proper? That's what the Court addressed to Mr. Kincannon in the opening colloquy. Court rule says plaintiffs can sue wherever somebody resides. Court rule says the corporate resides wherever it is, "actually doing business".
And we have the CREPY decision, and I may be mispronouncing it. But in CREPY the Court had a situation similar to this. Defendant is from Morris County, plaintiff sues in Essex County. The defendant actually has 332 sales calls in Essex County. The defendant actually has sales in Essex County. The defendant actually has advertising and marketing which enters Essex County. All of which Mr. Kincannon just said why we do business. And even accepting all of that as the CREPY court did, the CREPY court said that's not enough to impose venue.

I'm not sure that Your Honor needs to reach whether venue is proper because Your Honor can choose to transfer venue based on the inconvenience of venue and then not reach that issue. However, if Your Honor reaches it, CREPY is directly on point and venue is not proper here.
Finally, and I'm going to slow down a little, there's a --
THE COURT: No, I'm following. I'm good.
MR. KOTT: Well, no, because we're getting to something that's sensitive, the waiver argument. And I'll spend time on that. But let --
THE COURT: I don't think it's really necessary. I don't think you -- I mean, are you really pushing that? I mean, I'm aware of the time line of what occurred. I'm aware of Judge Polifroni's letter in January. I have -- I have it right here. I mean, they're on notice at that point. Counsel had conversations you thereafter have your consent order.
But regardless of anything you still kept filing in Bergen County. I mean, you're trying to argue that there's waiver for the nu-- for the cases prior to the consent order. I mean, in light of Judge Polifroni's order you knew January 25th, 2018 that venue wasn't guaranteed here.

MR. KINCANNON: I understand that Judge Polifroni wrote that in what I would consider kind -- that's not an order, that's not opinion, and it's not -- he's not basing it on any briefing or argument we've made to try and support Bergen County. That's -- we had asked him, how should we do this? Would you like us to consolidate, should we do an MCL? We wrote the letter saying, how would you like us to proceed and that was his response.

In terms of the ten-day waiver just as point of clarification. I didn't bring it up in my initial thing. I don't think that's where we're going to end up hanging our hat on this issue. But the fact of the matter is the venue rules say that if you want to transfer venue and object to plaintiff's pick, you have ten days do it after you answer. They didn't do that. Not once, not twice, they didn't do it 57 times they didn't do it, Your Honor.

And then after the fact then they came to us and said, hey, we're going to file motions for venue. And we said, well, these have all expired. And they said, well, there are newer ones that you've just filed that haven't expired yet. So, instead of us filing all of these motions to venue let's just enter into a consent order then we'll do the venue after the MCL.

And we agreed so that we wouldn't burden the Court with venue motions that might be moot.

THE COURT: But the -- if these cases are going to be moved as the acting assignment judge for this motion, I'm certainly not going to carve out the 57 cases you're referring to and then the remaining cases having to do with hernia mesh other than physiomesh go elsewhere. I mean, that's -- that's really impractical.

MR. KINCANNON: I agree and I -- I think that -- that's just another reason why the cases should stay in Bergen. Because under the rules 57 of these cases are not this -- this motion is not timely for them. And the word in the rule is, waived. They have waived the right to bring this motion in 57 of these cases.

THE COURT: But you're assuming that the presiding judge here and Judge Mizdol didn't notice that you filed the number that you filed involving these products here in Bergen County with no nexus to Bergen County. I mean, you're assuming that.

MR. KINCANNON: I'm not sure I understand -- what I'm doing is fi--

THE COURT: I mean, they at any time can sua -- Judge Mizdol sua sponte. And that is not related to this. Our assignment judge has had to do that where

plaintiff's counsel just filed cases in Bergen County and there's no nexus to Bergen County. And sua sponte --

MR. KINCANNON: Sure.

THE COURT: -- she has the power, makes the decision to transfer to the appropriate venue. So, you're -- you're argument has the premise that that would never have occurred. I mean, it was noticed that all these cases were being filed here by my (Indiscernible).

MR. KINCANNON: Right, but at that time many of their cases and the timeliness of their objection had already expired.

THE COURT: I understand that, but what I'm saying is --

MR. KINCANNON: Oh.

THE COURT: -- putting that aside you're argument assumes that Judge Mizdol would never have said, this venue isn't appropriate I'm not keeping these cases here in Bergen County.

MR. KINCANNON: I understand, Your Honor.

THE COURT: Right.

MR. KINCANNON: But our argument would be the same as it was at the beginning here, which is that if we were allowed to present our case to Judge Mizdol,

venue is proper and it's not inconvenient to the parties to litigate here.

That's the key here, venue is proper. When we say things like, no nexus to Bergen County --

THE COURT: There is no nexus to Bergen County. What's the nexus?

MR. KINCANNON: They do business here and that's the rule.

THE COURT: Well, the cases have no nexus here. None -- none of the plaintiffs are from Bergen County.

MR. KINCANNON: But the cases --

THE COURT: The implanting was not done here. The treatment was not done here. I mean, that's -- that's the nexus for the case.

MR. KINCANNON: But those -- but what the rule says is that if they're doing business here, we can get venue here.

THE COURT: Oh, I understand that --

MR. KINCANNON: And -- and -- I'm sorry, I just wanted to clarify that the exact thing that we're suing for is what they're doing business for. If you want to distinguish CREPY, CREPY was a wrongful termination case where he brought suit in a different venue and that venue had no connection at all to his

wrongful termination case.
This venue is connected because they derive substantial revenue out of Bergen County. So, they are doing business here. Our claim s are with regard to the business that they are doing here.
THE COURT: No, in CREPY there was doing business in that other county.
MR. KINCANNON: But not related to his wrongful termination claim. His claim, his tort was a unicorn compared to their connections to the venue. Here our --
THE COURT: That's what I'm saying, there's no nexus. You're claim has no nexus to Bergen County. The implantation, the damage, the injury didn't occur here in Bergen.
MR. KINCANNON: We agree that the damage and injuries did not occur here.
THE COURT: Right.
MR. KINCANNON: But -- but really our analysis is, are they doing business here? That's the rule, that's the analysis and they've conceded they're doing business here.
So, if we concede that that venue is proper laid in Bergen County by virtue of 432 and defendants doing business here, then we're talking about the

convenience issue and -- and, you know, we still have those 57 cases where they're not even supposed to be able to bring this motion.
So, to your point, look, I'm not going to bifurcate these (Indiscernible) send half of them to Somerset and say 57 have to leave here.
THE COURT: That -- that definitely I --
MR. KINCANNON: I wouldn't ask you that. I would argue it the other way that that means that these cases should stay here for all of those reasons. 57 of them can't go anywhere because the rule says they can't bring this motion.
And the others there has been no showing of inconvenience, no real showing of inconvenience. They can talk about 12 miles versus 8 miles, but as a practical matter we're going to get documents and hard drives in the mail. We're going to take depositions outside of Somerset County. There is no burden on anyone going to Somerset County except plaintiffs.
Now, if we go to Bergen, there's no palpable prejudice to these defendants. If anything, their cases will move faster. This will be more expeditious.
THE COURT: All right. Mr. Kott, would you wish to add anything?
MR. KOTT: Unless the Court has questions for

me, no, Your Honor.
THE COURT: Okay. I want you to know I've given a lot of thought to this motion. And I have read the papers. I have read all the -- the cases actually that you have cited and the exhibits.
As you will see as my decision is put on the record I am granting the application, but I am granting the application in part because as the assignment judge making the decision of this motion and given the concerns that plaintiffs raise of resources and staffing the appropriate venue is going to be Middlesex. Because Middlesex certainly has the staffing and resources and actually quite obviates a lot of the concerns that plaintiffs set forth in their papers regarding Somerset. But I'll put every thing on the record now.
I've already placed on the record the fact that Judge Mizdol has by order dated September 24, 2018 appointed this court to hear and determine the application for change of venue is a matter presently before us.
Before this Court motions to change venue by the defendants from Bergen County to Somerset County regarding 109 cases has been fully briefed and we've had oral argument. Although this only involves 109

cases this decision pertains to all cases filed by the plaintiffs against the defendants pertaining to personal injury product liability claims concerning hernia mesh other than physiomesh. And parenthetically, clearly, physiomesh products are all being heard in Atlantic County as an MCL.
As -- as -- as background it is necessary to the put the following on the record. Plaintiffs, except for two, reside outside the State of New Jersey. None live in Bergen County.
The complaints allege that plaintiffs were injured as a result of an Ethicon hernia mesh product that was implanted after plaintiffs underwent hernia repair surgery. Plaintiffs sued defendants Ethicon and Johnson & Johnson in Bergen County alleging that they were involved in the manufacture, design, and/or distribution of the product that allegedly caused injury to the plaintiff.
Neither the hernia repair surgery nor the alleged injury occurred in Bergen County. Plaintiffs do not reside in Bergen County. The manufacturer of the product, Ethicon, is not located in Bergen County. Ethicon is located in Somerset County. The other defendant in this action, Johnson & Johnson, is located in Middlesex County.

On January 11, 2018 counsel representing plaintiffs in product liability cases involving hernia mesh products against Ethicon and Johnson & Johnson together with many other plaintiffs' law firms wrote to the Honorable Robert L. Polifroni to request an early case management conference to discuss to consolidate the cases for discovery or an MCL application.

By letter dated January 25, 2018 Judge Polifroni rejected plaintiff's informal attempt to achieve MCL designation in Bergen County and reminded plaintiff's counsel of the New Jersey MCL application process. In this letter Judge Polifroni explained that decisions by counsel to select a county of venue and then request to have the matters consolidated and handled by one judge outside the MCL format will not be validated by this Court.

Judge Polifroni also noted that unless the individual plaintiffs live in Bergen County it seems unreasonable -- excuse me. It seems reasonable that the most convenient venue would be the corporate location of the defendants, which appears to be outside of Bergen County.

Regardless of this letter plaintiff's counsel continued to file hernia mesh lawsuits against defendants in Bergen County even though Bergen County

has no nexus to the parties or their suit's allegations.

On February 28th, 2018 plaintiff's counsel filed a Rule 4:38(a) MCL application with the AOC. The AOC issued a notice requesting comments or objections to plaintiff's counsel's MCL application by May 14, 2018. Defendants responded to plaintiff's MCL application.

While the application was pending the parties did enter into the consent order extending time for defendants to file motions to transfer venue in all Bergen County Ethicon hernia mesh cases. The consent order extended the time for defendants to file said motions for change of venue until 30 days after the AOC issued its ruling on the MCL application.

On August 15, 2018 the Honorable Glen Grant (phonetic) issued a another notice to the bar advising that the Supreme Court determined to designate cases involving allegations from use of physiomesh flexible composite mesh as multi-county litigation and rejected plaintiff's request for MCL litigation for hernia mesh cases that did not involve physiomesh. Defendants now file this motion here in Bergen to transfer venue from Bergen to Somerset.

Pursuant to Rule 4:3-3(a)(1) the Court may

also order a change of venue if the venue is not laid in accordance with Rule 4:3-2. That rule provides in pertinent part, that venue is properly laid in the county in which the cause of action arose or in which a party to the action resides at the time of its commencement. That's Rule 4:3-2(a)(3).

For purposes of venue a corporation is deemed to reside in the county in which it is registered office is located, or in any county in which it is actually doing business.

In CREPY VS. RECKITT, R-E-C-K-I-T-T, BENCKISER, B-E-N-C-K-I-S-E-R, LLC., 448 NJ Super 419 it's a reported Law Division case of 2016, the trial court concluded that the term actually doing business requires a level of business activity by a corporate defendant in the county of venue that exceeds merely conducting incidental or minimal business such as ordinary advertising or marketing.

The Court noted that the plaintiff failed to show how the defendant business activities were specifically targeted toward Essex County in ruling that the action should be transferred to Morris County where the defendant's New Jersey office was located. The Court required more than general business activity to be performed in the form venue even though the

defendant derived venue from that activity.

After CREPY a subcommittee of the New Jersey Supreme Court Rules Committee drafted a proposed amendment to Rule 4:3-2 which the committee stated was a clarification of the rule -- venue rule consistent with CREPY.

The proposed amendment read, B, business entity. For purposes of this rule a business entity shall be deemed to reside in the county in which its principle office in New Jersey is located or if it has no office in the New Jersey in the county in which it was the most significant contacts.

This proposed rule embraced the rationale set forth in CREPY and the intended meaning of, actually doing business, found in the New Jersey court rules.

This Court notes the Supreme Court Rules Committee did not adopt a rule change, but decided to let case law develop to provide guidance on the issue. That is exactly what this Court is doing now in adjudicating this motion in accordance with the principles articulated in CREPY and with the proposed amendment.

When a motion to change venue is made under Rule 4:3-3(a)(1) for improper venue, the respondent which is here the plaintiff, has the burden of

demonstrating good cause for not making the change. This is set forth in our current New Jersey court rules, PRESSLER (phonetic) and VENERO (phonetic), Rule 4:3-3 2018 edition.

The court rules instruct that motions for change of venue on the ground that venue was not properly laid should be routinely granted unless the party resisting the change makes a showing that a fair and impartial trial could not be had in the proper county or that the convenience of the parties and witnesses and the interest of justice justifies trial in a county other than the one where venue should have been laid.

Therefore, here defendants challenge improper venue based on a failure to follow Rule 4:3-2 and plaintiffs have the burden to demonstrate good cause to resist transfer to the venue designated by defendants.

Plaintiff has failed to establish that venue is proper in Bergen County. Ethicon headquarters are in Somerville, Somerset County. That is where the ma-- that is where the majority of Ethicon's activities and New Jersey business is conducted and where Ethicon's business activities are targeted in this State. Likewise Johnson & Johnson's principle New Jersey office is in Middlesex County which is where the

majority of its business is conducted in this State.

Accordingly, pursuant to Rul 4:3-2, and the principles articulated in CREPY, as well as the proposed amendment clarifying the rule consistent with CREPY venue is not properly laid in Bergen County.

This Court finds plaintiff cannot claim any prejudice due to any perceived delay. The -- an assignment judge or his or her designee, which is this Court, may order the change of venue pursuant to Rule 4:3-3(a)(1) or (a)(3) sua sponte if the judge finds that the conditions for transfer are satisfied.

This Court rejects waiver arguments raised by the plaintiff as this Court finds that the conditions for (Indiscernible) this action have been met.

As Judge Polifroni stated in his January 25, 2018 letter, this letter does not serve to comment on the discretion of the assignment judge to address issues involving venue via conference or sua sponte. Also courts may relax the strict deadlines in the interest of justice pursuant to Rule 1:1-2.

In addition, plaintiff's opposition fails to set forth any legitimate prejudice plaintiff may suffer as a result of any perceived delay in filing the motion to transfer venue on the 54 or 57 cases.

Plaintiff's arguments that plaintiff would

somehow suffer prejudice if this action is transferred to Somerset are rejected by this Court. Plaintiff asserts that plaintiff filed the action in Bergen County due to its experience in managing a large volume of cases involving other mesh products and that if plaintiff knew a transfer of venue was possible, the other plaintiffs would not have continued to file their cases in Bergen County.

Plaintiff's arguments seeking out this Court amounts to an admission of form shopping that courts should discourage. Plaintiffs raise identical arguments before the AOC and the New Jersey Supreme Court in their MCL application, which was rejected by the Supreme Court.

Specifically, plaintiff's counsel argued that there should be an MCL established for all hernia mesh products manufactured by Ethicon before this Court here in Bergen County due to my substantial relevant knowledge in handling the current and prior pelvic mesh cases.

The Supreme Court did not establish an MCL in Bergen County before this Court and created an MCL only for the cases involving physiomesh before Judge Johnson (phonetic) in Atlantic County and to prove my point now it is before Judge Porto (phonetic).

Plaintiffs certainly were aware of potential for venue to be transferred. Plaintiff and plaintiff's counsel were on notice of potential venue transfer as early as January 2018 when Judge Polifroni explicitly expressed that unless an individual lives in Bergen County the most convenient venue would be the corporate location of the defendants, which is Somerset County and Middlesex County.

Nevertheless, plaintiff's attorneys continued to file complaints in Bergen County. Plaintiff's arguments regarding waiver and/or prejudice are not compelling because actions continued to be filed here in Bergen after the July 12th, 2018 consent order was entered. Plaintiffs have continued to file cases in Bergen County after defendants filed their first motion to transfer venue.

Accordingly, plaintiff's argument that if plaintiff's knew about the potential for these cases to be transferred to Somerset County, I guess any other county, many of the plaintiffs subject to this motion may never have pursued this case in New Jersey is rejected by this Court.

I have the rare opportunity to handle motions such as this for change of venue as Judge Mizdol's designees, but like an assignment judge matters of

judicial economy and efficiency must be considered in all decision, including venue decisions.

As noted in plaintiff's opposition there are only three civil judges in Somerset County. The concern is the resources available and Somerset County to suddenly have over 150 cases like these as product liability cases. Not only must this Court consider the number of civil judges in Somerset County but also the corresponding amount of support staff and other resources in that county to handle its civil docket.

As noted in plaintiff's opposition as well as in the moving papers of defendants, defendant Johnson & Johnson is headquartered in Middlesex County and Middlesex County is the neighboring county of Somerset.

Neither party has proposed a recommendation to transfer a venue to Middlesex County, which is also a proper venue. As this Court has previously discussed Bergen County is not a proper venue. Somerset is a proper venue, but so is Middlesex County a proper venue as that is the county where Johnson & Johnson has its headquarters.

It cannot be disputed that Middlesex County has the resources and experience to handle cases such as these. Middlesex County has the judicial resources and support staffing resources to suddenly have a

filing of close to over 200 cases pertaining to a particular product.

This Court also notes that a previous application was made by plaintiff's counsel for all their cases to be given MCL designation. Having read the submission in support of the application this Court is not surprised that the MCL designation for these non-physiomesh hernia mesh cases was rejected.

However, this does not preclude a future application by plaintiffs seeking again MCL designation for these cases. This Court is aware of such a scenario that occurred with another product where the first MCL designation was declined, but upon second application was granted.

Please do not take these comments as any presumption or conclusion on my part that these non-physiomesh hernia cases will receive MCL designation in the future. What I am recognizing, what this Court is recognizing is that it's certainly is possible that upon a second application providing additional information an MCL may be approved.

I'm pointing this out as this is another factor I am weighing in making the decision that these cases shall be transferred to Middlesex County, which is an MCL county. Middlesex County is a proper venue

and has the resources to handle cases such as this. Moreover, sending these cases to Middlesex County obviates many of the issues that the plaintiffs were concerned about involving lack of judicial resources in Somerset as well as the fact that Ethicon is located in Somerset County.

This Court is confident that our New Jersey voir dire protocols can eliminate any potential issue concerning a potential juror's bias in connection to Ethicon or Johnson & Johnson. There's no indication whatsoever that a fair jury cannot be obtained in Middlesex County, although your issues is raised as to Somerset County, pertaining to these cases.

I personally know this can be done because there has been a product liability litigation in Middlesex County against Johnson & Johnson and that litigation resulted in a plaintiff's verdict.

In sum, these cases have absolutely no nexus to Bergen County. While this Court appreciates the compliments that plaintiffs have provided in their papers indicting that they have confidence that I would be able to handle these hernia mesh cases, that's not how assignment judges or our court system makes decisions regarding venue. To do so would be tantamount to judge shopping.

Our system does not allow the parties to pick a venue or a judge because they believe a particular judge would be well-suited for particular case or case type. Moreover, there's no guarantee that I would even be on this assignment during the litigation of these cases.

As I said before, one must reflect back to the pelvic mesh scenario where the cases were originally venued as an MCL Atlantic County before Judge Higby. Thereafter, Judge Higby was elevated to the Appellate Division and the cases were assigned to Bergen County before Judge Martinotti in 2014 and then reassigned to this court in 2016 as Judge Martinotti was elevated to the federal bench.

My point is that for counsel to indicate a particular judge would be well-suited to handle a case has nothing to do with venue for a venue decision. And moreover, there's no guarantee that the requested or suggested judge will oversee the litigation.

Accordingly, the motion of defense counsel is granted and these cases that are the subject of this motion are hereby transferred to Middlesex County as well as any other cases involving hernia mesh that do not involve physiomesh.

I'm asking defense counsel to provide a list

of those cases which I can annex to an order as an exhibit to make the transition and the transfer orderly.

I'm aware that there have been motions filed regarding consolidation. As a result of today's decision, those motions are denied as moot. Any decision regarding consolidation or case management of these cases by one judge shall be decided by motion filed in Middlesex County.

MS. PATTERSON: Thank you, Your Honor. As you might expect I have housekeeping questions. How would you like the caption or the order to appear with the appended list that Your Honor has requested?

THE COURT: Well, the caption for this motion was all of the cases. So, the order will indicate that pursuant to today's decision placed on the record those cases are transferred to Middlesex County. I --

MS. PATTERSON: Should we use the docket number of COTTLE that the arg-- that was placed on the record --

THE COURT: Yeah.

MS. PATTERSON: -- at the beginning of argument?

THE COURT: Yeah. We'll use that docket number, but I think for the order we have to all of the

157 cases listed.

MS. PATTERSON: Happy to do that or -- or --

THE COURT: Then we'll use that docket number --

MS. PATTERSON: Is that sufficient for the Court or is a separate actual order required for each of the cases? We'll do whatever the Court requires.

THE COURT: I'm thinking of housekeeping to make is easiest for not me or you, but the people who have to physically do the work.

I think we could put forth an order under the one docket number indicating that pursuant to this Court's order, I mean we could discuss the language, all cases listed in Exhibit A are hereby transferred to Middlesex County. But I don't think you have to go through the work of making individual orders. I think we could have an exhibit with each of the cases and the docket number.

MS. PATTERSON: And another housekeeping issue. There are 109 cases that are -- had motions filed already.

THE COURT: Uh-huh.

MS. PATTERSON: Can we just add to the list the cases that have been filed in Bergen for which we have not yet filed motions to transfer --

THE COURT: Yes.
MS. PATTERSON: Okay.
THE COURT: Yes. And -- and if there's any difficulty with the language, if you want me to look at it first if you want --
MS. PATERSON: We'll submit it under the 5D Rule.
THE COURT: Right. And if -- I can review it and I can also confer with the people who actually have to do the transferring to ask if they do require anything else. I think we can work that out.
MS. PATTERSON: Thank you, Your Honor.
MR. KINCANNON: I think an omnibus order would be fine. My question was with regard to how these will these be assigned. Is there any direction or will Middlesex handle that in terms of --
THE COURT: Middlesex will handle that.
MR. KINCANNON: So, I don't if it'll go to one judge or ten judges and be split up or how this will be administered. So, I'm not sure that's something we will deal with or? I mean, I don't know who to --
THE COURT: I'm going --
MR. KINCANNON: -- call in Middlesex and say, okay, how do you want us to get before you or deal with

these?
THE COURT: The assignment judge in Middlesex will be made aware of this and I would give it some time frame, but I -- I would then suggest a communication by your office to -- to the assignment judge with -- with your concerns or questions.
MR. KINCANNON: Understood. Thanks, Your Honor.
MS. PATTERSON: Thank you, Your Honor.
THE COURT: Anything further?
MR. KOTT: Not from the defendants, Your Honor.
THE COURT: Okay. So, in terms of -- I'm not going to sign any order because the order that you prepared has to go into Somerset as well as it just encompasses --
MR. KOTT: Right.
THE COURT: -- 109 cases.
MR. KOTT: Right. Well, --
MS. PATTERSON Plus. It would be, about -- it includes, about, ten more I think.
THE COURT: Right. We need to --
MS. PATTERSON: Uh-huh.
MR. KOTT: Yeah.
THE COURT: We need to rephrase the order.

Okay.
MR. KOTT: Yeah.
THE COURT: Thank you.
MR. KOTT: Okay. Thank you, Your Honor.
MR. KINCANNON: Thank you, Your Honor.
(Proceedings concluded)

CERTIFICATION

I, Brandy Winow, the assigned transcriber, do hereby certify the foregoing transcript of proceedings in the Bergen County Superior Court on September 28, 2018, digitally recorded, Time Index from 10:03:08 a.m. to 10:51:21 a.m., is prepared in full compliance with the current Transcript Format for Judicial Proceedings and is a true and accurate compressed transcript of the proceedings as recorded to the best of my knowledge and ability.

/s/ Brandy Winow

Brandy Winow T#654
ELITE TRANSCRIPTS, INC.
Butler, New Jersey 07405 October 5, 2018

EXHIBIT F

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FILED
OCT. 09 2018
RACHELLE L. HARZ
J.S.C.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY
DOCKET NO. BER-L-7065-17

JASON COTTLE,

Plaintiff,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

Civil Action

ORDER GRANTING DEFENDANTS' MOTION TO TRANSFER VENUE IN PART AND TRANSFERRING TO MIDDLESEX COUNTY THIS MATTER, ALL MATTERS INCLUDED ON SCHEDULE A ATTACHED TO THIS ORDER, AND ALL FUTURE MATTERS THAT INCLUDE PRODUCT LIABILITY CLAIMS INVOLVING AN ETHICON HERNIA MESH PRODUCT OTHER THAN PHYSIOMESH

THIS MATTER having been opened before the Court by McCarter & English, LLP, attorneys for Defendants Johnson & Johnson and Ethicon, Inc., seeking an Order transferring venue of the within matter from Bergen County to Somerset County; and The Court having considered the papers submitted in support of and in opposition to the motion; and The Court on September 28, 2018 having heard oral argument of counsel (Joshua S. Kincannon, Esq., of Lomurro, Munson, Comer, Brown & Schottland, LLC, and Adam Evans, Esq., of the Hollis Law Firm, P.A., counsel for Plaintiff, and David R. Kott, Esq., of McCarter & English, LLP, and Kelly S. Crawford, Esq., of Riker Danzig Scherer Hyland & Perretti, LLP, counsel for Defendants); and The Court having rendered an oral opinion on the record on September 28, 2018; and good cause appearing;

IT IS on this 9th day of October, 2018;

ORDERED that:

1. Defendants' Motion to Transfer Venue be and hereby is **GRANTED IN PART** and this matter, all matters included on Schedule A attached to this Order, and all future matters filed in Bergen County that include product liability claims involving an Ethicon Hernia Mesh Product other than Physiomesh are transferred to Middlesex County; and

2. The Clerk, Superior Court of New Jersey, Bergen County, is hereby directed to transfer this matter, all matters included on Exhibit A attached to this Order, and all future matters filed in Bergen County that include product liability claims involving an Ethicon Hernia Mesh Product other than Physiomesh to Middlesex County.

Rachelle L. Harz

HON. RACHELLE L. HARZ, J.S.C.

X Opposed

___ Unopposed

Judgment, as memorialized on the record

EXHIBIT A

SCHEDULE "A" BERGEN COUNTY NON PHYSIO MATTERS.

Plaintiff	Docket No.
Aaron, Daniel & Heather	BER-L-0870-18
Abhold, Mark & Pam	BER-L-5727-18
Adams, Richard J.	BER-L-3951-18
Alexander, Diane	BER-L-1241-18
Alumbaugh, Alan	BER-L-207-18
Alvarado, Daniel/Jessica	BER-L-1479-18
Anawaty, Viola	BER-L-1516-18
Austin, Diana	BER-L-4204-18
Banks, Lucy	BER-L-4077-18
Bassett, Richard	BER-L-7836-17
Bean, Norman	BER-L-198-18
Benton, Timothy & Sheila	BER-L-3317-18
Blackistone, Janice	BER-L-4332-18
Bolyard, Glenn	BER-L-5689-18
Booth, Gloria Jean & Russall	BER-L-3892-18
Boston, Courtney D.	BER-L-4103-18
Bovino, Edwin	BER-L-5691-18
Bradford, William	BER-L-1806-18
Briscoe, Anthony & Francelia	BER-L-1691-18
Brooks, Caroline	BER-L-3916-18
Campbell, Cassandra	BER-L-8998-17
Capshaw, Clifton	BER-L-1530-18
Chavira, Juan	BER-L-4489-18
Clements, Charles P.	BER-L-5721-18
Clulee, Sherry Marie	BER-L-3703-18
Collier, Greg	BER-L-2214-18
Cordova, Michael	BER-L-4532-18
Cottle, Jason	BER-L-7065-17
Darnell, David	BER-L-4038-18
Deffenbaugh, Gary	BER-L-3517-18
Dias, Alexsandro	BER-L-1471-18
Diloreto, Edward	BER-L-1018-18
Finotti, James G.	BEr-L-3994-18

SCHEDULE "A" BERGEN COUNTY NON PHYSIO MATTERS.

Plaintiff	Docket No.
Fontenot, Emily	BER-L-1513-18
Fowler, Susie	BER-L-8572-17
Gaddis, Troy	BER-L-658-18
Galvez, Michael	BER-L-1393-18
Garrett, Shenecca	BER-L-3726-18
Gately, Brenda	BER-L-9151-17
Gibson, Renee C.	BER-L-1110-18
Godfrey, Holly	BER-L-4334-18
Gold, Ilene	BER-L-8037-17
Gonzales, Maria Luisa A.	BER-L-5726-18
Green, Margaret	BER-L-5687-18
Griffin, Charles	BER-L-8827-17
Guidry, Stephanie	BER-L-4515-18
Hart, Dennis	BER-L-1349-18
Hecker, Austin	BER-L-3728-18
Hendrix, Patricia	BER-L- 3751-18
Henley, James G.	BER-L-3015-18
Hinn, John	BER-L-3753-18
Hodge, Pamela	BER-L-2577-18
Holman, Raymond & Cora	BER-L-3808-18
Johnson, Cathy	BER-L-3720-18
Johnson, Heather	BER-L-2003-18
Johnson, Shaunta	BER-L-5379-18
Jones, Christina	BER-L-4082-18
Jones, Eugenia	BER-L-3452-18
Jones, Georcie	BER-L-3913-18
Krampen-Yerry, Denise	BER-L-1466-18
Lang, Christine M.	BER-L-1067-18
Lecza, Cheryl	BER-L-4559-18
Lindly, James	BER-L-1402-18
Lindsey, Scott E.	BER-L-1210-18
Linnenbrink, Christina	BER-L-8829-17
Lloyd, William	BER-L-2952-18

SCHEDULE "A" BERGEN COUNTY NON PHYSIO MATTERS.

Plaintiff	Docket No.
Lotridge, Robin	BER-L-1467-18
Lowe, Sandra	BER-L-5724-18
Lowrey, Robert	BER-L-4577-18
Lynch, Roy	BER-L-4043-18
Mack, Edward & Robin	BER-L-1220-18
Maestas, Joseph	BER-L-1456-18
Masingo, Jerri Ann	BER-L-5275-18
Mata, Raul	BER-L-4035-18
Mathews, William D.	BER-L-5723-18
McCutcheon, Deanna	BER-L-4475-18
Miller, Ronald	BER-L-2345-18
Morrone, Adele	BER-L-5294-18
Mosby, Russell	BER-L-5722-18
Moskowitz, Scott	BER-L-5011-18
Mountjoy, James & Nancy	BER-L-1480-18
Muniz, Rick	BER-L-3516-18
Newburn, Nakeisha	BER-L-4523-18
Newman, Stephen	BER-L-5296-18
Noakes, Kenneth	BER-L-8276-17
Parham, Roderick	BER-L-4052-18
Payne, Jonathan	BER-L-5719-18
Perez, Maria	BER-L-4486-18
Perez, Nora	BER-L-4115-18
Pikulsky, Jamie & Jeffrey	BER-L-1052-18
Redding, Shonna	BER-L-184-18
Reynolds, Burton	BER-L 279-18
Rice, Melissa	BER-L-197-18
Rivas, Angelina	BER-L-4113-18
Schriner, Yesina	BER-L-1222-18
Scobee, Jerry A.	BER-L-2355-18
Senkel, William	BER-L-1433-18
Shackelford, Cecelia	BER-L-1200-18
Shepherd, Terry T.	BER-L-2354-18

SCHEDULE "A" BERGEN COUNTY NON PHYSIO MATTERS.

Plaintiff	Docket No.
Smith, Diane M.	BER-L-652-18
Smith, Joseph W.	BER-L-1692-18
Smith, Terrence	BER-L-4913-18
Snyder, David	BER L-2513-18
Soares, Calvin	BER-L-4476-18
Strawser, Janice	BER-L-5034-18
Szaroleta, Christopher	BER-L-1458-18
Tavian, Michael	BER-L-4056-18
Taylor, Cindy	BER-L-4573-18
Trebolo, Walter	BER-L-9133-17
Tyler, Daniel	BER-L-4884-18
Usey, Christina	BER-L-1244-18
Vinas, Daniel	BER-L-5290-18
Ward, Sue E.	BER-L-2353-18
Whitfield, Michael & Melissa	BER-L-4885-18
Williams, James	BER L-2337-18
Wilson, Donald & Bernadette	BER-L-4800-18
Wolfe, Donna	BER-L-3891-18
Wolfe, Patty	BER-L-3583-18
Woods, Lisa	BER-L-4482-18
Alguacil, Leila	BER-L-6881-18
Asturi, Annette	BER-L-5998-18
Austin, Jeffrey	BER-L-6488-18
Blocker, Shannon	BER-L-6786-18
Brawley, Ann	BER-L-6008-18
Brown, Lionel, Sr. and Doris	BER-L-5656-18
Burns, Gregory and Edie	BER-L-6927-18
Classen, Mary and Anthony C.	BER-L-6162-18
Corgan, Travis	BER-L-6338-18
Delph, Terrie and Matthew	BER-L-6784-18
Dill, Barbara	BER-L-6548-18
Falcon, Lloyd	BER-L-6342-18
Frank, Fontella	BER-L-6358-18

SCHEDULE "A" BERGEN COUNTY NON PHYSIO MATTERS.

Plaintiff	Docket No.
Guy, Louise & Raymond	BER-L-6030-18
Hall, Vivian L.	BER-L-6483-18
Harding, Sheri and Hargis	BER-L-5382-18
Henry, Tracy L.	BER-L-6879-18
Holland, James	BER-L-6486-18
Hughey, Lance	BER-L-6921-18
Ishii, Freedom	BER-L-5950-18
Jacuzzi, Victor	BER-L-5952-18
Johnson, Anna	BER-L-5959-18
Lyon, Michael	BER-L-6484-18
Mahne, Edward & Gale	BER-L-6036-18
McCutcheon, Teresa	BER-L-5954-18
McNally, Sandra	BER-L-5953-18
Moore, Rochelle	BER-L-6367-18
Murphy, Karen	BER-L-6163-18
Newland, Kenneth	BER-L-5956-18
Nomikos, Michael	BER-L-6211-18
Nuri, Lindita and Fatmir	BER-L-6290-18
Palka, Mary L.	BER-L-6487-18
Perez, Joseph	BER-L-6912-18
Pierce, Jerry and Teri	BER-L-6037-18
Redenauer, John, L. Sr.	BER-L-4238-18
Shaw, Jerry	BER-L-5962-18
Skiba, Joseph A.	BER-L-6880-18
Snyder, Rick C.	BER-L-6785-18
Spears, Mark	BER-L-6928-18
Strauss, Nathan K.	BER-L-5248-18
Thibodaux, Cecile G. and Danny	BER-L-6164-18
Vaughn, William	BER-L-5960-18
Warr, Anita	BER-L-5940-18
Waterfield, Floyd and Debra	BER-L-6497-18
Wetch, Debi	BER-L-6494-18
White, Steve	BER-L-6926-18

EXHIBIT G

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Attorneys for Plaintiff, Kathleen Bednarcyk and William Bednarcyk

KATHLEEN BEDNARCYK; and WILLIAM BEDNARCYK, Plaintiffs, v. JOHNSON & JOHNSON.; and ETHICON, INC., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION MIDDLESEX COUNTY Docket No.: **CIVIL ACTION** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs, Kathleen Bednarcyk and William Bednarcyk ("Plaintiffs"), by and through their counsel, hereby sue JOHNSON & JOHNSON ("J&J"), a New Jersey corporation; and ETHICON, INC. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is a product liability action brought by Plaintiff, Kathleen Bednarcyk ("Plaintiff") for injuries arising out of the Proceed Ventral Patch ("Proceed" or "Ethicon Multi-Layered Hernia Mesh").

2. Defendants manufactured and supplied to doctors a nine-layer hernia mesh patch known as the Proceed Ventral Patch.

3. The Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk of pain, dense adhesion formation, bowel complications, mesh shrinkage, hernia recurrence, seroma and fistula formation, and infection whether from a prolonged and pronounced inflammatory response caused by the nine layers, degradation of polymers due to exposure to gamma radiation, non-conforming subcomponents, or some other mechanism renders the Ethicon Multi-Layered Hernia Mesh a defective product.

5. The selection and implantation of the Ethicon Multi-Layered Hernia Mesh by Plaintiff's surgeon was a result of the misinformation, marketing, sales, promotion and direction by Ethicon.

JURISDICTION & VENUE

6. This is a lawsuit over defective hernia mesh designed, marketed, manufactured, promoted, and sold within New Jersey and the United States by Defendant Ethicon and its parent company J&J.

7. Plaintiffs currently reside in Holly Springs, North Carolina and are citizens and residents of North Carolina.

8. Plaintiff underwent hernia repair surgery on November 14, 2015 at WakeMed Cary

Hospital in Cary, North Carolina. At that time, the Ethicon Multi-Layered Hernia Mesh product that Defendants manufactured, designed, distributed, and warranted was implanted into Plaintiff. Her surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

9. Defendant J&J is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

10. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Ethicon Multi-Layered Hernia Mesh, the hernia repair mesh product at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies comprising the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

11. Defendant Ethicon is a wholly owned subsidiary of Defendant J&J. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Defendants conduct business in every county in New Jersey.

12. Defendant Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Ethicon Multi-Layered Hernia Mesh.

13. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Ethicon Multi-Layered Hernia Mesh.

14. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed, and marketed the defective Ethicon Multi-Layered Hernia Mesh in the State of New Jersey. Defendants derive substantial revenue from hernia mesh products used or implanted in the State of New Jersey. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in the State of New Jersey.

15. Defendants were also involved in the business of monitoring and reporting adverse events concerning the Ethicon Multi-Layered Hernia Mesh, and having a role in the decision process and any response related to these adverse events.

16. Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial business activity within the State of New Jersey, Bergen County.

b. Defendants' hernia mesh products, including the subject Ethicon Multi-Layered Hernia Mesh, were designed, manufactured, and placed into the stream of commerce in the State of New Jersey by Defendants.

c. Defendants maintain an office or agency within the State of New Jersey.

d. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

17. At all material times, Defendants developed, manufactured, advertised, promoted, marketed, sold, and/or distributed the defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically to Plaintiff and

Plaintiff's implanting physician or his practice group, or to the hospital where the Ethicon Multi-Layered Hernia Mesh was implanted.

18. Plaintiff's claims and causes of action are only state-law claims. Any reference to any federal agency, regulation, or rule is stated solely as background information and does not raise a federal question. Defendants J&J and Ethicon are both New Jersey corporations and both maintained their principal place of business in New Jersey. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

19. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Ethicon Multi-Layered Hernia Mesh device throughout the world, including in Bergen County, State of New Jersey.

20. Ethicon knowingly markets to, and derives income from, patients across the United States, including the State of New Jersey from the sale of the Ethicon Multi-Layered Hernia Mesh device.

21. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and costs.

FACTS COMMON TO ALL COUNTS

22. A defectively designed, manufactured and marketed Proceed Ventral Patch left the hands of Defendants in its defective condition, and was delivered into the stream of commerce. Brandon Price Roy, MD implanted the Proceed Ventral Patch in Plaintiff's abdomen to repair an incisional hernia on or about November 14, 2015 at WakeMed Cary Hospital in Cary, North Carolina. Plaintiff was implanted with a Proceed Ventral Patch, ref: PVPM, lot: J88HBDZO.

23. Plaintiff experienced increasing abdominal pain, hernia recurrence and nausea. On December 30, 2016, Plaintiff underwent an open repair of her recurrent incisional hernia with

Brandon Price Roy, MD at WakeMed, North Carolina. The records indicate that the previously placed mesh was significantly decreased in size from its original size (approximately the size of a quarter). The records further indicate that small bowel was adherent to the mesh and it was necessary to create a small serosal defect in order to free the bowel from the mesh. The serosal defect was repaired and adhesions were cleared.

24. Plaintiff experienced and/or continues to experience severe pain, hernia recurrence, bowel injury, removal surgery, adhesions, inflammation, loss of appetite, stress and anxiety which have impaired her activities of daily living.

25. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants warranted would not occur because of the Proceed design and composition.

26. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the Ethicon Multi-Layered Hernia Mesh, Plaintiffs have suffered and continues to suffer injuries and damages, including: past, present and future physical and mental pain and suffering; physical disability; past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; and other related damages.

27. Defendants were the designers, manufacturers, marketers, sellers, distributors and suppliers of the Ethicon Multi-Layered Hernia Mesh at all material times.

28. Defendants warranted the Ethicon Multi-Layered Hernia Mesh as safe and effective for use and placed the device into the United States stream of commerce.

29. Defendants knew that the oxidized regenerated cellulose layer of the Proceed was ineffective at preventing adhesion formation to the underlying polypropylene of the Proceed before Defendants set out to design the Proceed Ventral Patch in 2006, and even before Defendants set out to design the Proceed Surgical Mesh predicate device in 2003.

30. Before 2003, Defendants were aware that the Oxidized Regenerated Cellulose utilized in the Proceed had pores which were too large to prevent adhesion formation.

31. Before 2003, Defendants were aware that increased adhesion formation would result in increased mesh shrinkage.

32. Before 2003, Defendants were aware that utilizing Oxidized Regenerated Cellulose in their mesh products would result in dense adhesions in the presence of blood or fibrinous exudate.

33. Before 2003, Defendants were aware that polypropylene elicits a chronic, life-long inflammatory response that is accompanied by exudation of fibrinogen.

34. Before 2003, Defendants were aware that any exposure to gamma radiation would weaken and embrittle the polypropylene of the Ethicon Multi-Layered Hernia Mesh.

35. Before 2006, Defendants were aware that adding Vicryl and other additional layers to the Proceed Surgical Mesh to create the Proceed Ventral Patch, would increase the intensity and duration of inflammation and foreign body response (FBR), thus increasing fibrinous exudate.

36. Before placing the Ethicon Multi-Layered Hernia Mesh on the market, Defendants were required to mitigate risks of the product, including any element of design or sterilization which could render the device ineffective, weaken the structural integrity of the device, or increase or prolong inflammation once the device is implanted that would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

37. Defendants designed, manufactured, and marketed the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the materials utilized in the Ethicon Multi-Layered Hernia Mesh would cause dense adhesions, chronic pain, mesh shrinkage, bowel

obstructions, and early hernia recurrence.

38. Defendants sterilized the Proceed with gamma radiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma radiation.

39. The Proceed Ventral Patch is made of the following, starting with the component placed closest to the bowel of the patient-consumer:

- Oxidized Regenerated Cellulose (ORC) barrier layer
- Polydioxanone (PDS) film layer
- Large pore polypropylene (Prolene soft mesh)
- PDS film layer
- PDS reinforcing element
- PDS ring
- PDS film layer
- Vicryl
- PDS film layer

40. Polypropylene hernia meshes are traditionally sterilized with ethylene oxide.

41. The ORC layer of the Proceed will react and degrade in the presence of ethylene oxide.

42. Defendants sterilize the Proceed with gamma radiation.

43. Gamma radiation degrades, weakens, and embrittles the polypropylene base of the Proceed.

44. Decades before the release of the Ethicon Multi-Layered Hernia Mesh, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed gamma radiation.[1]

45. The embrittled polypropylene of the Ethicon Multi-Layered Hernia Mesh increases its propensity to tear away from the securing devices, such as sutures or tacks.

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).

46. The polypropylene base is the only permanent, non-resorbable portion of the Ethicon Multi-Layered Hernia Mesh.

47. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Multi-Layered Hernia Mesh to be utilized in anyone with a soft tissue defect, including, but not limited to: "infants, children, pregnant women, or women planning pregnancies..."[2]

48. For decades, the medical community had concerns about severe complications if polypropylene was placed too close to the bowel or other underlying organs, due to the formation of dense adhesions to the polypropylene.

49. Defendants were aware that the ORC layer in the Proceed was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the Proceed to market.[3]

50. Despite significant evidence to the contrary, Defendants marketed the Proceed and its ORC layer as a tissue-separating barrier that would prevent adhesion formation from the underlying polypropylene to any nearby organs.

51. The following studies have investigated complications associated with the Proceed:

> a. In 2006, a study out of The Netherlands evaluating the use of new prosthetic meshes for ventral hernia repair was published in Surgical Endoscopy. **Proceed showed significantly less incorporation... Proceed composite has a smooth surface designed to prevent adhesion formation. However, it is less smooth than other composite meshes with antiadhesive barriers. Furthermore, the barrier applied is oxidized cellulose, which may not prevent mesh adhesions as effectively as anticipated or as reported previously.**
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> Burger, J.W. et al, *Evaluation of New Prosthetic Meshes for Ventral Hernia Repair*. Surg Endosc. 20:1320 – 1325 (2006). DOI: 10.1007/s00464-005-0706-4.

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[2] Ethicon Multi-Layered Hernia Mesh Ventral Patch Instructions for Use, RMC 8550915, Status 9/08.
[3] Robert J. Fitzgibbons, Jr., M.D. et al., *A Laparoscopic Intraperitoneal Onlay Mesh Technique for the Repair of an Indirect Inguinal Hernia*, 219-2 ANNALS OF SURGERY 114 (1994).

b. In 2009, a study out of The Netherlands on adhesions prevention during hernia mesh repair was published in the Annals of Biomedical Engineering. **The uncoated Prolene meshes were found to invoke a moderate inflammatory response in their immediate vicinity, characterized by the presence of active macrophages. A stronger inflammatory response was observed with the Proceed meshes, presumably due to ongoing phagocytosis of the oxidizing regenerated cellulose and polydioxanone coating... Most remarkable were adhesions with Proceed. Although adhesion scores were the lowest at day 7, they increased by day 30 and exceeded adhesion scores of NVP/BMA-coated Prolene mesh and Prolene.**

Emans, P. et al, *Polypropylene Meshes to Prevent Abdominal Herniation. Can Stable Coatings Prevent Adhesions in the Long Term?* Annals of Biomedical Engineering. 37(2):410 – 418 (2009). DOI: 10.1007/s10439-008-9608-7.

c. In 2009, a study out of Saint Louis, Missouri measuring adhesions and mesh contraction was published by Surgical Innovation. The data was previously presented at the American Hernia Society, Third International Hernia Congress on June 9, 2006. **The highest degrees of mesh contraction occurred with DualMesh and Proceed... Proceed exhibited the greatest surface area of adhesion coverage and the highest-grade adhesions.**

Pierce, R. et al, *120-Day Comparative Analysis of Adhesion Grade and Quantity, Mesh Contraction, and Tissue Response to a Novel Omega-3 Fatty Acid Bioabsorbable Barrier Macroporous Mesh After Intraperitoneal Placement.* Surg Innov. (2009). DOI: 10.1177/1553350608330479.

d. In 2010, a study out of Saint Louis, Missouri on adhesion related complications associated with intraperitoneal mesh was published in Surgical Endoscopy. **Nevertheless, there appears to be some differentiation in the adhesion characteristics of the absorbable-barrier-coated meshes... We noticed a similar increase in the adhesion tenacity score of PROCEED in a preclinical study of intraperitoneal placement f absorbable-barrier-coated meshes in a rabbit model.**

Jenkins, E. et al, *Prospective Evaluation of Adhesion Characteristics to Intraperitoneal Mesh and Adhesiolysis-Related Complications During Laparoscopic Re-Exploration After Prior Ventral Hernia Repair.* Surg Endosc. 24:3002 – 3007. DOI: 10.1007/s00464-010-1076-0.

e. In 2010, a study out of Belgium on the lack of convincing data in medical literature regarding to use of intraperitoneal hernia mesh was published in The World Journal of Hernia and Abdominal Wall Surgery.

The content of the paper was presented during the 32nd International Congress of the European Hernia Society, in Istanbul, on October 6-8, 2010. **After release of the omental adhesions, we found the [Proceed] mesh to have shrunk and folded up, to a dimension of approximately 3.0 cm in diameter. This means a shrinkage from a circle of diameter 6.4 cm (surface: 3.14 x 3.2^2 = 32.2 cm^2) to a "circle" of diameter 3.0 cm (surface: 3.14 x 1.5^2 = 7.1 cm^2), equivalent to a mesh surface shrinkage of 77.9%... There is a complete lack of convincing data on these mesh devices in the medical literature.**

Muysoms, F.E. et al, *Complications of Mesh Devices for Intraperitoneal Umbilical Hernia Repair: A Word of Caution.* Journal of Hernia. 15:463-468 (2011). DOI: 10.1007/s10029-010-0692-x.

f. In 2012, a study out of Saint Louis, Missouri on the effectiveness of barrier hernia mesh was published in Surgical Endoscopy. **This study also demonstrated increased adhesion formation for all of the barrier mesh prostheses between 7 and 30 days, which the authors attributed to increased inflammation related to the degradation and resorption of the barrier layer components, which were ongoing between 7 and 30 days. This effect was most pronounced in PROCEED Surgical Mesh materials, which again highlights the influence that the chemistry of the particular barrier components may have over the inflammatory response and subsequent adhesion formation.**

Deeken, C. et al, *A Review of the Composition, Characteristics, and Effectiveness of Barrier Mesh Prostheses Utilized for Laparoscopic Ventral Hernia Repair.* Surg Endosc. 26:566-575 (2012). DOI: 10.1007/s00464-011-1899-3.

g. In 2014, a study out of Belgium on the Proceed Ventral Patch (PVP) was published in The World Journal of Hernia and Abdominal Wall Surgery. **Polypropylene meshes, like the PVP, have demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4 cm in diameter is in sufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP in hernias of 2cm or more.**

Bontinck, J. et al, *Single Centre Observational Study to Evaluate the Safety and Efficacy of the Proceed Ventral Patch to Repair Small Ventral Hernias.* Journal of Hernia. 18:671 – 680 (2014). DOI: 10.1007/s10029-013-1140-5.

h. In 2015, a study out of Belgium on the Proceed (PP/ORC) was

published in The World Journal of Hernia and Abdominal Wall Surgery. **In our opinion, there are several factors contributing to the extensive FBR and shrinkage/mesh contraction of the PP/ORC device. First, the composition of the PP/ORC device out of nine different layers will lead to a more extensive FBR. Second, absorption of 8 of these 9 layers will create a severe inflammatory reaction as, e.g.. shown with vicryl mesh absorption, also being one of the components of the PP/ORC device. A third possible explanation is delamination of the device.**

Reynvoet, E. et al, *Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model.* Journal of Hernia. 19:955 – 963 (2015). DOI: 10.1007/s10029-015-1368-3.

i. In 2016, a study out of Bosnia and Herzegovina was published by The Royal Belgian Society for Surgery. **The extent of [adhesion] site involvement after 28 days was statistically significantly greater in the Proceed group.**

Delibegovic, S. et al, *Formation of Adhesions After Intraperitoneal Applications of TiMesh: Experimental Study on a Rodent Model.* The Royal Belgian Society for Surgery. (2016). DOI 10.1080/00015458.2016.1179513

j. In 2016, a study out of Germany on the adhesion prevention efficacy of Proceed (PCM) was published in International Journal of Medical Sciences. **PCM does not provide significant adhesion prevention.**

Winny, M. et al, *Adhesions Prevention Efficacy of Composite Meshes Parietex, Proceed, and 4DryField PH Covered Polypropylene Meshes in an IPOM Rat Model.* Int. J. Med. Sci. 13:936 – 941 (2016). DOI: 10.7150/ijms.16215.

k. In 2017, a Proceed (PVP) randomized controlled trial out of The Netherlands was published in the World Journal of Surgery. **At this point, PVP device usage shows an easier and faster operating procedure. Nevertheless, this advantage is outweighed by the significantly higher incidence of early re-operations due to early complications.**

Ponten, J.E. et al, *Mesh Versus Patch Repair for Epigastric and Umbilical Hernia (MORPHEUS Trial); One-Year Results of a Randomized Controlled Trial.* World J. Surg. (2017). DOI: 10.1007/s00268-017-4297-8.

l. In 2017, a study out of Brazil was published on adhesions and collagen formation following mesh implantation. **The study follow-up time, 90 days, was established because there were no articles in the literature with prolonged follow-up... What we can formulate is that**

> **absorption of the regenerated oxidized cellulose exposes the polypropylene layer to the abdominal visceral content and that this consequently led to the adhesions found... The adhesion formation is a complex process and is basically started by the tissue injury process which breaks down the balance between coagulation and fibrinolysis. Fibrin deposition results in a matrix where the fibroblasts produce extracellular matrix. The end process generates various degrees of adhesion... In the present study, type III collagen was expressed more in the coated group and based on the result of the research this could increase hernia formation.**
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> Rossi, L. et al, *Peritoneal Adhesions Type I, III and Total Collagen on Polypropylene and Coated Polypropylene Meshes: Experimental Study in Rats*. ABCD Arq Bras Cir Dig 30(2):77 – 82 (2017). DOI: 10.1590/0102-6720201700020001.

THE FDA'S 510(k) CLEARANCE PROCESS

72. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976, when the MDA was enacted.

73. No clinical testing is required under this process.

74. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

75. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA before 1976 could be sold to patients in a matter of 90 days without any clinical testing.

76. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

77. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted

a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

78. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

79. Defendants cleared the Proceed Ventral Patch, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

80. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

81. The first Proceed Surgical Mesh did not undergo premarket approval, but instead received 510(k) clearance on or about September 17, 2003. The only predicate device listed on the 510(k) application is the Prolene Soft Polypropylene Mesh, a non-barrier hernia mesh. Defendants did not claim that the Proceed Surgical Mesh was a resorbable adhesion barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

82. Defendants applied for 510(k) clearance for the Proceed Surgical Mesh again in May of 2006. The only predicate device listed on the 510(k) application is the prior Proceed Surgical Mesh. In this 510(k) application, Defendants did not claim the intended use of the Proceed was a resorbable adhesion barrier; however, in the device description Defendants note that the "ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh." Defendants continued to market the Proceed Surgical Mesh as a resorbable adhesion barrier.

83. Defendants applied for 510(k) clearance for the Proceed Ventral Patch in December of 2006. Defendants do not mention in the 510(k) application for the Proceed Ventral Patch that the mesh is intended to act as a resorbable adhesion barrier. After 510(k) clearance, Defendants marketed and continue to market the Proceed Ventral Patch as a resorbable adhesion barrier. Even the Proceed IFU notes "The ORC side of the patch provides a bioresorbable layer that physically separates the polypropylene mesh form underlying tissue and organ surfaces while minimizing tissue attachment to the polypropylene mesh during the critical wound healing period."

FAILURE TO WARN OF THE DANGERS ASSOCIATED WITH PROCEED

52. Defendants marketed the Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs).

53. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects in its devices through communications, e-mails, letters, recalls, warnings in product inserts, and/or through its product representatives, who communicate, interact and work with surgeons.

54. The nine layers of the Proceed Ventral Patch increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying organs to the Ethicon Multi-Layered Hernia Mesh, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

55. Defendants downplayed the intensity of the inflammatory reaction caused by Vicryl by stating in the Proceed Instructions for Use (IFU) that the Vicryl elicits "only a mild tissue reaction during absorption."

56. Defendants state in the Proceed Ventral Patch IFU that "The PROLENE Soft Mesh components are constructed of knitted filaments of extruded polypropylene, identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P." This statement is false, or at the very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

57. Defendants also state in the Proceed IFU that the polypropylene material "when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical

adaptability, with a porous structure to enable mesh incorporation into surrounding tissues." This statement is false, or at the very least misleading, as Defendants are aware that the Proceed is reactive and does not retain its strength. Furthermore, Defendants are aware of reports that the small polypropylene sutures do elicit a small reaction, and increasing amounts of polypropylene greatly increase such reaction. The very reason the Defendants added the ORC layer to the Prolene Soft Mesh was to protect organs from reacting with the polypropylene of the Prolene Soft Mesh.

58. The Proceed IFU has a section for contraindications, which lists "None known."

59. The Proceed IFU has a section for adverse reactions, which lists "Potential adverse reactions are those typically associated with surgically implantable materials..." The polypropylene base of the Proceed carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the nine layers of the Proceed Ventral Patch further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

60. The Proceed IFU notes that "Selected mesh size should allow for adequate overlap of the fascial defect on all sides." The IFU never defines what constitutes "adequate overlap." Defendants are aware that the Proceed shrinks over time, with reports of the Proceed Ventral Patch shrinking as much as 77%.

61. Defendants failed to warn that the Proceed will elicit a fibrinous exudate.

62. Defendants failed to warn that the Proceed creates a solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

63. Defendants never performed any clinical trials and/or studies before marketing the Ethicon Multi-Layered Hernia Mesh.

64. Defendants did not fully and/or adequately test the configuration of its new, nine-layer hernia mesh patch design with ORC, polypropylene, Vicryl, and six layers of PDS, that was implanted into Plaintiff.

65. Although the United States does not have a complete and accurate database to track problems with hernia mesh implants, controlled studies have investigated the problems with the Ethicon Multi-Layered Hernia Mesh.

66. A single center study was conducted in Belgium, where three surgeons implanted only the Proceed in 101 patients between April 2009 and December 2011. The Proceed was able to be visualized by ultrasound in 47 patients. Of those 47 patients, 10 were noted to have mesh contraction. The Proceed "was removed during the operation in four patients and important centripetal contraction of the mesh, diminishing the surface area, was observed in all cases." The authors concluded the Proceed has "demonstrated an in vivo centripetal shrinkage percentage of up to 77% in some patients. This finding of mesh contraction was confirmed in those patients that were reoperated for recurrence and in 21% of the patients where the radiologist was able to visualize the mesh. The overlap obtained with a mesh of 6.4cm in diameter was insufficient with hernias larger than 2 cm. Therefore, we recommend not to use PVP (Proceed Ventral Patch) in hernias of 2 cm or more." The authors go on to note that their study is likely underpowered as "Most recurrences after ventral hernia repair occur within 2 years after the operation. Since our study had a mean follow-up of 16 months, it is likely that a longer follow-up would yield a higher recurrence rate."[4]

[4] J. Bontinck, Single Centre Observational Study to Evaluate the Safety and Efficacy of the Ethicon Multi-Layered Hernia Mesh Ventral Patch to Repair Small Ventral Hernias, 18 Hernia 671, Clinical.Trials.gov: NCT01307696

67. In 2015, another study in Belgium confirmed "massive shrinkage" with the Proceed. The authors concluded that "This can however not be considered the ideal indication for a mesh device repair with a suggested mesh overlap of at least 5 cm for incisional hernias."[5]

68. Defendants continue to market the Proceed without warning of the massive mesh shrinkage or the necessary overlap to prevent early hernia recurrence due to mesh shrinkage.

69. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendants' physician/technical consultants, and/or through industry-targeted promotional materials.

70. Despite these reassurances, the defective design and manufacture of the Ethicon Multi-Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in adhesion formation, bowel injuries, mesh contracture, pain, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, and additional complications.

71. Defendants were aware that the ORC layer was ineffective in preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the nine-layer mesh would contract massively over time. Nonetheless, Defendants employed the design in the Proceed Ventral Patch in reckless disregard for the safety of patients, including Plaintiff.

72. Moreover, despite direct knowledge of significant adverse events reported by patients and physicians, as well as awareness of failures that have been reported in literature and published clinical trials, Defendants have continued to market the Proceed as being safe and effective for hernia repair.

73. From the time Defendants first began selling the Ethicon Multi-Layered Hernia

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(2013).

[5] E. Reynvoet, Intraperitoneal Mesh Devices for Small Midline Hernias: Mesh Behavior in a Porcine Model, 19 Hernia 955 (2015).

Mesh in the United States through today, product labeling and the product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the Ethicon Multi-Layered Hernia Mesh, specifically its propensity to massively shrink, the increased in duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN UNDER NEW JERSEY PRODUCT LIABILTY ACT (NJ PLA)

82. Plaintiffs incorporate herein by reference the allegations in all prior paragraphs and further allege as follows:

83. Defendants had a duty to design and manufacture, distribute, market, promote and sell, the Ethicon Proceed so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

84. In and before 2003, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling hernia mesh implants and did design, manufacture, distribute, market and sell the Ethicon Proceed.

85. Defendants expected the Ethicon Proceed Devices they were manufacturing, selling, distributing, supplying, and/or promoting to reach, and they did in fact reach, implanting physicians and consumers in the State of New Jersey and the United States, including Plaintiff and her implanting physician, without substantial change in their condition.

86. At the time the Ethicon Proceed left Defendants' possession and the time the Ethicon Proceed entered the stream of commerce in the State of New Jersey, it was in an

unreasonably dangerous or defective condition. These defects include, but are not limited to the following:

- the Ethicon Proceed was not reasonably safe as intended to be used;
- the Ethicon Proceed had an inadequate design for the purpose of hernia repair;
- the Ethicon Proceed contained unreasonably dangerous design defects, including a large pore ORC layer that is ineffective at preventing adhesion formation to the underlying polypropylene;
- the Ethicon Proceed is unreasonably dangerous, due to the degraded state of the polypropylene utilized, which has been exposed to gamma irradiation;
- the Ethicon Proceed contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs the inflammatory response;
- the Ethicon Proceed was not appropriately or adequately tested before distribution; and
- the Ethicon Proceed had an unreasonably high propensity for adhesion formation, mesh contracture, hernia recurrence, chronic pain, bowel complications, seroma formation, fistula formation, hematoma formation, infection, erosion, and extrusion.

87. At the time the Defendants' initial design, manufacture, marketing, and sale of the Ethicon Proceed, a feasible, alternative safer design for the Ethicon Proceed was known and available, including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

88. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Ethicon Proceed, including before Plaintiff's hernia surgery, Defendants

had the ability to eliminate the unsafe character of the Ethicon Proceed without impairing its usefulness.

89. Had the Defendants properly and adequately tested the Ethicon Proceed, they would have discovered that the ORC layer was ineffective at preventing adhesion formation to the polypropylene; multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene was too weak; and that these defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, a pronounced foreign body response, among other complications.

90. The Ethicon Proceed, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, were therefore defective in design for formulation in that, when it left Defendants, the foreseeable risk of harm form the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

91. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings or the Ethicon Proceed, Plaintiffs have sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

92. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq (hereinafter "NJ PLA").

COUNT II: STRICT PRODUCTS LIABILITY – FAILURE TO WARN UNDER NJ PLA

94. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

95. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Ethicon Proceed; and directly advertised or marketed the product to the FDA, health care professionals, and consumers, including Plaintiff. Therefore, Defendants had a duty to warn of the risks associated with the use of the Ethicon Proceed.

96. Defendants distributed and sold the Ethicon Proceed in its original form of manufacture, which included the defects described in this Complaint.

97. The Ethicon Proceed was expected to and did reach Plaintiff and her implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

98. Each Ethicon Proceed designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants, was in a dangerous and defective condition and posed a threat to any user or consumer.

99. At all material times, Plaintiff was a person Defendants should have considered to be subject to the harm caused by the defective nature of the Ethicon Proceed.

100. The Ethicon Proceed was implanted in Plaintiff, and used in a manner for which it was intended.

101. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

102. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting physician, of the true risks of the Ethicon Proceed, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ complications,

hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

103. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Ethicon Proceed. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Ethicon Proceed, or no consumer, including Plaintiff, would have purchased and/or consented to the use of the Ethicon Proceed.

104. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Proceed.

105. The Ethicon Proceed, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Ethicon Proceed and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Ethicon Proceed.

106. The Ethicon Proceed, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Ethicon Proceed resulting in revision surgery, although Defendants knew of a safer alternative design including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

107. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

108. Plaintiff and her physician used the Ethicon Proceed for its intended purpose, *i.e.*, hernia repair.

109. Plaintiff could not have discovered any defect in the Ethicon Proceed through the exercise of due care.

110. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

111. Neither Plaintiff, nor her implanting physician had substantially the same knowledge about the Ethicon Proceed as Defendants.

112. Defendants reasonably should have known the Ethicon Proceed was unsuitable to repair a hernia defect in patients like Plaintiff.

113. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct, Plaintiff, has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages, as set forth in this Complaint.

114. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT UNDER NJ PLA

115. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

116. Defendants designed, developed, manufactured, tested, packaged, advertised,

promoted, marketed, distributed, labeled and/or sold the Ethicon Proceed, in a condition which rendered it unreasonably dangerous due to it propensity to result in early failure of the device. The Ethicon Proceed was unreasonably dangerous in construction or composition.

117. The Ethicon Proceed Defendants manufacture was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from their manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Ethicon Proceed could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risk of complications and death from such further surgery, Defendants continued to market the Ethicon Proceed as a safe and effective absorbable barrier hernia mesh.

118. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

119. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

120. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to North Carolina common and statutory law.

COUNT IV: NEGLIGENCE- PURSUANT TO NJ PLA, NEW JERSEY COMMON LAW AND NORTH CAROLINA PRODUCT LIABILITY ACT

115. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

116. Although Defendants had a duty to use reasonable care in designing, testing,

inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for the Ethicon Proceed, they failed to do so.

117. Defendants knew, or in the exercise of reasonable care should have known, that the Ethicon Proceed was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff in whom the Proceed was implanted. They also knew or should have known that Plaintiff and her physicians were unaware of the dangers and defects inherent in the Ethicon Proceed.

118. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for the Ethicon Proceed, Plaintiffs suffered injuries and damages as summarized in this Complaint.

119. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

120. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to New Jersey common law.

121. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. §99B et seq.

COUNT V: BREACH OF IMPLIED WARRANTY UNDER NJ PLA AND NORTH CAROLINA COMMON AND STATUTORY LAW

115. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

116. At the time Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Ethicon Proceed for

use by Plaintiff, they knew of the intended use of the Proceed, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

117. When the Ethicon Proceed was implanted in Plaintiff to treat her hernia, the Proceed was being used for the ordinary purposes for which it was intended.

118. Plaintiff, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Proceed implanted in her.

119. Contrary to such implied warranties, the Ethicon Proceed was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Proceed was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants failed to warn of known or reasonably scientifically knowable defects in the Proceed.

120. As a direct and proximate result of the conduct of Defendants, Plaintiffs suffered the injuries and damages described in this Complaint.

121. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

122. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. §99B et seq.

123. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. § 25-2-314 et seq.

COUNT VI: BREACH OF EXPRESS WARRANTY UNDER NEW PLA AND NORTH CAROLINA COMMON AND STATUTORY LAW

124. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as

follows:

125. At all relevant times, Defendant manufactured, distributed, advertised, promoted, and sold the Ethicon Proceed.

126. At all relevant times, Defendant intended the Ethicon Proceed be used in the manner that Plaintiff in fact used it and Defendants expressly warranted in its brochures and advertising that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

127. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Ethicon Proceed. Therefore, Plaintiff was a foreseeable user of Defendants' Ethicon Proceed.

128. Plaintiff and/or her implanting physician were at all relevant times in privity with Defendants.

129. Defendants' Ethicon Proceed was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

130. Defendants breached various express warranties with respect to the Ethicon Proceed, including the following particulars:

- Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that the Ethicon Proceed was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Ethicon Proceed.

- Defendants represented to Plaintiff and her physicians and healthcare providers that their Ethicon Proceed was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Ethicon Proceed was not safer than alternatives available on the market; and
- Defendants represented to Plaintiff and her physicians and healthcare providers that the Ethicon Proceed was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Ethicon Proceed.

131. In reliance upon Defendants' express warranty, Plaintiff was implanted with Defendants' Ethicon Proceed as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

132. At the time of making such express warranties, Defendants knew or should have known that the Ethicon Proceed does not conform to these express representations because the Ethicon Proceed was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Ethicon Proceed unreasonably unsafe for its intended purpose.

133. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiffs and the public, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Ethicon Proceed.

134. Defendants breached their express warranties to Plaintiffs in that the Ethicon Proceed was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

135. As a direct and proximate result of Defendants' conduct, Plaintiffs have sustained

and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages.

136. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

137. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. §99B et seq.

138. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. § 25-2-313 et seq.

COUNT VII: PUNITIVE DAMAGES UNDER NEW JERSEY AND NORTH CAROLINA COMMON AND STATUTORY LAW, NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *et seq.*) and NEW JERSEY PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1, *et seq.*)

150. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

151. Plaintiffs are entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the Ethicon Multi-Layered Hernia Mesh and by failing to provide adequate instructions and training concerning its use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Multi-Layered Hernia Mesh, despite available information demonstrating that the Ethicon Multi-Layered Hernia Mesh lacked adequate testing, was ineffective at preventing adhesion formation of polypropylene, would significantly contract upon

implantation, would fail early, and would cause an increased and prolonged inflammatory and foreign body response, high rates of bowel complications, seromas, infections, fistulas, pain, and other harm to patients. Such risk and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Multi-Layered Hernia Mesh or provided proper training and instruction to physicians regarding use of the Ethicon Multi-Layered Hernia Mesh. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of the Ethicon Multi-Layered Hernia Mesh.

152. Defendants were or should have been in possession of evidence demonstrating that the Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, Defendants continued to market the Ethicon Multi-Layered Hernia Mesh by providing false and misleading information with regard to its safety and efficacy.

153. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Ethicon Multi-Layered Hernia Mesh, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the Ethicon Multi-Layered Hernia Mesh.

154. Defendants failed to provide adequate training, testing and instructions to physicians that could have prevented failure of the Ethicon Multi-Layered Hernia Mesh causing serious harm and suffering to patients, including Plaintiff.

155. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq. and New Jersey common law.

156. Plaintiffs are entitled to punitive damages as a result of Defendants' reckless conduct in wanton disregard of Plaintiff's safety pursuant to N.J.S.A. 2A:15-5.9, *et seq.*

157. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to any and all applicable North Carolina common law or statutes, including but not limited to N.C. Gen. Stat. § 1D-1 et seq.

COUNT VIII: LOSS OF CONSORTIUM

160. Plaintiffs incorporate the allegations in all prior paragraphs, and further allege as follows:

161. At all times material, Plaintiff, Kathleen Bednarcyk, was married to Plaintiff, William Bednarcyk. As a result of the injuries and damages sustained by Kathleen Bednarcyk, William Bednarcyk, has suffered the loss of care, comfort, society and affections from Mrs. Bednarcyk.

162. Defendants are strictly liable in tort to Plaintiffs for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

163. Defendants are liable in tort to Plaintiffs for their wrongful conduct pursuant to North Carolina common and statutory law.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory damages and punitive damages, together with interest, cost of suit and attorney's fees and such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and an award of damages against Defendants, as follows:

a) special damages, to include past and future medical and incidental expenses, according to proof;

b) past and future loss of earnings and/or earning capacity, according to proof;
c) past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
d) pre-judgment and post-judgment interest;
e) the costs of this action; and
f) treble and/or punitive damages to Plaintiffs; and
g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demands a trial by jury to the full extent permitted by law.

NOTICE OF OTHER ACTIONS PURSUANT TO R. 4:5-1

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: BER-L-7065-17; Bassett v. Ethicon, Inc., et al, Docket No.: BER-L-7836-17; Gold v. Ethicon, Inc., et al, Docket No.: BER-L-8037-17; Noakes v. Ethicon, Inc., et al, Docket No.: BER-L-8276-17; Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Griffin v. Ethicon, Inc., et al, Docket No.: BER-L-8827-17; Linnenbrink v. Ethicon, Inc., et al, Docket No.: BER-L-8829-17; Campbell v. Ethicon, Inc., et al, Docket No.: BER-L-8998-17; Martin v. Ethicon, Inc., et al, Docket No.: BER-L-9127-17; Ruiz v. Ethicon, Inc., et al, Docket No.: BER-L-9130-17; Trebolo, Jr. v. Ethicon, Inc. et al, Docket No.: BER-L-9133-17; Gateley v. Ethicon, Inc., et al, Docket No.: BER-L-9151-17; Redding v. Ethicon, Inc., et al, Docket No.: BER-L-184-18; Rice v. Ethicon, Inc., et al, Docket No.: BER-L-197-18; Bean v. Ethicon, Inc., et al, Docket No.: BER-L-198-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: BER-L-207-18; Reynolds v. Ethicon, Inc., et al, Docket No.: BER-L-279-18; Smith v. Ethicon, Inc., et al, Docket No.: BER-L-652-18; Gaddis v. Ethicon, Inc., et al, Docket No.: BER-L-658-18; Clark v. Ethicon, Inc., et al, Docket No.: BER-L-691-18; Fielding v. Ethicon, Inc., et al, Docket No.: BER-L-693-18; Hollimon v. Ethicon, Inc., et al, Docket No.: BER-L-694-18; Miller v. Ethicon, Inc., et al,

Docket No.: BER-L-695-18; Moore v. Ethicon, Inc., et al, Docket No.: BER-L-697-18; Rodriguez v. Ethicon, Inc., et al, Docket No.: BER-L-699-18; Sollis v. Ethicon, Inc., et al, Docket No.: BER-L-703-18; Adams v. Ethicon, Inc., et al, Docket No.: BER-L-728-18; Crossland v. Ethicon, Inc., et al, Docket No.: BER-L-729-18; Denney v. Ethicon, Inc., et al, Docket No.: BER-L-732-18; Westerbeck v. Ethicon, Inc., et al, Docket No.: BER-L-733-18; Dollanmeyer v. Ethicon, Inc., et al, Docket No.: BER-L-774-18; Jarrell v. Ethicon, Inc., et al, Docket No.: BER-L-775-18; Jennings v. Ethicon, Inc., et al, Docket No.: BER-L-777-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-778-18; Kennedy v. Ethicon, Inc., et al, Docket No.: BER-L-779-18; McKinney v. Ethicon, Inc., et al, Docket No.: BER-L-780-18; Morgan v. Ethicon, Inc., et al, Docket No.: BER-L-781-18; Robins v. Ethicon, Inc., et al, Docket No,: BER-L-809-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Diloreto v. Ethicon, Inc., et al, Docket No.: BER-L-1018-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1052-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Gibson v. Ethicon, Inc., et al, Docket No.: BER-L-1110-18; Shackelford v. Ethicon, Inc., et al, Docket No.: BER-L-1200-18; Schriner v. Ethicon, Inc., et al, Docket No.: BER-L-1222-18; Alexander v. Ethicon, Inc., et al, Docket No.: BER-L-1241-18; Usey v. Ethicon, Inc., et al, Docket No.: BER-L-1244-18; Hart v. Ethicon, Inc., et al, Docket No.: BER-L-1349-18; Galvez v. Ethicon, Inc., et al, Docket No.: BER-L-1393-18; Lindly v. Ethicon, Inc., et al, Docket No.: BER-L-1402-18; Senkel v. Ethicon, Inc., et al, Docket No.: BER-L-1433-18; Maestas v. Ethicon, Inc., et al, Docket No.: BER-L-1456-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: BER-L-1458-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: BER-L-1466-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1479-18; Mountjoy, et al v. Ethicon,

Inc., et al, Docket No.: BER-L-1480-18; Fontenot v. Ethicon, Inc., et al, Docket No.: BER-L-1513-18; Anawaty v. Ethicon, Inc., et al, Docket No.: BER-L-1516-18; Capshaw v. Ethicon, Inc., et al, Docket No.: BER-L-1530-18; Bradford v. Ethicon, Inc., et al, Docket No.: BER-L-1806-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-2003-18; Collier v. Ethicon, Inc., et al, Docket No.: BER-L-2214-18; Williams v. Ethicon, Inc., et al, Docket No.: BER-L-2337-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-2345-18; Ward v. Ethicon, Inc., et al, Docket No.: BER-L-2353-18; Shepherd v. Ethicon, Inc., et al, Docket No.: BER-L-2354-18; Scobee v. Ethicon, Inc., et al, Docket No.: BER-L-2355-18; Wojtusiak, et al v. Ethicon, Inc., et al, Docket No.: BER-L-2456-18; Fontana v. Ethicon, Inc., et al, Docket No.: BER-L-2511-18; Hardy v. Ethicon, Inc., et al, Docket No.: BER-L-2512-18; Snyder v. Ethicon, Inc., et al, Docket No.: BER-L-2513-18; Hodge v. Ethicon, Inc., et al, Docket No.: BER-L-2577-18; Kruggel, et al v. Ethicon, Inc., et al, Docket No.: BER-L-2694-18; McCormick v. Ethicon, Inc., et al, Docket No.: BER-L-2856-18; Lloyd v. Ethicon, Inc., et al, Docket No.: BER-L-2952-18; and Benton, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3317-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Martin, Ruiz, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Smith, Gaddis, Clark, Fielding, Hollimon, Miller, Moore, Rodriguez, Sollis, Adams, Crossland, Denney, Westerbeck, Dollanmeyer, Jarrell, Jennings, Johnson, Kennedy, McKinney, Morgan, Robins, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, Wojtusiak, Fontana, Hardy, Snyder, Hodge, Kruggel, McCormick, Lloyd, and Benton cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no

other parties who shall be joined in this action at this time.

CERTIFICATION PURSUANT TO R. 1:38-7(c)

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

TRIAL COUNSEL DESIGNATION

Please take notice that pursuant to the provisions of R 4:25-4, Tobias L. Millrood is hereby designated as trial counsel on behalf of Plaintiff.

SANDERS PHILLIPS GROSSMAN, LLC

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Dated: November 29, 2018

SUMMONS

Attorney(s) Marc Grossman
Office Address 100 Garden City Plaza, Suite 500
Town, State, Zip Code Garden City, NY 11530

Telephone Number (516) 741-5600
Attorney(s) for Plaintiff Kathleen Bednarcyk, et al.

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

Kathleen Bednarcyk, et al.
Plaintiff(s)

vs.
Ethicon, Inc.

Defendant(s)

CIVIL ACTION SUMMONS

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.

/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 11/30/2018

Name of Defendant to Be Served: Ethicon, Inc.

Address of Defendant to Be Served: Route 22 West, Somerville, NJ 08876

SUMMONS

Attorney(s) Marc Grossman
Office Address 100 Garden City Plaza, Suite 500
Town, State, Zip Code Garden City, NY 11530

Telephone Number (516) 741-5600
Attorney(s) for Plaintiff Kathleen Bednarcyk, et al.

Superior Court of New Jersey

Middlesex County
Civil Law Division
Docket No:

Kathleen Bednarcyk et al.
Plaintiff(s)

vs.

Johnson & Johnson, et al.

Defendant(s)

CIVIL ACTION SUMMONS

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at http://www.njcourts.gov/forms/10153_deptyclerklawref.pdf.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

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/s/ Michelle M. Smith
Clerk of the Superior Court

DATED: 11/30/2018

Name of Defendant to Be Served: Johnson & Johnson

Address of Defendant to Be Served: One Johnson & Johnson Plaza, New Brunswick, New Jersey

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-007975-18

Case Caption: BEDNARCYK KATHLEEN VS ETHICON, INC.
Case Initiation Date: 11/30/2018
Attorney Name: MARC DAVID GROSSMAN
Firm Name: SANDERS PHILLIPS GROSSMAN, LLC
Address: 100 GARDEN CITY PLAZA, STE 500
GARDEN CITY NY 11530
Phone:
Name of Party: PLAINTIFF : Bednarcyk, Kathleen
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? YES
Is this a professional malpractice case? YES
Related cases pending: YES
If yes, list docket numbers: See notice of related cases.
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE
CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

11/30/2018
Dated

/s/ MARC DAVID GROSSMAN
Signed

EXHIBIT H

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
JOSHUA S. KINCANNON, ESQ.
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Robert E. Price, Esquire *(Pro Hac Vice to be filed)*
FL Attorney ID No.: 85284
A. Renee Preston, Esquire *(Pro Hac Vice to be filed)*
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rpreston@levinlaw.com
Attorneys for Plaintiff Debi Wetch

DEBI WETCH,

Plaintiff,

v.

JOHNSON & JOHNSON and ETHICON, INC.;

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
BERGEN COUNTY
DOCKET NO.: BER-L-6494-18

CIVIL ACTION

SUMMONS

From The State of New Jersey To The Defendant(s) Named Above:

JOHNSON & JOHNSON

The plaintiff, named above, have filed a lawsuit against you in the Superior Court of New Jersey. The Complaint attached to this Summons states the basis for this lawsuit. If you dispute this Complaint, you or your attorney must file a written Answer or Motion and proof of service with the Deputy Clerk of the Superior Court in the County listed above within 35 days from the date you received this Summons, not counting the date you received it. (A directory of the addresses of each Deputy Clerk of the Superior Court is available in the Civil Division Management Office in the County listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf. If the Complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer,

State of New Jersey and a completed Case Information Statement (available from the Deputy Clerk of the Superior Court) must accompany your Answer or Motion when it is filed. You must also send a copy of your Answer or Motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written Answer or Motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

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If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf.

/s/ Michelle M. Smith
Clerk, Superior Court of NJ

Dated: September 12, 2018

Name of defendant to be served: JOHNSON & JOHNSON
Registered Agent: Johnson & Johnson

Address of the Defendant to be served: 1 Johnson & Johnson Plaza
New Brunswick, NJ 08933.

Revised November 14, 2014, CN 10792-English (Appendix XII-A)
Note: Adopted July 13, 1994, effective September 1, 1994; amended June 28, 1996, effective September 1, 1996; address/phone information updated July 1, 1999, effective September 1, 1999; amended July 12, 2002 to be effective September 3, 2002; amended July 27, 2006 to be effective September 1, 2006; address/phone information updated October 10, 2006 to be effective immediately; address/phone information updated November 1, 2006 to be effective immediately; address/phone information updated November 17, 2006 to be effective immediately; amended July 23, 2010 to be effective September 1, 2010; amended and Directory of Superior Court Deputy Clerk's Offices, County Lawyer Referral, and Legal Services Offices deleted July 19, 2012 to be effective September 4, 2012.

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
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rprice@levinlaw.com
rpreston@levinlaw.com
Attorneys for Plaintiff Debi Wetch

DEBI WETCH, Plaintiff, v. **JOHNSON & JOHNSON and ETHICON, INC.;** Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY DOCKET NO.: BER-L-6494-18 CIVIL ACTION **SUMMONS**

From The State of New Jersey To The Defendant(s) Named Above:

ETHICON, INC.

The plaintiff, named above, have filed a lawsuit against you in the Superior Court of New Jersey. The Complaint attached to this Summons states the basis for this lawsuit. If you dispute this Complaint, you or your attorney must file a written Answer or Motion and proof of service with the Deputy Clerk of the Superior Court in the County listed above within 35 days from the date you received this Summons, not counting the date you received it. (A directory of the addresses of each Deputy Clerk of the Superior Court is available in the Civil Division Management Office in the County listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf. If the Complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer,

State of New Jersey and a completed Case Information Statement (available from the Deputy Clerk of the Superior Court) must accompany your Answer or Motion when it is filed. You must also send a copy of your Answer or Motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written Answer or Motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

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/s/ Michelle M. Smith
Clerk, Superior Court of NJ

Dated: September 12, 2018

Name of defendant to be served: ETHICON, INC.
Registered Agent: Johnson & Johnson

Address of the Defendant to be served: 1 Johnson & Johnson Plaza
New Brunswick, NJ 08933.

Revised November 14, 2014, CN 10792-English (Appendix XII-A)
Note: Adopted July 13, 1994, effective September 1, 1994; amended June 28, 1996, effective September 1, 1996; address/phone information updated July 1, 1999, effective September 1, 1999; amended July 12, 2002 to be effective September 3, 2002; amended July 27, 2006 to be effective September 1, 2006; address/phone information updated October 10, 2006 to be effective immediately; address/phone information updated November 1, 2006 to be effective immediately; address/phone information updated November 17, 2006 to be effective immediately; amended July 23, 2010 to be effective September 1, 2010; amended and Directory of Superior Court Deputy Clerk's Offices, County Lawyer Referral, and Legal Services Offices deleted July 19, 2012 to be effective September 4, 2012.

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
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rpreston@levinlaw.com
Attorney for Plaintiff Debi Wetch

DEBI WETCH, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION BERGEN COUNTY Docket No.: **CIVIL ACTION** **COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Debi Wetch, by and through her counsel, hereby sues JOHNSON & JOHNSON ("J&J"), a New Jersey corporation; and ETHICON, INC. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is an action for strict products liability, failure to warn, defective design, brought by Plaintiff Debi Wetch for injuries arising out of the Proceed Surgical Mesh ("Proceed" or "Ethicon Multi-Layered Hernia Mesh").

Date Served: 10/1/18
Company Served: Ethicon Inc, J&J

Personal Service MD

2. Defendant Ethicon manufactured and supplied to doctors a multi-layered hernia mesh known as the Proceed Surgical Mesh.

3. The Ethicon Multi-Layered Hernia Mesh created an unreasonable risk of harm to Debi Wetch.

4. The unreasonable risk of pain, dense adhesion formation, bowel complications, mesh shrinkage, hernia recurrence, seroma and fistula formation, and infection, whether from a prolonged and pronounced inflammatory response caused by the multiple layers, degradation of polymers due to exposure to gamma irradiation, non-conforming subcomponents, or some other mechanism, renders the Ethicon Multi-Layered Hernia Mesh a defective product.

5. The selection and implantation of the Ethicon Multi-Layered Hernia Mesh by Debi Wetch's surgeon was a result of the misinformation, marketing, sales, promotion and direction by Ethicon.

JURISDICTION & VENUE

6. This is a lawsuit over defective hernia mesh designed, marketed, manufactured, promoted and sold within New Jersey and the United States by Defendant Ethicon and its parent company J&J.

7. Debi Wetch currently resides in Pittsburg, California and is a citizen and resident ofCalifornia. Plaintiff underwent hernia repair surgery on April 12, 2010 inDelta Medical Center in Antioch, California. At that time, the Ethicon Multi-Layered Hernia Mesh product that Defendants manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Debi Wetch's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hernia surgery.

8. Defendant J&J is a corporation incorporated in New Jersey, and according to its

website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

9. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Proceed Surgical Mesh, the hernia repair product at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by Defendant J&J and include Ethicon, Inc.

10. Defendant Ethicon is a wholly owned subsidiary of Defendant J&J. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Defendants conduct business in every county in New Jersey.

11. Defendant Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Ethicon Multi-Layered Hernia Mesh.

12. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Ethicon Multi-Layered Hernia Mesh.

13. At all relevant times, Defendants either directly, or through their agents, apparent agents, servants or employees sold, distributed and marketed the defective Ethicon Multi-Layered

Hernia Mesh in the State of New Jersey. Defendants derive substantial revenue from hernia mesh products used or implanted in the State of New Jersey. As such, Defendants expected or should have expected that their business activities could or would subject them to legal action in the State of New Jersey.

14. All Defendants were also involved in the business of monitoring and reporting adverse events concerning the Ethicon Multi-Layered Hernia Mesh, and having a role in the decision process and response of Defendants, if any, related to these adverse events.

15. The Ethicon Multi-Layered Hernia Mesh Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial and not isolated business activity within the State of New Jersey, Bergen County.

b. Defendants' hernia mesh products, including the subject Proceed Surgical Mesh, were designed, manufactured, and placed into the stream of commerce in the State of New Jersey by Defendants.

c. Defendants maintain an office or agency within the State of New Jersey.

d. Upon information and belief, at all relevant times, Defendants committed tortious acts within the State of New Jersey out of which these causes of action arise.

16. At all times relevant hereto, the Defendants developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Ethicon Multi-Layered Hernia Mesh throughout the United States, including within the State of New Jersey and specifically to Debi Wetch's implanting physician or her practice group, or to the hospital where the Ethicon Multi-Layered Hernia Mesh was implanted.

17. Plaintiff Debi Wetch has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal

question. Defendants J&J and Ethicon are both New Jersey corporations and both maintained their principal place of business in New Jersey. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

18. Defendants designed, manufactured, fabricated, marketed, packaged, advertised, and sold the Ethicon Multi-Layered Hernia Mesh throughout the world, including in Bergen County, State of New Jersey.

19. Ethicon knowingly markets to, and derives income from, patients in the State of New Jersey from the sale of Ethicon Multi-Layered Hernia Mesh.

20. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and cost.

PROCEED HISTORY

21. Defendants were the designers, manufacturers, marketers, distributors and suppliers of the Ethicon Proceed Surgical Mesh at all material times.

22. Defendants warranted the Ethicon Multi-Layered Hernia Mesh and placed the device into the United States stream of commerce.

23. Defendants knew that the oxidized regenerated cellulose layer of the Ethicon Multi-Layered Hernia Mesh was ineffective at preventing adhesion formation to the underlying polypropylene of the Proceed before the Defendants set out to design the Proceed Surgical Mesh in 2003.

24. Before 2003, Defendants were aware that the Oxidized Regenerated Cellulose utilized in the Ethicon Multi-Layered Hernia Mesh had pores which were too large to prevent adhesion formation.

25. Before 2003, Defendants were aware that increased adhesion formation would

result in increased mesh shrinkage.

26. Before 2003, Defendants were aware that Oxidized Regenerated Cellulose would result in dense adhesions in the presence of blood or fibrinous exudate.

27. Before 2003, Defendants were aware that polypropylene elicits a chronic, life-long inflammatory response that is accompanied by exudation of fibrinogen.

28. Before 2003, Defendants were aware that any exposure to gamma irradiation would weaken and embrittle the polypropylene of the Ethicon Multi-Layered Hernia Mesh.

29. Before placing the Ethicon Multi-Layered Hernia Mesh on the market, Defendants were required to mitigate risks of the product, including any element of design or sterilization which could render the device ineffective, weaken the structural integrity of the device, or increase or prolong inflammation once the device is implanted, which would result in an increase in adhesion formation, mesh shrinkage, pain, bowel complications, hernia recurrence, and/or the need for early surgical revision in patients-consumers.

30. Defendants designed, manufactured, and marketed the Ethicon Multi-Layered Hernia Mesh, despite long-standing knowledge that the materials utilized in the Proceed would cause dense adhesions, chronic pain, mesh shrinkage, bowel obstructions, and early hernia recurrence.

31. Defendants sterilize the Ethicon Multi-Layered Hernia Mesh with gamma irradiation, despite long-standing knowledge that polypropylene will degrade and embrittle if exposed to any amount of gamma irradiation.

32. The Ethicon Multi-Layered Hernia Mesh is made of the following, starting with the component which would be placed closest to the bowel of the patient-consumer:

- Oxidized Regenerated Cellulose (ORC) barrier layer
- Polydioxanone (PDS) film layer

- Large pore polypropylene (Prolene soft mesh)

33. Polypropylene hernia meshes are traditionally sterilized with ethylene oxide.

34. The ORC layer of the Ethicon Multi-Layered Hernia Mesh will react and degrade in the presence of ethylene oxide.

35. Defendants sterilize the Ethicon Multi-Layered Hernia Mesh with gamma irradiation.

36. Gamma irradiation degrades, weakens, and embrittles the polypropylene base of the Ethicon Multi-Layered Hernia Mesh.

37. Decades prior to the release of the Ethicon Multi-Layered Hernia Mesh, Defendants were aware that polypropylene degrades, weakens, and embrittles when exposed to gamma irradiation.[1]

38. The embrittled polypropylene of the Ethicon Multi-Layered Hernia Mesh increases the propensity of the polypropylene to tear away from the securing devices, such as sutures or tacks.

39. The polypropylene base is the only permanent, non-resorbable portion or the Ethicon Multi-Layered Hernia Mesh.

40. Defendants designed, manufactured, promoted, sold and/or marketed the Ethicon Multi-Layered Hernia Mesh to be utilized in anyone with a soft tissue defect, including, but not limited to: "infants, children, pregnant women, or women planning pregnancies..."[2]

41. For decades, there were concerns in the medical community about severe complications if polypropylene was placed too close to the bowel or other underlying organs, due

[1] U.S. Patent No. 3,943,933 (Issued Mar. 16, 1976).
[2] Proceed Surgical Mesh Instructions for Use, Status 04/2010.

to the formation of dense adhesions to the polypropylene.

42. Defendants were aware that the ORC layer utilized in the Ethicon Multi-Layered Hernia Mesh was ineffective at preventing adhesion formation to polypropylene over a decade before Defendants brought the Ethicon Multi-Layered Hernia Mesh to market.[3]

43. Despite significant evidence to contrary, Defendants marketed the Ethicon Multi-Layered Hernia Mesh and its ORC layer as a tissue separating barrier that would prevent adhesion formation from the underlying polypropylene to any nearby organs.

FAILURE TO WARN PHYSICIANS OF THE DANGERS ASSOCIATED WITH ETHICON MULTI-LAYERED HERNIA MESH

44. Defendants marketed the Ethicon Multi-Layered Hernia Mesh to general surgeons, hospitals, and group purchasing organizations (GPOs), rather than end-user patients.

45. Defendants had the ability to inform surgeons, hospitals, or GPOs of developing problems or defects in its devices through e-mail, letter, recalls, warnings in product inserts, and/or through its product representatives, who work directly with the surgeon.

46. The multiple layers of the Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response. That response in turn increases dense adhesion formation from underlying organs to the Ethicon Proceed, resulting in bowel complications, mesh contracture, hernia recurrence, increased foreign body reaction, chronic severe pain, and more.

47. Defendants state in the Proceed IFU that "The PROLENE Soft Mesh component is constructed of knitted filaments of extruded polypropylene identical in composition to that used in PROLENE Polypropylene Suture, Nonabsorbable Surgical Suture, U.S.P." This statement is false,

[3] Robert J. Fitzgibbons, Jr., M.D. et al., *A Laparoscopic Intraperitoneal Onlay Mesh Technique for the Repair of an Indirect Inguinal Hernia*, 219-2 ANNALS OF SURGERY 114 (1994).

or at very least misleading, as the Proceed undergoes gamma irradiation that changes the composition of the polypropylene.

48. Defendants also state in the Proceed IFU that the polypropylene material "when used as a suture, has been reported to be nonreactive and to retain its strength indefinitely in clinical use. The PROLENE Soft Mesh affords excellent strength, durability and surgical adaptability, with a porous structure to enable mesh incorporation into surrounding tissues." This statement is false, or at very least misleading, as Defendants are aware that the Ethicon Proceed is reactive and does not retain its strength. Furthermore, Defendants are aware of reports that the small polypropylene sutures do elicit a small reaction, and increasing amounts of polypropylene greatly increase such reaction. The very reason the Defendants added the ORC layer to the Prolene Soft Mesh was to protect organs from reacting with the polypropylene of the Prolene Soft Mesh.

49. The Proceed IFU has a section for contraindications, which list "None known."

50. The Proceed IFU has a section for adverse reactions, which list "Potential adverse reactions are those typically associated with surgically implantable materials..." The polypropylene base of the Ethicon Multi-Layered Hernia Mesh carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of the Ethicon Multi-Layered Hernia Mesh further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation, fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

51. Defendants failed to warn that the Ethicon Multi-Layered Hernia Mesh will elicit a fibrinous exudate.

52. Defendants failed to warn that the Ethicon Multi-Layered Hernia Mesh creates a

solid barrier preventing the body from adequately clearing or transporting fluid, which results in seroma formation, potentiating infections and fistula formation.

53. Defendants never performed any clinical trials and/or studies prior to marketing the Ethicon Multi-Layered Hernia Mesh.

54. Defendants did not fully and/or adequately test the configuration of this new, multi-layered hernia mesh, designed with ORC, polypropylene, and PDS, that was implanted into Plaintiff Debi Wetch.

55. Defendants continue to market the Ethicon Multi-Layered Hernia Mesh without warning of the massive mesh shrinkage or the necessary overlap to prevent early hernia recurrence due to mesh shrinkage.

56. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from Defendants' physician/technical consultants, and/or through industry targeted promotional materials.

57. Despite these reassurances, the defective design and manufacture of the Ethicon Multi-Layered Hernia Mesh continued to elicit severe and chronic inflammatory responses, resulting in adhesion formation, bowel injuries, mesh contracture, pain, hernia recurrence, infections, seromas, fistulas, erosion, extrusion, and additional complications.

58. Defendants were aware that the ORC layer was ineffective at preventing adhesions to the polypropylene; gamma irradiation would weaken the polypropylene; and the multi-layered mesh would contract massively over time. Nonetheless, Defendants employed the design in its Ethicon Multi-Layered Hernia Mesh in a reckless disregard for the safety of patients, including Plaintiff Debi Wetch.

59. Moreover, despite direct knowledge of significant adverse events reported by

patients and physicians, as well as awareness of failures that have been reported in literature and published clinical trials, Defendants have continued to market the Ethicon Multi-Layered Hernia Mesh as being safe and effective for hernia repair.

60. From the time that Defendants first began selling the Ethicon Multi-Layered Hernia Mesh in the United States through today, product labeling and product information failed to contain adequate information, instructions, and warnings concerning the following: implantation of the Proceed, specifically its propensity to massively shrink, the increased in duration and intensity of inflammation, and the elevated rate of adhesions, bowel complications, chronic pain, hernia recurrence, seroma formation, hematoma formation, fistula formation, erosion, extrusion, infection, and other injuries that occur at a higher rate than other surgically implanted devices.

USE OF THE PRODUCT

61. A defectively designed, manufactured and marketed Ethicon Multi-Layered Hernia Mesh left the hands of Defendants in its defective condition and was delivered into the stream of commerce. Dr. Bobby Glickman implanted the Proceed Surgical Mesh in Debi Wetch's abdomen to repair a ventral hernia on or about April 12, 2010 at Delta Medical Center in Antioch, California. Debi Wetch was implanted with a 15cm x 20cm Proceed Surgical Mesh, Model No. PCDG1.

62. As a direct and proximate result of Defendants' defective design, manufacture, marketing, distribution, and/or sale of the Ethicon Multi-Layered Hernia Mesh and placing the defective product into the stream of commerce, Plaintiff Debi Wetch has been injured and damaged as follows:

a. On or about January 9, 2017, Debi Wetch underwent removal of the Ethicon Proceed at Delta Medical Center, by Dr. Joseph Brandl. Upon visualizing the Ethicon Proceed, the surgeon found that the mesh had grown directly into the bowel as there was a tangled mass of small bowel directly underlying the mesh. The

surgeon noted that it was difficult to peel the various fragments of the mesh off of the bowel, which adhesions caused a serosal tear. He removed "as much of the mesh as could be mobilized." The surgeon diagnosed Debi Wetch with a small-bowel obstruction secondary to extensive adhesions of her mesh.

b. Debi Wetch experienced and/or continues to experience severe pain, nausea, diarrhea, loss of appetite, chills and inflammation, which have impaired her activities of daily living

c. Debi Wetch continues to suffer complications as a result of her implantation with the Ethicon Proceed.

d. Debi Wetch is at a higher risk of severe complications during an abdominal surgery, to the extent that future abdominal operations might not be feasible.

63. The mechanism of failure in Debi Wetch's device was a mechanism of failure that Defendants had marketed and warranted would not occur because of the Ethicon Multi-Layered Hernia Mesh design and composition. It was also the same failure mechanism that the medical and scientific community had been studying and documenting since the 1990s, *i.e.,* ORC was ineffective at preventing adhesions to polypropylene, and polypropylene contracts when dense adhesions form to it.

64. Moreover, the symptoms and findings associated with Ethicon Multi-Layered Hernia Mesh product failures that have been reported in the literature are identical to those Debi Wetch suffered.

65. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings of the defective Ethicon Multi-Layered Hernia Mesh, Debi Wetch has suffered and continues to suffer both injuries and damages, including, but not limited to: past, present and future physical and mental pain and suffering; physical disability, and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses, and other related damages.

THE FDA'S 510(k) CLEARANCE PROCESS

66. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

67. No clinical testing is required under this process.

68. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

69. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

70. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

71. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

72. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and

effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

73. Defendants cleared the Ethicon Proceed Surgical Mesh, and its related components, under the 510(k) Premarket Notification. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by the FDA. Instead, the device was supposed to demonstrate substantial equivalence to a predicate medical device.

74. On June 18, 2002, the Food and Drug Administration issued a document titled "Guidance for Resorbable Adhesion Barrier Devices for Use in abdominal and/or Pelvic Surgery; Guidance for Industry." The 26 page document starts by explaining:

> **FDA has determined that the resorbable adhesion barrier is a significant risk device as defined in 21 CFR 812.3(m)(4). The resorbable adhesion barrier is a class III device which is subject to premarket approval in accordance with section 515 of the Federal Food, Drug, and Cosmetics (FD&C) Act.**

75. The Proceed Surgical Mesh did not undergo premarket approval, but instead received 510(k) clearance on or about September 17, 2003. The only predicate device listed on the 510(k) application is the Prolene Soft Polypropylene Mesh, a non-barrier hernia mesh. Defendants did not claim that the Proceed Surgical Mesh was a resorbable adhesions barrier in their 510(k) application. However, after 510(k) clearance, Defendants marketed the Proceed Surgical Mesh as a resorbable adhesion barrier.

76. Defendants applied for 510(k) clearance for the Proceed Surgical Mesh again in May of 2006. The only predicate device listed on the 510(k) application is the prior Proceed

Surgical Mesh. In this 510(k) application, Defendants did not claim the intended use of the Proceed was a resorbable adhesion barrier; however, in the device description Defendants note that the "ORC side provides a bioresorbable layer that physically separates the polypropylene mesh from underlying tissue and organ surfaces during the wound-healing period to minimize tissue attachment to the mesh." Defendants continued to market the Proceed Surgical Mesh as a resorbable adhesion barrier.

CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW

COUNT I: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1, et seq.)

77. Plaintiff Debi Wetch incorporates herein by reference the allegations in all prior paragraphs and further alleges as follows:

78. Defendants had a duty to design and manufacture, distribute, market, promote and sell, the Ethicon Multi-Layered Hernia Mesh so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

79. In and before 2003, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling hernia mesh implants and did design, manufacture, distribute, market and sell the Ethicon Multi-Layered Hernia Mesh.

80. Defendants expected the Ethicon Multi-Layered Hernia Mesh Devices they were manufacturing, selling, distributing, supplying, and/or promoting to reach, and they did in fact reach, implanting physicians and consumers in the State of New Jersey and the United States, including Plaintiff Debi Wetch and her implanting physician, without substantial change in their condition.

81. At the time the Ethicon Multi-Layered Hernia Mesh left Defendants' possession and the time the Ethicon Proceed entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to the following:

- the Ethicon Multi-Layered Hernia Mesh was not reasonably safe as intended to be used;
- the Ethicon Multi-Layered Hernia Mesh had an inadequate design for the purpose of hernia repair;
- the Ethicon Multi-Layered Hernia Mesh contained unreasonably dangerous design defects, including a large pore ORC layer that is ineffective at preventing adhesion formation to the underlying polypropylene;
- the Ethicon Multi-Layered Hernia Mesh is unreasonably dangerous, due to the degraded state of the polypropylene utilized, which has been exposed to gamma irradiation;
- the Ethicon Multi-Layered Hernia Mesh contained unreasonably dangerous design defects, utilizing multiple layers, which increases and prolongs the inflammatory response;
- the Ethicon Multi-Layered Hernia Mesh was not appropriately or adequately tested before distribution; and
- the Ethicon Multi-Layered Hernia Mesh had an unreasonably high propensity for adhesion formation, mesh contracture, hernia recurrence, chronic pain, bowel complications, seroma formation, fistula formation, hematoma formation, infection, erosion, and extrusion.

82. At the time the Defendants' initial design, manufacture, marketing, and sale of the Ethicon Multi-Layered Hernia Mesh, a feasible, alternative safer design for the Ethicon Proceed was known and available, including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

83. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Ethicon Multi-Layered Hernia Mesh, including before Debi Wetch's hernia surgery, Defendants had the ability to eliminate the unsafe character of the Ethicon Multi-Layered Hernia Mesh without impairing its usefulness.

84. Had the Defendants properly and adequately tested the Ethicon Multi-Layered Hernia Mesh, they would have discovered that the ORC layer was ineffective at preventing adhesion formation to the polypropylene; multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene was too weak; and that these defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, a pronounced foreign body response, among other complications.

85. The Ethicon Multi-Layered Hernia Mesh, manufactured, supplied, distributed, marketed, promoted and sold by Defendants, were therefore defective in design for formulation in that, when it left Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

86. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings or the Ethicon Multi-Layered Hernia Mesh, Plaintiff Debi Wetch has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

87. Defendants are strictly liable in tort to Plaintiff Debi Wetch for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

COUNT II: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-1, et seq.)

88. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

89. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Ethicon Multi-Layered Hernia Mesh; and directly advertised or marketed the product to the FDA, health care professionals, and consumers, including Plaintiff Debi Wetch. Therefore, Defendants had a duty to warn of the risks associated with the use of the Ethicon Multi-Layered Hernia Mesh.

90. Defendants distributed and sold the Ethicon Multi-Layered Hernia Mesh in their original form of manufacture, which included the defects described herein.

91. The Ethicon Multi-Layered Hernia Mesh was expected to and did reach Plaintiff Debi Wetch and her implanting physician, without substantial change or adjustment in its condition as manufactured and sold by Defendants.

92. Each Ethicon Multi-Layered Hernia Mesh designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce by Defendants, was in a dangerous and defective condition and posed a threat to any user or consumer.

93. At all material times, Plaintiff Debi Wetch was the person the Defendants should have considered to be subject to the harm caused by the defective nature of the Ethicon Multi-Layered Hernia Mesh.

94. The Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch and used in a manner for which it was intended.

95. This use has resulted in severe physical, financial, emotional and other injuries to Plaintiff Debi Wetch.

96. Defendants failed to adequately warn health care professionals and the public, including Plaintiff Debi Wetch and her implanting physician, of the true risks of the Ethicon Multi-Layered Hernia Mesh, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

97. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Ethicon Multi-Layered Hernia Mesh. Had they done so, proper warnings would have been heeded and no health care professional, including Debi Wetch's physician, would have used the Ethicon Multi-Layered Hernia Mesh, or no consumer, including Debi Wetch, would have purchased and/or consented to the use of the Ethicon Multi-Layered Hernia Mesh.

98. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Multi-Layered Hernia Mesh.

99. The Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Ethicon Multi-Layered Hernia Mesh and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and

the consuming public, including Plaintiff Debi Wetch, and continued to aggressively promote the Ethicon Multi-Layered Hernia Mesh.

100. The Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Ethicon Proceed resulting in revision surgery, although Defendants knew of a safer alternative design including, but not limited to, a flat, non-coated, single-layer mesh placed away from the bowel.

101. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

102. Plaintiff Debi Wetch and her physician used the Ethicon Multi-Layered Hernia Mesh for its intended purpose, *i.e.*, hernia repair.

103. Debi Wetch could not have discovered any defect in the Ethicon Multi-Layered Hernia Mesh through the exercise of due care.

104. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

105. Neither Plaintiff Debi Wetch nor her implanting physician had substantially the same knowledge about the Ethicon Multi-Layered Hernia Mesh as Defendants.

106. Defendants reasonably should have known the Ethicon Multi-Layered Hernia Mesh was unsuited to repair a hernia in Plaintiff Debi Wetch.

107. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct, Debi Wetch

has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth in this Complaint.

108. Defendants are strictly liable in tort to Plaintiff Debi Wetch for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

COUNT III: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1, et seq.)

109. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

110. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Ethicon Multi-Layered Hernia Mesh, in a condition which rendered it unreasonably dangerous due to it propensity to result in early failure of the device. The Ethicon Multi-Layered Hernia Mesh was unreasonably dangerous in construction or composition.

111. The Ethicon Multi-Layered Hernia Mesh Defendants manufacture was defective in construction or composition in that, when it left the hands of Defendants, it deviated in a material way from their manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that the Ethicon Multi-Layered Hernia Mesh could fail early in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risk of complications and death from such further surgery, Defendants continued to market the Ethicon Multi-Layered Hernia Mesh as a safe and effective absorbable barrier hernia mesh.

112. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff Debi

Wetch suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

113. Defendants are strictly liable in tort to Plaintiff Debi Wetch for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 et seq.

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF CALIFORNIA

114. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

115. Plaintiff Debi Wetch was injured outside the state of New Jersey as a result of being implanted with Ethicon Multi-Layered Hernia Mesh. To the extent the court chooses to apply the law of a state other than New Jersey, Plaintiff Debi Wetch hereby places Defendants on notice of her intention to plead and assert all claims available under the state's law applied by this Court.

COUNT IV: NEGLIGENCE-
PURSUANT TO COMMON LAW

116. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

117. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for the Ethicon Multi-Layered Hernia Mesh, they failed to do so.

118. Defendants knew, or in the exercise of reasonable care should have known, that the Ethicon Multi-Layered Hernia Mesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff Debi Wetch in whom the Ethicon Multi-Layered Hernia Mesh was implanted. They also knew or should

have known that Plaintiff Debi Wetch and her physicians were unaware of the dangers and defects inherent in the Ethicon Multi-Layered Hernia Mesh.

119. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for the Ethicon Multi-Layered Hernia Mesh, Plaintiff Debi Wetch suffered injuries and damages as summarized in this Complaint.

COUNT V: STRICT LIABILITY – DESIGN DEFECT- PURSUANT TO COMMON LAW

120. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

121. At the time the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch, the mesh product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

122. Defendants expected and intended the Ethicon Multi-Layered Hernia Mesh product to reach users such as Plaintiff Debi Wetch in the condition in which the product was sold.

123. The implantation of Ethicon Multi-Layered Hernia Mesh in Plaintiff Debi Wetch was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

124. The risks of the Ethicon Multi-Layered Hernia Mesh design significantly outweigh any benefits that Defendants contend could be associated with the design.

125. At the time the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch, it contained unreasonably dangerous design defects. Specifically, the ORC layer is

ineffective at preventing adhesion formation to the polypropylene; the multiple layers increase and prolong the inflammatory response; the mesh experiences significant contraction over time; recurrence rates are unacceptably high; the polypropylene is too weak. These defects result in bowel obstructions, seromas, fistulas, infections, erosion, extrusion, mesh contraction, and a pronounced foreign body response, among other complications.

126. At the time subsequent to Defendants' initial design and manufacture and marketing and sale of the Ethicon Multi-Layered Hernia Mesh, including before Debi Wetch's hernia surgery, Defendants had the ability to eliminate the unsafe character of the Ethicon Multi-Layered Hernia Mesh without impairing its usefulness.

127. At the time the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch, the warnings and instructions provided by Defendants for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

128. At the time the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

129. The Ethicon Multi-Layered Hernia Mesh implanted in Plaintiff Debi Wetch failed to reasonably perform as intended and had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair. Thus, it provided no benefit to her.

130. As a direct and proximate result of the defective and unreasonably dangerous condition of the Ethicon Multi-Layered Hernia Mesh, Plaintiff Debi Wetch suffered injuries and damages as summarized in this Complaint.

COUNT VI: STRICT LIABILITY- FAILURE TO WARN- PURSUANT TO COMMON LAW

131. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

132. At the time the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch, the warnings and instructions Defendants provided for the Proceed were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

133. Defendants expected and intended the Ethicon Multi-Layered Hernia Mesh to reach users such as Plaintiff Debi Wetch in the condition in which the product was sold.

134. Plaintiff Debi Wetch and her physicians were unaware of the defects and dangers of the Ethicon Multi-Layered Hernia Mesh, and were unaware of the frequency, severity, and duration of the defects and risks associated with the Proceed.

135. Defendants failed to adequately warn health care professionals and the public, including Debi Wetch and her implanting physician, of the true risks of the Ethicon Multi-Layered Hernia Mesh, which was ineffective at protecting underlying organs from adhesion formation and would contract significantly upon implantation, resulting in significant pain, bowel and other organ complications, hernia recurrence, reoperation, infections, fistulas, seromas, hematomas, erosion, extrusion, subsequent operations, and more.

136. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Ethicon Multi-Layered Hernia Mesh.

137. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

138. The Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce, was defective due to inadequate post-marketing warnings and/or instruction because Defendants knew or should have known that there was reasonable evidence of an association between the Ethicon Multi-Layered Hernia Mesh and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff Debi Wetch, and continued to aggressively promote the Ethicon Multi-Layered Hernia Mesh.

139. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with the Ethicon Multi-Layered Hernia Mesh were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

140. If Plaintiff Debi Wetch or her physician had been properly warned of the defects and dangers of Ethicon Multi-Layered Hernia Mesh, and of the frequency, severity and duration of the risks associated with the Proceed, she would not have consented to allow the Proceed to be implanted in her body, and her physician would not have implanted it in her.

141. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Debi Wetch suffered injuries and damages as summarized in this Complaint.

COUNT VII: STRICT LIABILITY- MANUFACTURING DEFECT- PURSUANT TO COMMON LAW

142. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

143. The Ethicon Multi-Layered Hernia Mesh contained a manufacturing defect when it left the possession of Defendants. The Ethicon Multi-Layered Hernia Mesh differs from their intended result and/or from other ostensibly identical units of the same product line.

144. The manufacturing defects in the Ethicon Multi-Layered Hernia Mesh were a producing cause of Plaintiff Debi Wetch's injuries and damages as specified in this Complaint.

COUNT VIII: BREACH OF IMPLIED WARRANTY

145. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

146. At the time Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Ethicon Multi-Layered Hernia Mesh for use by Plaintiff Debi Wetch, they knew of the intended use of the Proceed, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

147. When the Ethicon Multi-Layered Hernia Mesh was implanted in Plaintiff Debi Wetch to treat her hernia, the Proceed was being used for the ordinary purposes for which it was intended.

148. Plaintiff Debi Wetch, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Ethicon Multi-Layered Hernia Mesh implanted in her.

149. Contrary to such implied warranties, the Ethicon Multi-Layered Hernia Mesh was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Proceed was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants failed to warn of known or reasonably scientifically knowable defects in the Proceed.

150. As a direct and proximate result of the conduct of Defendants, Plaintiff Debi Wetch suffered the injuries and damages described in this Complaint.

COUNT IX: BREACH OF EXPRESS WARRANTY

151. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

152. At all relevant times, Defendants manufactured, distributed, advertised, promoted, and sold the Ethicon Multi-Layered Hernia Mesh.

153. At all relevant times, Defendants intended the Ethicon Multi-Layered Hernia Mesh be used in the manner that Plaintiff Debi Wetch in fact used it and Defendants expressly warranted in its brochures and advertising that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

154. At all relevant times, Defendants were aware that consumers, including Plaintiff Debi Wetch, would use the Ethicon Multi-Layered Hernia Mesh. Therefore, Plaintiff Debi Wetch was a foreseeable user of Defendants' Ethicon Multi-Layered Hernia Mesh.

155. Plaintiff Debi Wetch and/or her implanting physician were at all relevant times in privity with Defendants.

156. Defendants' Ethicon Multi-Layered Hernia Mesh was expected to reach and did in fact reach consumers, including Plaintiff Debi Wetch and her implanting physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

157. Defendants breached various express warranties with respect to the Ethicon Multi-Layered Hernia Mesh, including the following particulars:

- Defendants represented to Plaintiff Debi Wetch and her physicians and healthcare providers through their labeling, advertising marketing materials, detail persons, seminar presentations publications, notice letters, and regulatory submissions that the Ethicon Proceed was safe and fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with using the Ethicon Proceed;

- Defendants represented to Plaintiff Debi Wetch and her physicians and healthcare providers that their Ethicon Proceed was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Ethicon Proceed was not safer than alternatives available on the market; and

- Defendants represented to Plaintiff Debi Wetch and her physicians and healthcare providers that the Ethicon Proceed was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the Ethicon Proceed.

158. In reliance upon Defendants' express warranty, Plaintiff Debi Wetch was implanted with Defendants' Ethicon Multi-Layered Hernia Mesh as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

159. At the time of making such express warranties, Defendants knew or should have known that the Ethicon Multi-Layered Hernia Mesh does not conform to these express

representations because the Ethicon Multi-Layered Hernia Mesh was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Ethicon Multi-Layered Hernia Mesh unreasonably unsafe for its intended purpose.

160. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff Debi Wetch and the public, relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Ethicon Multi-Layered Hernia Mesh.

161. Defendants breached their express warranties to Plaintiff Debi Wetch in that the Ethicon Multi-Layered Hernia Mesh was not of merchantable quality, safe, and fit for its intended purpose, nor was it adequately tested.

162. As a direct and proximate result of Defendants' conduct, Plaintiff Debi Wetch has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages.

COUNT X: PUNITIVE DAMAGES

163. Plaintiff Debi Wetch incorporates the allegations in all prior paragraphs, and further alleges as follows:

164. Plaintiff Debi Wetch is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff Debi Wetch, by making false representations about the safety and efficacy of the Ethicon Multi-Layered Hernia Mesh and by failing to provide adequate instructions and training concerning its use. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Multi-Layered Hernia Mesh, despite

available information demonstrating that the Ethicon Multi-Layered Hernia Mesh lacked adequate testing, was ineffective at preventing adhesion formation of polypropylene, would significantly contract upon implantation, would fail early, and would cause an increased and prolonged inflammatory and foreign body response, high rates of bowel complications, seromas, infections, fistulas, pain, and other harm to patients. Such risk and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious and permanent side effects and risks associated with the use of the Ethicon Multi-Layered Hernia Mesh or provided proper training and instruction to physicians regarding use of the Ethicon Multi-Layered Hernia Mesh. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Debi Wetch, concerning the safety of the Ethicon Multi-Layered Hernia Mesh.

165. Defendants were or should have been in possession of evidence demonstrating that the Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, Defendants continued to market the Ethicon Multi-Layered Hernia Mesh by providing false and misleading information with regard to its safety and efficacy.

166. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Ethicon Multi-Layered Hernia Mesh, thus preventing health care professionals and consumers, including Debi Wetch, from weighing the true risks against the benefits of using the Ethicon Multi-Layered Hernia Mesh.

167. Defendants failed to provide adequate training, testing and instructions to physicians that could have prevented failure of the Ethicon Multi-Layered Hernia Mesh causing serious harm and suffering to patients, including Debi Wetch.

WHEREFORE, Debi Wetch demands judgment against Defendants for compensatory damages and punitive damages, together with interest, cost of suit and attorney's fees and such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Debi Wetch prays for judgment and an award of damages against Defendants, as follows:

a. special damages, to include past and future medical and incidental expenses, according to proof;
b. past and future loss of earnings and/or earning capacity, according to proof;
c. past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
d. pre-judgment and post-judgment interest;
e. the costs of this action; and
f. treble and/or punitive damages to Debi Wetch; and
g. granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

NOTICE OF OTHER ACTIONS PURSUANT TO R. 4:5-1

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: BER-L-7065-17; Bassett v. Ethicon, Inc., et al, Docket No.: BER-L-7836-17; Gold v. Ethicon, Inc., et al, Docket No.: BER-L-8037-17; Noakes v. Ethicon, Inc., et al, Docket No.: BER-L-8276-17; Fowler v. Ethicon, Inc., et al, Docket No.: BER-L-8572-17; Griffin v. Ethicon, Inc., et al, Docket No.: BER-L-8827-17; Linnenbrink v. Ethicon, Inc., et al, Docket No.: BER-L-8829-17; Campbell v. Ethicon, Inc., et al, Docket No.: BER-L-8998-17; Trebolo, Jr. v. Ethicon, Inc. et

al, Docket No.: BER-L-9133-17; Gateley v. Ethicon, Inc., et al, Docket No.: BER-L-9151-17; Redding v. Ethicon, Inc., et al, Docket No.: BER-L-184-18; Rice v. Ethicon, Inc., et al, Docket No.: BER-L-197-18; Bean v. Ethicon, Inc., et al, Docket No.: BER-L-198-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: BER-L-207-18; Reynolds v. Ethicon, Inc., et al, Docket No.: BER-L-279-18; Smith v. Ethicon, Inc., et al, Docket No.: BER-L-652-18; Gaddis v. Ethicon, Inc., et al, Docket No.: BER-L-658-18; Aaron v. Ethicon, Inc., et al, Docket No.: BER-L-870-18; Diloreto v. Ethicon, Inc., et al, Docket No.: BER-L-1018-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1052-18; Lang v. Ethicon, Inc., et al, Docket No.: BER-L-1067-18; Gibson v. Ethicon, Inc., et al, Docket No.: BER-L-1110-18; Shackelford v. Ethicon, Inc., et al, Docket No.: BER-L-1200-18; Lindsey v. Ethicon, Inc., et al, Docket No.: BER-L-1210-18; Mack, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1220-18; Schriner v. Ethicon, Inc., et al, Docket No.: BER-L-1222-18; Alexander v. Ethicon, Inc., et al, Docket No.: BER-L-1241-18; Usey v. Ethicon, Inc., et al, Docket No.: BER-L-1244-18; Hart v. Ethicon, Inc., et al, Docket No.: BER-L-1349-18; Galvez v. Ethicon, Inc., et al, Docket No.: BER-L-1393-18; Lindly v. Ethicon, Inc., et al, Docket No.: BER-L-1402-18; Senkel v. Ethicon, Inc., et al, Docket No.: BER-L-1433-18; Maestas v. Ethicon, Inc., et al, Docket No.: BER-L-1456-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: BER-L-1458-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: BER-L-1466-18; Lotridge v. Ethicon, Inc., et al, Docket No.: BER-L-1467-18; Dias v. Ethicon, Inc., et al, Docket No.: BER-L-1471-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1479-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: BER-L-1480-18; Fontenot v. Ethicon, Inc., et al, Docket No.: BER-L-1513-18; Anawaty v. Ethicon, Inc., et al, Docket No.: BER-L-1516-18; Capshaw v. Ethicon, Inc., et al, Docket No.: BER-L-1530-18; Briscoe v. Ethicon, Inc., et al, Docket No.: BER-L-1691-18; Smith v. Ethicon, Inc., et al, Docket No.: BER-L-1692-18; Bradford v. Ethicon, Inc.,

et al, Docket No.: BER-L-1806-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-2003-18; Collier v. Ethicon, Inc., et al, Docket No.: BER-L-2214-18; Williams v. Ethicon, Inc., et al, Docket No.: BER-L-2337-18; Miller v. Ethicon, Inc., et al, Docket No.: BER-L-2345-18; Ward v. Ethicon, Inc., et al, Docket No.: BER-L-2353-18; Shepherd v. Ethicon, Inc., et al, Docket No.: BER-L-2354-18; Scobee v. Ethicon, Inc., et al, Docket No.: BER-L-2355-18; Snyder v. Ethicon, Inc., et al, Docket No.: BER-L-2513-18; Hodge v. Ethicon, Inc., et al, Docket No.: BER-L-2577-18; Trombley v. Ethicon, Inc., et al, Docket No.: MRS-L-750-18; Lloyd v. Ethicon, Inc., et al, Docket No.: BER-L-2952-18; Henley v. Ethicon, Inc., et al, Docket No.: BER-L-3015-18; Benton, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3317-18; Jones v. Ethicon, Inc., et al, Docket No.: BER-L-3452-18; Muniz v. Ethicon, Inc., et al, Docket No.: BER-L-3516-18; Deffenbaugh v. Ethicon, Inc., et al, Docket No.: BER-L-3517-18; Clulee v. Ethicon, Inc., et al, Docket No.: BER-L-3703-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-3720-18; Garrett v. Ethicon, Inc., et al, Docket No.: BER-L-3726-18; Hecker v. Ethicon, Inc., et al, Docket No.: BER-L-3728-18; Hendrix v. Ethicon, Inc., et al, Docket No.: BER-L-3751-18; Hinn v. Ethicon, Inc., et al, Docket No.: BER-L-3753-18; Holman, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3808-18; Wolfe v. Ethicon, Inc., et al, Docket No.: BER-L-3891-18; Booth, et al v. Ethicon, Inc., et al, Docket No.: BER-L-3892-18; Jones v. Ethicon, Inc., et al, Docket No.: BER-L-3913-18; Brooks v. Ethicon, Inc., et al, Docket No.: BER-L-3916-18; Adams v. Ethicon, Inc., et al, Docket No.: BER-L-3951-18; Finotti v. Ethicon, Inc., et al, Docket No.: BER-L-3994-18; Mata v. Ethicon, Inc., et al, Docket No.: BER-L-4035-18; Darnell v. Ethicon, Inc., et al, Docket No.: BER-L-4038-18; Lynch v. Ethicon, Inc., et al, Docket No.: BER-L-4043-18; Parham v. Ethicon, Inc., et al, Docket No.: BER-L-4052-18; Tavian v. Ethicon, Inc., et al, Docket No.: BER-L-4056-18; Banks v. Ethicon, Inc., et al, Docket No.: BER-L-4077-18; Jones v. Ethicon, Inc., et al, Docket No.: BER-L-4082-18; Boston v.

Ethicon, Inc., et al, Docket No.: BER-L-4103-18; Rivas v. Ethicon, Inc., et al, Docket No.: BER-L-4113-18; Perez v. Ethicon, Inc., et al, Docket No.: BER-L-4115-18; Austin v. Ethicon, Inc., et al, Docket No.: BER-L-4204-18; Rudenauer v. Ethicon, Inc., et al, Docket No.: BER-L-4238-18; Blackistone v. Ethicon, Inc., et al, Docket No.: BER-L-4332-18; Godfrey v. Ethicon, Inc., et al, Docket No.: BER-L-4334-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: BER-L-4475-18; Soares v. Ethicon, Inc., et al, Docket No.: BER-L-4476-18; Woods v. Ethicon, Inc., et al, Docket No.: BER-L-4482-18; Perez v. Ethicon, Inc., et al, Docket No.: BER-L-4486-18; Chavira v. Ethicon, Inc., et al, Docket No.: BER-L-4489-18; Guidry v. Ethicon, Inc., et al, Docket No.: BER-L-4515-18; Newburn v. Ethicon, Inc., et al, Docket No.: BER-L-4523-18; Cordova v. Ethicon, Inc., et al, Docket No.: BER-L-4532-18; Lecza v. Ethicon, Inc., et al, Docket No.: BER-L-4559-18; Taylor v. Ethicon, Inc., et al, Docket No.: BER-L-4573-18; Lowrey v. Ethicon, Inc., et al, Docket No.: BER-L-4577-18; Wilson, et al v. Ethicon, Inc., et al, Docket No.: BER-L-4800-18; Tyler v. Ethicon, Inc., et al, Docket No.: BER-L-4884-18; Whitfield, et al v. Ethicon, Inc., et al, Docket No.: BER-L-4885-18; Smith, et al v. Ethicon, Inc., et al, Docket No.: BER-L-4913-18; Moskowitz v. Ethicon, Inc., et al, Docket No.: BER-L-5011-18; Strauss v. Ethicon, Inc., et al, Docket No.: BER-L-5248-18; Masingo v. Ethicon, Inc., et al, Docket No.: BER-L-5275-18; Vinas v. Ethicon, Inc., et al, Docket No.: BER-L-5290-18; Morrone v. Ethicon, Inc., et al, Docket No.: BER-L-5294-18; Newman v. Ethicon, Inc., et al, Docket No.: BER-L-5296-18; Strawser v. Ethicon, Inc, et al, Docket No.: BER-L-5304-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-5379-18; Harding, et al v. Ethicon, Inc., et al, Docket No.: BER-L-5382-18; Brown, et al v. Ethicon, Inc., et al, Docket No.: BER-L-5656-18; Green v. Ethicon, Inc., et al, Docket No.: BER-L-5687-18; Bolyard v. Ethicon, Inc., et al, Docket No.: BER-L-5689-18; Bovino v. Ethicon, Inc., et al, Docket No.: BER-L-5691-18; Payne v. Ethicon, Inc., et al, Docket No.: BER-L-5719-18;

Clements v. Ethicon, Inc., et al, Docket No.: BER-L-5721-18; Mosby v. Ethicon, Inc., et al, Docket No.: BER-L-5722-18; Mathews v. Ethicon, Inc., et al, Docket No.: BER-L-5723-18; Lowe v. Ethicon, Inc., et al, Docket No.: BER-L-5724-18; Gonzales v. Ethicon, Inc., et al, Docket No.: BER-L-5726-18; Abhold, et al v. Ethicon, Inc., et al, Docket No.: BER-L-5727-18; Warr v. Ethicon, Inc., et al, Docket No.: BER-L-5940-18; Ishii v. Ethicon, Inc., et al, Docket No.: BER-L-5950-18; Jacuzzi v. Ethicon, Inc., et al, Docket No.: BER-L-5952-18; McNally v. Ethicon, Inc., et al, Docket No.: BER-L-5953-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: BER-L-5954-18; Newland v. Ethicon, Inc., et al, Docket No.: BER-L-5956-18; Johnson v. Ethicon, Inc., et al, Docket No.: BER-L-5959-18; Vaughan v. Ethicon, Inc., et al, Docket No.: BER-L-5960-18; Shaw v. Ethicon, Inc., et al, Docket No.: BER-L-5962-18; Asturi v. Ethicon, Inc., et al, Docket No.: BER-L-5998-18; Brawley v. Ethicon, Inc., et al, Docket No.: BER-L-6008-18; Guy, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6030-18; Mahne, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6036-18; Pierce, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6037-18; Classen, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6162-18; Murphy v. Ethicon, Inc., et al, Docket No.: BER-L-6163-18; Thibodaux, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6164-18; Nomikos v. Ethicon, Inc., et al, Docket No.: BER-L-6211-18; Nuri, et al v. Ethicon, Inc., et al, Docket No.: BER-L-6290-18; Corgan v. Ethicon, Inc., et al, Docket No.: BER-L-6338-18; Falcon v. Ethicon, Inc., et al, Docket No.: BER-L-6342-18; Frank v. Ethicon, Inc., et al, Docket No.: BER-L-6358-18; Moore v. Ethicon, Inc., et al, Docket No.: BER-L-6367-18; Hall v. Ethicon, Inc., et al, Docket No.: BER-L-6483-18; Lyon v. Ethicon, Inc., et al, Docket No.: BER-L-6484-18; Palka v. Ethicon, Inc., et al, Docket No.: BER-L-6487-18; and Austin v. Ethicon, Inc., et al, Docket No.: BER-L-6488-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Gaddis, Aaron, Diloreto, Pikulsky,

Lang, Gibson, Shackelford, Lindsey, Mack, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Briscoe, Smith, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, Snyder, Hodge, Trombley, Lloyd, Henley, Benton, Jones, Muniz, Deffenbaugh, Clulee, Johnson, Garrett, Hecker, Hendrix, Hinn, Holman, Wolfe, Booth, Jones, Brooks, Adams, Finotti, Mata, Darnell, Lynch, Parham, Tavian, Banks, Jones, Boston, Rivas, Perez, Austin, Rudenauer, Blackistone, Godfrey, McCutcheon, Soares, Woods, Perez, Chavira, Guidry, Newburn, Cordova, Lecza, Taylor, Lowrey, Wilson, Tyler, Whitfield, Smith, Moskowitz, Strauss, Masingo, Vinas, Morrone, Newman, Strawser, Johnson, Harding, Brown, Green, Bolyard, Bovino, Payne, Clements, Mosby, Mathews, Lowe, Gonzales, Abhold, Warr, Ishii, Jacuzzi, McNally, McCutcheon, Newland, Johnson, Vaughan, Shaw, Asturi, Brawley, Guy, Mahne, Pierce, Classen, Murphy, Thibodaux, Nomikos, Corgan, Falcon, Frank, Moore, Hall, Lyon, Palka, and Austin cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

CERTIFICATION PURSUANT TO R. 1:38-7(c)

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

TRIAL COUNSEL DESIGNATION

Please take notice that pursuant to the provisions of R. 4:25-4, JOSHUA S. KINCANNON, ESQUIRE, is hereby designated as trial counsel on behalf of PLAINTIFF.

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
Attorneys for Plaintiff

/s JOSHUA S. KINCANNON
JOSHUA S. KINCANNON, ESQ.

Dated: September 7, 2018

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-006494-18

Case Caption: WETCH DEBI VS ETHICON, INC.
Case Initiation Date: 09/07/2018
Attorney Name: JOSHUA S KINCANNON
Firm Name: LOMURRO MUNSON COMER BROWN & SCHOTTLAND LLC
Address: 4 PARAGON WAY SUITE 100
FREEHOLD TWP NJ 07728
Phone:
Name of Party: PLAINTIFF : Wetch, Debi
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: Per Ravi at eCourts Help, please refer to the Notice of Other Actions paragraph for related actions
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE
CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

09/07/2018
Dated

/s/ JOSHUA S KINCANNON
Signed

BERGEN COUNTY COURTHOUSE
SUPERIOR COURT LAW DIV
BERGEN COUNTY JUSTICE CTR RM 415
HACKENSACK NJ 07601-7680

TRACK ASSIGNMENT NOTICE

COURT TELEPHONE NO. (201) 221-0700
COURT HOURS 8:30 AM - 4:30 PM

DATE: SEPTEMBER 07, 2018
RE: WETCH DEBI VS ETHICON, INC.
DOCKET: BER L -006494 18

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACK 3.

DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS FROM SERVICE ON THE FIRST DEFENDANT, WHICHEVER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED IS: HON LISA PEREZ-FRISCIA

IF YOU HAVE ANY QUESTIONS, CONTACT TEAM 004 AT: (201) 527-2600.

IF YOU BELIEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.
PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE WITH R.4:5A-2.

ATTENTION:

ATT: JOSHUA S. KINCANNON
LOMURRO MUNSON COMER BROWN &
4 PARAGON WAY
SUITE 100
FREEHOLD TWP NJ 07728

ECOURTS

EXHIBIT I

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
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Attorneys for Plaintiff Jennifer Wilson

JENNIFER WILSON, Plaintiff, v. **JOHNSON & JOHNSON and ETHICON, INC.,** Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION MIDDLESEX COUNTY DOCKET NO.: MID-L-8497-18 CIVIL ACTION **SUMMONS**

From the State of New Jersey To the Defendant(s) Named Above:

JOHNSON & JOHNSON

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The Complaint attached to this Summons states the basis for this lawsuit. If you dispute this Complaint, you or your attorney must file a written Answer or Motion and proof of service with the Deputy Clerk of the Superior Court in the County listed above within 35 days from the date you received this Summons, not counting the date you received it. (A directory of the addresses of each Deputy Clerk of the Superior Court is available in the Civil Division Management Office in the County listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf. If the Complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the Deputy Clerk of the Superior Court) must

accompany your Answer or Motion when it is filed. You must also send a copy of your Answer or Motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written Answer or Motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written Answer or Motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf.

/s/ Michelle M. Smith
Clerk, Superior Court of NJ

Dated: January 8, 2019

Name of defendant to be served: JOHNSON & JOHNSON
Registered Agent: Johnson & Johnson

Address of the Defendant to be served: 1 Johnson & Johnson Plaza
New Brunswick, NJ 08933.

Revised November 14, 2014, CN 10792-English (Appendix XII-A)
Note: Adopted July 13, 1994, effective September 1, 1994; amended June 28, 1996, effective September 1, 1996; address/phone information updated July 1, 1999, effective September 1, 1999; amended July 12, 2002 to be effective September 3, 2002; amended July 27, 2006 to be effective September 1, 2006; address/phone information updated October 10, 2006 to be effective immediately; address/phone information updated November 1, 2006 to be effective immediately; address/phone information updated November 17, 2006 to be effective immediately; amended July 23, 2010 to be effective September 1, 2010; amended and Directory of Superior Court Deputy Clerk's Offices, County Lawyer Referral, and Legal Services Offices deleted July 19, 2012 to be effective September 4, 2012.

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Attorneys for Plaintiff Jennifer Wilson

JENNIFER WILSON, Plaintiff, v. **JOHNSON & JOHNSON and ETHICON, INC.,** Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION MIDDLESEX COUNTY DOCKET NO.: MID-L-8497-18 CIVIL ACTION **SUMMONS**

From the State of New Jersey To the Defendant(s) Named Above:

ETHICON, INC.

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The Complaint attached to this Summons states the basis for this lawsuit. If you dispute this Complaint, you or your attorney must file a written Answer or Motion and proof of service with the Deputy Clerk of the Superior Court in the County listed above within 35 days from the date you received this Summons, not counting the date you received it. (A directory of the addresses of each Deputy Clerk of the Superior Court is available in the Civil Division Management Office in the County listed above and online at http://www.judiciary.state.nj.us/prose/10153_deputyclerklawref.pdf. If the Complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the Deputy Clerk of the Superior Court) must

accompany your Answer or Motion when it is filed. You must also send a copy of your Answer or Motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written Answer or Motion (with fee of $175.00 and completed Case Information Statement) if you want the court to hear your defense.

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/s/ Michelle M. Smith
Clerk, Superior Court of NJ

Dated:	January 8, 2019
Name of defendant to be served:	ETHICON, INC.
Registered Agent:	Johnson & Johnson
Address of the Defendant to be served:	1 Johnson & Johnson Plaza New Brunswick, NJ 08933.

Revised November 14, 2014, CN 10792-English (Appendix XII-A)
Note: Adopted July 13, 1994, effective September 1, 1994; amended June 28, 1996, effective September 1, 1996; address/phone information updated July 1, 1999, effective September 1, 1999; amended July 12, 2002 to be effective September 3, 2002; amended July 27, 2006 to be effective September 1, 2006; address/phone information updated October 10, 2006 to be effective immediately; address/phone information updated November 1, 2006 to be effective immediately; address/phone information updated November 17, 2006 to be effective immediately; amended July 23, 2010 to be effective September 1, 2010; amended and Directory of Superior Court Deputy Clerk's Offices, County Lawyer Referral, and Legal Services Offices deleted July 19, 2012 to be effective September 4, 2012.

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rpreston@levinlaw.com
Attorney for Plaintiff Jennifer Wilson

Date Served: 1/9/19
Company Served: J+J Ethicon
Personal Service KB

JENNIFER WILSON,

Plaintiff,

v.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO.:

CIVIL ACTION

COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Jennifer Wilson, by and through her counsel, brings this suit against Johnson & Johnson ("J&J"), a New Jersey corporation; and its wholly owned subsidiary Ethicon, Inc. ("Ethicon"), a New Jersey corporation (collectively "Defendants").

NATURE OF THE ACTION

1. This is a products liability action against Defendants J&J and Ethicon brought by Plaintiff Jennifer Wilson for injuries arising out of Defendants' Prolene (Polypropylene) Hernia

System ("**Prolene Hernia System**"), which deviates from the standard single layer mesh design by incorporating an additional layer in the hernia mesh product "Ethicon Multi-Layered Hernia Mesh."

2. Defendants J&J and Ethicon designed, manufactured, marketed, supplied, warranted, promoted, and sold to health care professionals and others, their "Ethicon Multi-Layered Hernia Mesh," a design which was used in various hernia repair devices, including the Prolene Hernia System implanted in Plaintiff Jennifer Wilson.

3. The Prolene Hernia System, which incorporates the Ethicon Multi-Layered Hernia Mesh design, created an unreasonable risk of harm to Jennifer Wilson.

4. When implanted, the unreasonable risk of injury and harm, including pain, dense adhesion formation, organ complications, mesh shrinkage, hernia recurrence, seroma and fistula formation, and infection—whether due to a prolonged and pronounced inflammatory response caused by the multiple mesh layers, degradation of polymers, non-conforming subcomponents, or some other mechanism—renders Defendants' Prolene Hernia System, an Ethicon Multi-Layered Hernia Mesh, a defective product, unsafe for its intended use.

5. The selection and implantation of the Prolene Hernia System in Jennifer Wilson by her surgeon was a result of Defendants' negligent misinformation, marketing, sales, promotion and direction.

JURISDICTION & VENUE

6. This is a lawsuit over a defective hernia mesh device, which Defendant Ethicon, Inc. and its parent company Defendant Johnson & Johnson designed, marketed, manufactured, warranted, promoted and sold within the United States, including the State of New Jersey.

7. Both Defendants conduct business in every county in the State of New Jersey.

8. Jennifer Wilson currently resides in Girard, Ohio and is a citizen and resident of Ohio.

9. Plaintiff underwent hernia repair surgery on or about January 22, 2016 at Northside Medical Center in Youngstown, Ohio. At that time, the Prolene Hernia System that Defendants designed, marketed, manufactured, promoted, distributed, and sold, and warranted as safe and effective for use, was implanted into Plaintiff Jennifer Wilson. Her implanting surgeon conformed to the accepted standard of care for hernia repair surgery.

10. Defendant J&J is a corporation incorporated in New Jersey. According to its website, J&J is the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

11. Defendant J&J organizes its subsidiary businesses into individual Business Units, which coordinate the development, manufacture, testing, marketing, promotion, training, distribution, and sale of J&J products, including its hernia repair mesh devices such as the Prolene Hernia System at issue here. The corporate structure of J&J contains three sectors: (1) medical devices and diagnostics; (2) pharmaceutical; and (3) consumer.

12. Within the medical devices and diagnostic sector are "Business Units" as well, including the "Ethicon Franchise." J&J charged the Ethicon Franchise with the design, development, promotion, marketing, testing, training, distribution and sale of the Prolene Hernia System, the hernia repair device implanted in Plaintiff Jennifer Wilson.

13. Gary Pruden, the Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, is a J&J employee. The companies comprising the Ethicon Franchise are thus controlled by Defendant Johnson & Johnson, and include Defendant Ethicon, Inc.

14. Defendant Ethicon, a wholly owned subsidiary of Defendant J&J, is a corporation incorporated in the State of New Jersey, with its principal place of business in Somerville, New Jersey.

15. Defendant Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Prolene Hernia System, which is an Ethicon Multi-Layered Hernia Mesh.

16. Either directly and/or through the actions of its subsidiary Ethicon, J&J has at all material times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Ethicon Multi-Layered Hernia Mesh, a design utilized in some of Defendants' hernia repair devices, including the Prolene Hernia System.

17. Either directly, or through their agents, apparent agents, servants or employees, Defendants at all material times sold, distributed and marketed the defective hernia repair devices in the State of New Jersey. Defendants derive substantial revenue from those products used or implanted in the State of New Jersey. Therefore, Defendants expected, or should have expected, that their business activities could or would subject them to legal action in the State of New Jersey.

18. Defendants were also involved in the business of monitoring and reporting adverse events concerning their Ethicon Multi-Layered Hernia Meshes, and having a role in the decision process and response related to any adverse events.

19. The Ethicon Multi-Layered Hernia Mesh Defendants are subject to jurisdiction within the State of New Jersey and this Court because:

a. Defendants are engaged in substantial business activity within the State of New Jersey, Middlesex County.

b. Defendants designed, manufactured, and placed into the stream of commerce their Ethicon Multi-Layered Hernia Mesh devices, including the Prolene Hernia System.

c. Defendants maintain offices within the State of New Jersey.

d. Upon information and belief, at all material times Defendants committed tortious acts within the State of New Jersey, out of which Plaintiff's causes of action arise.

20. Defendants designed, manufactured, fabricated, marketed, promoted, distributed, advertised, and sold Ethicon Multi-Layered Hernia Mesh throughout the United States and worldwide, including in Middlesex County, State of New Jersey.

21. At all material times, Defendants developed, manufactured, advertised, promoted, marketed, and distributed their defective Prolene Hernia System throughout the United States, including within the State of New Jersey; and specifically to Plaintiff Jennifer Wilson and her implanting surgeon or practice groups, or to hospitals where Defendants' product was implanted.

22. Since Defendants J&J and Ethicon are both New Jersey corporations maintaining their principal places of business in New Jersey, Plaintiff's claims and causes of action are solely state-law claims. Any reference to a federal agency, regulation or rule is stated as background information only, and does not raise a federal question. Accordingly, this Court may rightfully exercise jurisdiction, and venue is proper.

23. Defendant Ethicon knowingly markets to, and derives income from, patients across the United States, including the State of New Jersey, from the sale of Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System.

24. This is an action for damages in excess of Fifteen Thousand Dollars ($15,000.00), exclusive of interest and cost.

FACTS COMMON TO ALL COUNTS

25. The Prolene Hernia System, which was defectively designed and manufactured like other Ethicon Multi-Layered Hernia Meshes, left Defendants' hands in its defective condition and

was delivered into the stream of commerce. Dr. Peter Devito implanted the Prolene Hernia System in Plaintiff Jennifer Wilson's groin to repair a right inguinal hernia on or about January 22, 2016 at Northside Medical Center in Youngstown, Ohio. Jennifer Wilson was implanted with a size medium Prolene Hernia System, Cat# PHSM, Lot 26817-02.

26. On or about March 16, 2017, Jennifer Wilson underwent surgery to remove the migrated mesh and repair a right femoral herniorrhaphy at Northside Medical Center in Youngstown, Ohio by Dr. James Smith. Dr. Smith noted that the mesh had migrated away from the prior hernia repair site causing the Plaintiff's pain. Therefore, the mesh was explanted.

27. The mechanism of failure in Plaintiff's device was a mechanism of failure that Defendants had marketed and/or warranted would not occur because of Ethicon Multi-Layered Hernia Mesh design and composition. The implanted device that Defendants marketed and warranted (*i.e.*, the Prolene Hernia System) would not have failed but for the defective design and composition of Ethicon Multi-Layered Hernia Mesh.

28. As a direct and proximate result of Defendants' defective design, manufacturing, marketing, distribution, sale and warnings concerning the Prolene Hernia System, Plaintiff Jennifer Wilson has suffered and continues to suffer injuries and damages, including: past, present and future physical and mental pain and suffering; physical disabilities; and past, present, and future medical, hospital, rehabilitative, and pharmaceutical expenses; as well as other related damages.

29. At all material times, Defendants were the designers, manufacturers, marketers, sellers, distributors and suppliers of the Prolene Hernia System.

30. Defendants warranted the Prolene Hernia System as safe and effective for use, and placed the device into the U.S. stream of commerce.

31. The Prolene Hernia System has a unique design, which incorporates two distinct layers of polypropylene connected by a central polypropylene tube. This design is not used in any other hernia repair product sold in the United States.

32. Although Defendants represented and warranted the multi-layer polypropylene design to prevent or minimize hernia recurrence and chronic pain, the design did not do so. Instead, the multi-layer polypropylene mesh occupied two inguinal compartments instead of one, increasing the intense inflammatory and chronic foreign body response, which resulted in mesh stiffening, mesh hardening, mesh contracture, mesh deformation, mesh migration, granulomatous and/or fibrotic tissue, increased foreign body sensation, and increased chronic and debilitating pain.

33. When an implanted Prolene Hernia System fails, the complications are harder to treat. Further, its eventual explantation results in large amounts of tissue loss due to the Prolene Hernia System's occupying of two inguinal compartments.

34. The polypropylene mesh material for the Ethicon Multi-Layered Hernia Mesh, used in the Prolene Hernia System, is unreasonably susceptible to in vivo oxidative degradation. Such degradation causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain, and mesh deformation.

35. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "three dimensional implants (plug-and-patch and bilayer) are not recommended because of the excessive

use of foreign material, the need to enter both the anterior and posterior planes and the additional cost."

THE FDA'S 510(k) CLEARANCE PROCESS

36. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 MDA of the Federal Food, Drug and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

37. No clinical testing is required under this process.

38. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k) cleared devices.

39. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

40. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

41. In 2012, at the request of the FDA, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, coming to the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

42. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and

effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

43. The Prolene Hernia System did not undergo premarket approval, but instead received 510(k) clearance on or about September 20, 1997. The Prolene Hernia System was initially approved for the intended use of repairing "indirect and direct inguinal hernia defects." However, in the Instructions for Use for the Prolene Hernia System, Defendants market the Prolene Hernia System as "indicated for the repair of inguinal (direct & indirect) and abdominal wall hernia defects."

DEFENDANTS' FAILURE TO WARN OF THE DANGERS ASSOCIATED WITH ETHICON MULTI-LAYERED HERNIA MESH

44. Before placing Ethicon Multi-Layered Hernia Mesh, or any hernia repair device using it, on the market, Defendants were required to adequately test their product and mitigate its risks, including any design element which could cause the following: render the device ineffective, weaken the structural integrity of the device, prevent safe treatment when complications arise, increase complications, or increase or prolong inflammation after implantation. Such complications can result in an increase in adhesion formation, mesh shrinkage, mesh deformation, pain, organ complications, hernia recurrence, and/or the need for early surgical revision in patients/consumers.

45. Defendants designed, manufactured, promoted, marketed and sold Ethicon Multi-Layered Hernia Mesh, despite their long-standing knowledge that their material and design would

cause dense adhesions, chronic pain, mesh shrinkage, mesh deformation, foreign body sensation, organ complications, and hernia recurrence. Further, Defendants knew that treating such complications when they inevitably arose would result in even greater complications and a larger defect.

46. Defendants marketed Ethicon Multi-Layered Hernia Mesh, such as the Prolene Hernia System at issue here, to health care professionals, hospitals, and group purchasing organizations (GPOs).

47. Defendants had the ability to inform the above purchasers of developing problems or defects related to those products through varied communications, such as e-mails, letters, recalls, warnings in product inserts, and/or through product representatives who communicate, interact and work with surgeons, but failed to do so.

48. The multiple layers of Ethicon Multi-Layered Hernia Mesh increase the intensity and duration of the inflammatory response in Defendants' hernia repair devices, including their Prolene Hernia System. That response in turn increases dense adhesion formation from underlying structures and organs to the product, resulting in mesh contracture, mesh deformation, chronic pain, foreign body sensation, foreign body reaction, organ and tissue damage, hernia recurrence, and more.

49. The Prolene Hernia System IFU has a section for adverse reactions, which list "Potential adverse reactions are those typically associated with surgically implantable materials..." The polypropylene of the Prolene Hernia System carries many potential adverse reactions, such as a life-long inflammatory response that other surgically implantable materials do not present. Additionally, the multiple layers of the Prolene Hernia System further increase the inflammatory response and rate of infection, adhesion formation, chronic pain, seroma formation,

fistula formation, hematomas, mesh contracture, hernia recurrence, mesh migration, bowel complications, foreign body response, extrusion, and other additional injuries.

50. There is not a contraindication section in the Prolene Hernia System IFU.

51. Defendants never performed any clinical trials and/or studies before marketing Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System.

52. Defendants did not fully and/or adequately test these new, multi-layered hernia mesh devices, one of which—the Prolene Hernia System—was implanted in Plaintiff Jennifer Wilson.

53. Reassurances of device safety were made through direct promotional contact by Defendants' sales representatives and distributors, through word-of-mouth from their physician/technical consultants, and/or through industry-targeted promotional materials.

54. Despite these reassurances, the defective design and manufacture of the Ethicon Multi-Layered Hernia Mesh, including Defendants' Prolene Hernia System, continued to elicit post-implant severe and chronic inflammatory responses. Such responses resulted in mesh contracture, mesh deformation, chronic pain, foreign body sensation, adhesion, seroma and fistula formation, organ injuries, hernia recurrence, infections, erosion, extrusion, and additional complications.

55. From the time Defendants first began selling Ethicon Multi-Layered Hernia Mesh in the U.S. through the present, their product labeling and product data have failed to contain adequate information, instructions, and warnings concerning the following: implantation of the mesh, explantation of the mesh, propensity of the mesh to massively shrink and change shape, the increased duration and intensity of inflammation, and the elevated rate of adhesions, organ complications, chronic and debilitating pain, foreign body sensation, hernia recurrence, seroma,

hematoma and fistula formation, erosion, extrusion, infection, and other injuries occurring at a higher rate than other surgically implanted devices.

CAUSES OF ACTION PURSUANT TO NEW JERSEY LAW

COUNT I: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1, *et seq.*)

56. Plaintiff Jennifer Wilson incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

57. Defendants had a duty to design and manufacture, distribute, market, promote and sell their Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System, so that they were neither defective nor unreasonably dangerous when put to the use for which they were designed, manufactured, distributed, marketed and sold.

58. In 1999, Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling various types of hernia mesh implant devices, and did design, manufacture, distribute, market and sell the Prolene Hernia System as one of those devices.

59. Defendants expected their Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System, which they were manufacturing, selling, distributing, supplying, and/or promoting, to reach—and it did in fact reach—health care professionals and consumers in the State of New Jersey and the United States, including Plaintiff and her implanting surgeon, without substantial change in its condition.

60. When the Prolene Hernia System, a type of Ethicon Multi-Layered Hernia Mesh, left Defendants' possession and entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include the following:

- Ethicon Multi-Layered Hernia Mesh was not reasonably safe as intended to be used;

- Ethicon Multi-Layered Hernia Mesh had an inadequate design for the purpose of hernia repair;

- Ethicon Multi-Layered Hernia Mesh, which utilized multiple layers, contained unreasonably dangerous design defects, increasing and prolonging the inflammatory response;

- Ethicon Multi-Layered Hernia Mesh was not appropriately or adequately tested before distribution; and

- Ethicon Multi-Layered Hernia Mesh had an unreasonably high propensity for adhesion formation, mesh contracture, mesh deformation, chronic pain, foreign body sensation, organ complications, seroma formation, fistula formation, hematoma formation, hernia recurrence, infection, erosion, and extrusion.

AND

- The Prolene Hernia System contained unreasonably dangerous design defects. Those included two connecting disc layers of polypropylene intended to occupy two inguinal compartments once implanted. But due to the contours of the preperitoneal space, the deeper disc cannot be expected to be positioned flat, which results in increased complications and an inability to safely treat such complications; and

- the Prolene Hernia System is unreasonably dangerous, due to the heavyweight polypropylene in it, which increases the inflammatory and foreign body response; the small pore size utilized, which increases inflammatory and foreign body response; the shrinkage and stiffening of the mesh over time; and degradation after implant.

61. When Defendants initially designed, manufactured, marketed, and sold Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System, feasible, alternative safer designs were known and available, including a flat, non-coated, single-layer, lightweight, large-pore mesh, or a fully resorbable mesh.

62. After Defendants' initial design and manufacture, marketing and sale of Ethicon Multi-Layered Hernia Mesh—but before Plaintiff Jennifer Wilson underwent hernia surgery—

Defendants had the ability to eliminate the unsafe character of the product without impairing its usefulness, but they did not.

63. Had Defendants properly and adequately tested the Ethicon Multi-Layered Hernia Mesh, they would have discovered the following: multiple mesh layers increase and prolong the inflammatory response; the mesh experiences significant contraction and deformation over time; the mesh cannot be safely removed; and these defects result in chronic and debilitating pain, foreign body sensation, a pronounced foreign body response, seroma and fistula formation, infections, erosion, and extrusion, among other complications.

64. Defendants' Ethicon Multi-Layered Hernia Mesh were therefore defective in design, in that when the products left Defendants, the foreseeable risk of harm from them exceeded or outweighed the benefit or utility a consumer would expect, and/or they failed to comply with federal requirements for these medical devices.

65. As a direct and proximate result of Defendants' wrongful conduct—including their defective and dangerous design and inadequate warnings of Ethicon Multi-Layered Hernia Mesh, Plaintiff Jennifer Wilson has sustained, and will continue to sustain, severe and debilitating injuries, economic loss, and other damages, including cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

66. Defendants are strictly liable in tort to Plaintiff Jennifer Wilson for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq*.

COUNT II: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-1, *et seq.*)

67. Plaintiff Jennifer Wilson incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

68. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce Ethicon Multi-Layered Hernia Mesh; and directly advertised or marketed their products to the FDA, health care professionals, GPOs, and consumers, including Plaintiff Jennifer Wilson and her surgeon. Therefore, Defendants had a duty to warn of the risks associated with the use of their products.

69. Defendants distributed and sold Ethicon Multi-Layered Hernia Mesh, including their Prolene Hernia System, in their original forms of manufacture, which included the defects described in this Complaint.

70. The products were expected to, and did reach Plaintiff and her implanting surgeon, without substantial change in their condition as manufactured and sold by Defendants.

71. The products that Defendants designed, developed, tested, manufactured, distributed, promoted, marketed, and/or sold or otherwise placed into the stream of commerce, were in dangerous and defective conditions, and posed a threat to any user/consumer.

72. At all material times, Plaintiff Jennifer Wilson was the person Defendants should have considered to be subject to the harm caused by the defective nature of their products.

73. The Prolene Hernia System was implanted in Plaintiff Jennifer Wilson and used in a manner for which it was intended.

74. Its use has resulted in severe physical, financial, emotional and other injuries to Plaintiff.

75. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting surgeon, of the true risks of those products. The Prolene Hernia System was ineffective in reducing chronic pain or hernia recurrence, and would contract and deform significantly upon implantation, resulting in debilitating pain, organ complications, hernia recurrence, reoperation, infections, fistula, seroma and hematoma formation, erosion, extrusion, subsequent operations, and more.

76. Defendants failed to timely and reasonably warn of material adverse facts regarding the safety and efficacy of their Prolene Hernia System. Had they done so, proper warnings would have been heeded, Plaintiff's surgeon would not have used the hernia repair product, and no consumer, including Plaintiff, would have purchased and/or consented to its use.

77. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Prolene Hernia System.

78. Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and released into the stream of commerce, were defective due to inadequate post-marketing warnings and/or instruction. Defendants knew or should have known that there was reasonable evidence of an association between their mesh products—including the Prolene Hernia System—and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the public, including Plaintiff Jennifer Wilson, and continued to aggressively promote their products.

79. Ethicon Multi-Layered Hernia Mesh, which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce, were defective also due to inadequate post-

marketing warnings and/or instructions regarding their increased risk of failure, resulting in revision surgery—although Defendants knew of safer alternative designs, including a flat, lightweight, large-pore, non-coated, single-layer mesh, or a fully resorbable mesh.

80. Defendants failed to perform or otherwise facilitate adequate testing on the products in question; failed to reveal and/or concealed their testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

81. Plaintiff Jennifer Wilson and her surgeon used the Prolene Hernia System for its intended purpose, *i.e.*, hernia repair.

82. Neither Plaintiff nor her surgeon could have discovered any defect in Defendants' product through the exercise of due care.

83. As designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices, Defendants are held to the level of knowledge of experts in their field.

84. Neither Plaintiff nor her implanting surgeon had substantially the same knowledge about Defendants' product as Defendants did.

85. Defendants reasonably should have known that the Prolene Hernia System, a type of Ethicon Multi-Layered Hernia Mesh, was unsuited to repair a hernia in Plaintiff Jennifer Wilson.

86. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or their failure to provide an adequate warning and other wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as described in this Complaint.

87. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq.*

COUNT III: PRODUCTS LIABILITY ACT – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1, *et seq.*)

88. Plaintiff Jennifer Wilson incorporates by reference the allegations in all prior paragraphs, and further alleges as follows:

89. Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and sold Ethicon Multi-Layered Hernia Mesh, including the Prolene Hernia System, in a condition which rendered the products unreasonably dangerous due to their propensity to result in early failure after implant. Thus, the products were unreasonably dangerous in construction or composition.

90. The products Defendants manufactured, including their Prolene Hernia System, were defective in construction or composition in that, when they left Defendants' possession, they deviated in a material way from their manufacturing performance standards and/or differed from otherwise identical products manufactured to the same design formula. Defendants knew or should have known that their products could fail in patients, thereby giving rise to pain and suffering, debilitation and the need for revision surgery to replace the devices—here, the Prolene Hernia System—with the attendant risk of complications and death from such further surgery. Nonetheless, Defendants continued to market their products as safe and effective.

91. As a direct and proximate result of the use of the products Defendants manufactured, designed, sold, supplied and introduced into the stream of commerce, Plaintiff Jennifer Wilson suffered harm, damages and economic loss as previously described, and will continue to suffer such harm, damages and economic loss in the future.

92. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq*.

ASSERTION OF CLAIMS PURSUANT TO THE LAWS OF OHIO

93. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

94. Plaintiff Jennifer Wilson was injured from being implanted with the Prolene Hernia System outside the State of New Jersey. To the extent the Court chooses to apply the law of a state other than New Jersey, Plaintiff places Defendants on notice of her intention to plead and assert all claims available under the state's law applied by this Court.

COUNT IV: NEGLIGENCE- PURSUANT TO COMMON LAW

95. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

96. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for their Ethicon Multi-Layered Hernia Mesh, they failed to adequately do so.

97. Defendants knew, or in the exercise of reasonable care should have known, that their products were defectively and unreasonably designed and/or manufactured, and were unreasonably dangerous and likely to injure patients like Plaintiff Jennifer Wilson in whom the Prolene Hernia System was implanted. Defendants also knew or should have known that Plaintiff and her surgeon were unaware of the dangers and defects inherent in their products.

98. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Ethicon Multi-Layered Hernia Mesh—including the Prolene

Hernia System implanted in Plaintiff Jennifer Wilson—she suffered injuries and damages as described in this Complaint.

COUNT V: STRICT LIABILITY – DESIGN DEFECT – PURSUANT TO COMMON LAW

99. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

100. When the Prolene Hernia System was implanted in Plaintiff, it was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

101. Defendants expected and intended the Prolene Hernia System to reach users such as Plaintiff in the condition in which it was sold.

102. The implantation of the Prolene Hernia System in Plaintiff was medically reasonable, and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the device.

103. The risks of the Prolene Hernia System significantly outweigh any benefits Defendants contend could be associated with its design.

104. When the Prolene Hernia System was implanted in Plaintiff, it contained unreasonably dangerous design defects. Specifically, the multiple layers of the Ethicon Multi-Layered Hernia Mesh in the Prolene Hernia System increase and prolong the inflammatory response; the mesh experiences significant contraction over time; and complication rates are unacceptably high. These defects result in mesh contraction, mesh deformation, chronic and debilitating pain, foreign body sensation, organ obstructions, seroma and fistula formation,

infections, erosion, extrusion, a pronounced foreign body response, and an inability to safely remove the product, among other complications.

105. After Defendants' initial design and manufacture and marketing and sale of Ethicon Multi-Layered Hernia Mesh—but before Plaintiff's surgery with the Prolene Hernia System—Defendants had the ability to eliminate the unsafe character of the products without impairing their usefulness, but they did not do so.

106. When the Prolene Hernia System was implanted in Plaintiff Jennifer Wilson, Defendants' warnings and instructions for their product were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning the risks.

107. When Defendants' Prolene Hernia System was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

108. The hernia repair device implanted in Plaintiff failed to reasonably perform as intended and had to be surgically removed, necessitating further invasive surgery to repair the very issue the product was intended to repair. Thus, it provided no benefit to him/her.

109. As a direct and proximate result of the defective and unreasonably dangerous condition of Defendants' hernia mesh repair products, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT VI: STRICT LIABILITY – FAILURE TO WARN – PURSUANT TO COMMON LAW

110. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

111. When the Prolene Hernia System was implanted in Plaintiff Jennifer Wilson, Defendants' warnings and instructions were inadequate and defective. As described above, there was an unreasonable risk that the device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning the risks of the Prolene Hernia System.

112. Defendants expected and intended their products to reach users such as Plaintiff in the condition in which they were sold.

113. Plaintiff and her surgeon were unaware of the Prolene Hernia System's defects and dangers, and were unaware of the frequency, severity, and duration of the defects and risks associated with it.

114. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her implanting surgeon, of the true risks of the product. They did not warn that the Prolene Hernia System would contract significantly upon implantation, resulting in chronic and debilitating pain, foreign body sensation, organ complications, hernia recurrence, reoperation, infections, fistula, seroma and hematoma formation, erosion, extrusion, subsequent operations, and more.

115. Defendants failed to timely and reasonably provide adequate instructions and training concerning the safe and effective use of their Prolene Hernia System.

116. Defendants failed to perform or otherwise facilitate adequate testing of the product; failed to reveal and/or concealed their testing and research data; and selectively and misleadingly revealed and/or analyzed such testing and research data.

117. Ethicon Multi-Layered Hernia Mesh—which Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and released into the stream of commerce—was defective due to inadequate post-marketing warnings and/or instruction. Defendants knew or should have known that there was reasonable evidence of an association between their devices and dense adhesion formation, mesh contracture, and hernia recurrence, causing serious injury and pain. Nonetheless, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote their hernia repair devices and the mesh they contained, including the Prolene Hernia System.

118. With respect to the complications listed in their warnings, Defendants provided inadequate information or warning regarding the frequency, severity and duration of those complications, although the associated complications were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

119. If Plaintiff Jennifer Wilson or her surgeon had been properly warned of the defects and dangers of the Prolene Hernia System, and of the frequency, severity and duration of the associated risks, she would not have consented to allow it to be implanted in her body, and her surgeon would not have implanted the product.

120. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as described in this Complaint.

COUNT VII: STRICT LIABILITY – MANUFACTURING DEFECT – PURSUANT TO COMMON LAW

121. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

122. The Prolene Hernia System contained a manufacturing defect when it left Defendants' possession. The product differs from its intended result and/or from other ostensibly identical units of the same product line.

123. The manufacturing defects in Defendants' Prolene Hernia System were a producing cause of Plaintiff's injuries and damages, as described in this Complaint.

COUNT VIII: BREACH OF IMPLIED WARRANTY

124. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

125. Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed their Prolene Hernia System for use by Plaintiff Jennifer Wilson and others. When they did so, Defendants knew of its intended use, and impliedly warranted it to be of merchantable quality, and safe and fit for its intended use.

126. When the Prolene Hernia System was implanted in Plaintiff to treat her hernia, it was being used for the ordinary purposes for which it was intended.

127. In consenting to have the Prolene Hernia System implanted, Plaintiff, individually and/or by and through her surgeon, relied upon Defendants' implied warranties of merchantability.

128. But contrary to Defendants' implied warranties, the Prolene Hernia System was not of merchantable quality, and was not safe and/or was not fit for its intended use. Rather, it was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants

failed to warn of known or reasonably scientifically knowable defects in the Prolene Hernia System.

129. As a direct and proximate result of Defendants' conduct, Plaintiff Jennifer Wilson suffered the injuries and damages described in this Complaint.

COUNT IX: BREACH OF EXPRESS WARRANTY

130. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

131. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold the Prolene Hernia System.

132. At all material times, Defendants intended that the Prolene Hernia System be used in the manner Plaintiff used it. Further, they expressly warranted in their brochures and advertising that their product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other mesh products, and that it was adequately tested and fit for its intended use.

133. At all material times, Defendants were aware that consumers, including Plaintiff Jennifer Wilson, would use their Prolene Hernia System. Therefore, Plaintiff was a foreseeable user of Defendants' product.

134. Plaintiff and/or her implanting surgeon were at all material times in privity with Defendants.

135. Defendants' Prolene Hernia System was expected to reach, and did in fact reach consumers, including Plaintiff and her implanting surgeon, without substantial change in the condition in which Defendants manufactured and sold it.

136. Defendants breached various express warranties with respect to their Ethicon Multi-Layered Hernia Mesh, including the following:

- Defendants represented to Plaintiff and her surgeon or other health care providers, through their labeling, advertising marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, that Ethicon Multi-Layered Hernia Mesh was safe; but they fraudulently withheld and concealed information about substantial risks or serious injury and/or death associated with the use of the product or the hernia repair devices made from it;

- Defendants represented to Plaintiff and her surgeon or other health care providers that their Ethicon Multi-Layered Hernia Mesh and the hernia repair devices made from it, were as safe and/or safer than other alternative procedures and devices; and they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

- Defendants represented to Plaintiff and her surgeon or other health care providers that Ethicon Multi-Layered Hernia Mesh was more efficacious than other alternatives; but they fraudulently concealed information regarding its lack of efficacy.

137. In reliance upon Defendants' express warranties, Plaintiff was implanted with their Prolene Hernia System, with a type of Ethicon Multi-Layered Hernia Mesh, as prescribed and directed; and therefore, in the foreseeable manner for which Defendants normally intended, recommended, promoted, and marketed it.

138. When they made such express warranties, Defendants knew or should have known that the Prolene Hernia System did not conform to their express representations because it was not safe and had numerous serious side effects. Defendants did not accurately warn about many of those side effects, thus making the product unreasonably unsafe for its intended purpose.

139. Members of the medical community, including physicians and other health care professionals, as well as Plaintiff and the public, relied upon Defendants' representations and

warranties in connection with the use, recommendation, description, and/or dispensing of their Prolene Hernia System.

140. Defendants breached their express warranties to Plaintiff in that their Prolene Hernia System was not of merchantable quality, safe, or fit for its intended purpose, nor was it adequately tested.

141. As a direct and proximate result of Defendants' conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, and other damages.

COUNT X: PUNITIVE DAMAGES

142. Plaintiff Jennifer Wilson incorporates the allegations in all prior paragraphs, and further alleges as follows:

143. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of their Prolene Hernia System and other types of Ethicon Multi-Layered Hernia Mesh; and by failing to provide adequate instructions and training concerning the use of their products. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and associated risks, despite available information demonstrating the following: the Prolene Hernia System lacked adequate testing, would significantly contract upon implantation, would cause an increased and prolonged inflammatory and foreign body response, high rates of chronic and debilitating pain, foreign body sensation, organ complications, seroma and fistula formation, infections, pain, and other harm to patients. Such risks and adverse effects could have been avoided had Defendants not concealed their

knowledge of the serious and permanent side effects and risks associated with the use of Ethicon Multi-Layered Hernia Mesh, or provided proper training and instruction to health care professionals regarding their use. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of their products.

144. Defendants were, or should have been, in possession of evidence demonstrating that their Ethicon Multi-Layered Hernia Mesh caused serious side effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to their safety and efficacy.

145. Defendants failed to provide warnings that would have dissuaded health care professionals from using their Ethicon Multi-Layered Hernia Mesh devices, including the Prolene Hernia System, thus preventing health care professionals and consumers, including Plaintiff Jennifer Wilson, from weighing the true risks against the benefits of using the products.

146. Defendants failed to provide adequate training, testing and instructions to health care professionals, which could have prevented the failure of hernia repair devices made with Ethicon Multi-Layered Hernia Mesh, thus preventing serious harm and suffering to patients, including Plaintiff.

WHEREFORE, Plaintiff Jennifer Wilson demands judgment against Defendants for compensatory damages and punitive damages, together with interest, costs of suit and attorney's fees, and such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Jennifer Wilson prays for judgment and an award of damages against Defendants, as follows:

a. special damages, to include past and future medical and incidental expenses, according to proof;
b. past and future loss of earnings and/or earning capacity, according to proof;
c. past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
d. pre-judgment and post-judgment interest;
e. costs of this action;
f. treble and/or punitive damages to Plaintiff; and
g. any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

NOTICE OF OTHER ACTIONS PURSUANT TO R. 4:5-1

I hereby certify that there are related civil proceedings: Cottle v. Ethicon, Inc., et al, Docket No.: MID-L-6828-18; Bassett v. Ethicon, Inc., et al, Docket No.: MID-L-6788-18; Gold v. Ethicon, Inc., et al, Docket No.: MID-L-6852-18; Noakes v. Ethicon, Inc., et al, Docket No.: MID-L-6951-18; Fowler v. Ethicon, Inc., et al, Docket No.: MID-L-6845-18; Griffin v. Ethicon, Inc., et al, Docket No.: MID-L-6878-18; Linnenbrink v. Ethicon, Inc., et al, Docket No.: MID-L-6916-18; Campbell v. Ethicon, Inc., et al, Docket No.: MID-L-6812-18; Trebolo, Jr. v. Ethicon, Inc. et al, Docket No.: MID-L-7000-18; Gateley v. Ethicon, Inc., et al, Docket No.: MID-L-6849-18; Redding v. Ethicon, Inc., et al, Docket No.: MID-L-6957-18; Rice v. Ethicon, Inc., et al, Docket No.: MID-L-6960-18; Bean v. Ethicon, Inc., et al, Docket No.: MID-L-6789-18; Alumbaugh v. Ethicon, Inc., et al, Docket No.: MID-L-6782-18; Reynolds v. Ethicon, Inc., et al, Docket No.: MID-L-6959-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-6990-18; Gaddis v. Ethicon,

Inc., et al, Docket No.: MID-L-6846-18; Aaron v. Ethicon, Inc., et al, Docket No.: MID-L-6761-18; Diloreto v. Ethicon, Inc., et al, Docket No.: MID-L-6832-18; Pikulsky, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6956-18; Lang v. Ethicon, Inc., et al, Docket No.: MID-L-6910-18; Gibson v. Ethicon, Inc., et al, Docket No.: MID-L-6850-18; Shackelford v. Ethicon, Inc., et al, Docket No.: MID-L-6966-18; Lindsey v. Ethicon, Inc., et al, Docket No.: MID-L-6914-18; Mack, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6932-18; Schriner v. Ethicon, Inc., et al, Docket No.: MID-L-6962-18; Alexander v. Ethicon, Inc., et al, Docket No.: MID-L-6780-18; Usey v. Ethicon, Inc., et al, Docket No.: MID-L-7002-18; Hart v. Ethicon, Inc., et al, Docket No.: MID-L-6880-18; Galvez v. Ethicon, Inc., et al, Docket No.: MID-L-6847-18; Lindly v. Ethicon, Inc., et al, Docket No.: MID-L-6913-18; Senkel v. Ethicon, Inc., et al, Docket No.: MID-L-6965-18; Maestas v. Ethicon, Inc., et al, Docket No.: MID-L-6934-18; Szaroleta v. Ethicon, Inc., et al, Docket No.: MID-L-6997-18; Krampen-Yerry v. Ethicon, Inc., et al, Docket No.: MID-L-6909-18; Lotridge v. Ethicon, Inc., et al, Docket No.: MID-L-6925-18; Dias v. Ethicon, Inc., et al, Docket No.: MID-L-6831-18; Alvarado, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6783-18; Mountjoy, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6946-18; Fontenot v. Ethicon, Inc., et al, Docket No.: MID-L-6844-18; Anawaty v. Ethicon, Inc., et al, Docket No.: MID-L-6784-18; Capshaw v. Ethicon, Inc., et al, Docket No.: MID-L-6814-18; Briscoe v. Ethicon, Inc., et al, Docket No.: MID-L-6806-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-6991-18; Bradford v. Ethicon, Inc., et al, Docket No.: MID-L-6804-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6890-18; Collier v. Ethicon, Inc., et al, Docket No.: MID-L-6826-18; Williams v. Ethicon, Inc., et al, Docket No.: MID-L-7006-18; Miller v. Ethicon, Inc., et al, Docket No.: MID-L-6940-18; Ward v. Ethicon, Inc., et al, Docket No.: MID-L-7004-18; Shepherd v. Ethicon, Inc., et al, Docket No.: MID-L-6967-18; Scobee v. Ethicon, Inc., et al, Docket No.: MID-L-6964-18; Snyder

v. Ethicon, Inc., et al, Docket No.: MID-L-6993-18; Hodge v. Ethicon, Inc., et al, Docket No.: MID-L-6887-18; Trombley v. Ethicon, Inc., et al, Docket No.: MRS-L-750-18; Lloyd v. Ethicon, Inc., et al, Docket No.: MID-L-6917-18; Henley v. Ethicon, Inc., et al, Docket No.: MID-L-6883-18; Benton, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6790-18; Jones v. Ethicon, Inc., et al, Docket No.: MID-L-6906-18; Muniz v. Ethicon, Inc., et al, Docket No.: MID-L-6947-18; Deffenbaugh v. Ethicon, Inc., et al, Docket No.: MID-L-6830-18; Clulee v. Ethicon, Inc., et al, Docket No.: MID-L-6825-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6889-18; Garrett v. Ethicon, Inc., et al, Docket No.: MID-L-6848-18; Hecker v. Ethicon, Inc., et al, Docket No.: MID-L-6881-18; Hendrix v. Ethicon, Inc., et al, Docket No.: MID-L-6882-18; Hinn v. Ethicon, Inc., et al, Docket No.: MID-L-6884-18; Holman, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6888-18; Wolfe v. Ethicon, Inc., et al, Docket No.: MID-L-7008-18; Booth, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6796-18; Jones v. Ethicon, Inc., et al, Docket No.: MID-L-6908-18; Brooks v. Ethicon, Inc., et al, Docket No.: MID-L-6808-18; Adams v. Ethicon, Inc., et al, Docket No.: MID-L-6779-18; Finotti v. Ethicon, Inc., et al, Docket No.: MID-L-6833-18; Mata v. Ethicon, Inc., et al, Docket No.: MID-L-6936-18; Darnell v. Ethicon, Inc., et al, Docket No.: MID-L-6829-18; Lynch v. Ethicon, Inc., et al, Docket No.: MID-L-6931-18; Parham v. Ethicon, Inc., et al, Docket No.: MID-L-6952-18; Tavian v. Ethicon, Inc., et al, Docket No.: MID-L-6998-18; Banks v. Ethicon, Inc., et al, Docket No.: MID-L-6787-18; Jones v. Ethicon, Inc., et al, Docket No.: MID-L-6892-18; Boston v. Ethicon, Inc., et al, Docket No.: MID-L-6799-18; Rivas v. Ethicon, Inc., et al, Docket No.: MID-L-6961-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-6955-18; Austin v. Ethicon, Inc., et al, Docket No.: MID-L-6786-18; Rudenauer v. Ethicon, Inc., et al, Docket No.: MID-L-7050-18; Blackistone v. Ethicon, Inc., et al, Docket No.: MID-L-6794-18; Godfrey v. Ethicon, Inc., et al, Docket No.: MID-L-6851-18; McCutcheon v. Ethicon, Inc., et al, Docket No.:

MID-L-6939-18; Soares v. Ethicon, Inc., et al, Docket No.: MID-L-6994-18; Woods v. Ethicon, Inc., et al, Docket No.: MID-L-7010-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-6954-18; Chavira v. Ethicon, Inc., et al, Docket No.: MID-L-6822-18; Guidry v. Ethicon, Inc., et al, Docket No.: MID-L-6879-18; Newburn v. Ethicon, Inc., et al, Docket No.: MID-L-6949-18; Cordova v. Ethicon, Inc., et al, Docket No.: MID-L-6827-18; Lecza v. Ethicon, Inc., et al, Docket No.: MID-L-6912-18; Taylor v. Ethicon, Inc., et al, Docket No.: MID-L-6999-18; Lowrey v. Ethicon, Inc., et al, Docket No.: MID-L-6930-18; Wilson, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7007-18; Tyler v. Ethicon, Inc., et al, Docket No.: MID-L-7001-18; Whitfield, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7005-18; Smith, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6992-18; Moskowitz v. Ethicon, Inc., et al, Docket No.: MID-L-6945-18; Strauss v. Ethicon, Inc., et al, Docket No.: MID-L-7055-18; Masingo v. Ethicon, Inc., et al, Docket No.: MID-L-6935-18; Vinas v. Ethicon, Inc., et al, Docket No.: MID-L-7003-18; Morrone v. Ethicon, Inc., et al, Docket No.: MID-L-6942-18; Newman v. Ethicon, Inc., et al, Docket No.: MID-L-6950-18; Strawser v. Ethicon, Inc, et al, Docket No.: MID-L-6996-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-6891-18; Harding, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7030-18; Brown, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7017-18; Green v. Ethicon, Inc., et al, Docket No.: MID-L-6877-18; Bolyard v. Ethicon, Inc., et al, Docket No.: MID-L-6795-18; Bovino v. Ethicon, Inc., et al, Docket No.: MID-L-6800-18; Payne v. Ethicon, Inc., et al, Docket No.: MID-L-6953-18; Clements v. Ethicon, Inc., et al, Docket No.: MID-L-6824-18; Mosby v. Ethicon, Inc., et al, Docket No.: MID-L-6943-18; Mathews v. Ethicon, Inc., et al, Docket No.: MID-L-6937-18; Lowe v. Ethicon, Inc., et al, Docket No.: MID-L-6926-18; Gonzales v. Ethicon, Inc., et al, Docket No.: MID-L-6853-18; Abhold, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6763-18; Warr v. Ethicon, Inc., et al, Docket No.: MID-L-7058-18; Ishii v. Ethicon, Inc., et al, Docket

No.: MID-L-7034-18; Jacuzzi v. Ethicon, Inc., et al, Docket No.: MID-L-7035-18; McNally v. Ethicon, Inc., et al, Docket No.: MID-L-7040-18; McCutcheon v. Ethicon, Inc., et al, Docket No.: MID-L-7039-18; Newland v. Ethicon, Inc., et al, Docket No.: MID-L-7043-18; Johnson v. Ethicon, Inc., et al, Docket No.: MID-L-7036-18; Vaughan v. Ethicon, Inc., et al, Docket No.: MID-L-7057-18; Shaw v. Ethicon, Inc., et al, Docket No.: MID-L-7051-18; Asturi v. Ethicon, Inc., et al, Docket No.: MID-L-7013-18; Brawley v. Ethicon, Inc., et al, Docket No.: MID-L-7016-18; Guy, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7028-18; Mahne, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7038-18; Pierce, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7049-18; Classen, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7019-18; Murphy v. Ethicon, Inc., et al, Docket No.: MID-L-7042-18; Thibodaux, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7056-18; Nomikos v. Ethicon, Inc., et al, Docket No.: MID-L-7044-18; Nuri, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7045-18; Corgan v. Ethicon, Inc., et al, Docket No.: MID-L-7020-18; Falcon v. Ethicon, Inc., et al, Docket No.: MID-L-7023-18; Frank v. Ethicon, Inc., et al, Docket No.: MID-L-7024-18; Moore v. Ethicon, Inc., et al, Docket No.: MID-L-7041-18; Hall v. Ethicon, Inc., et al, Docket No.: MID-L-7029-18; Lyon v. Ethicon, Inc., et al, Docket No.: MID-L-7037-18; Holland v. Ethicon, Inc., et al; Docket No.: MID-L-7032-18; Palka v. Ethicon, Inc., et al, Docket No.: MID-L-7047-18; Austin v. Ethicon, Inc., et al, Docket No.: MID-L-7014-18; Wetch v. Ethicon, Inc., et al, Docket No.: MID-L-7060-18; Waterfield, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7059-18; Dill, et al v. Ethicon, Inc., et al; Docket No.: MID-L-7022-18; Blocker v. Ethicon, Inc., et al, Docket No.: MID-L-7015-18; Delph, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7021-18; Rigney, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7724-18; Henry v. Ethicon, Inc., et al, Docket No.: MID-L-7031-18; Skiba v. Ethicon, Inc., et al, Docket No.: MID-L-7052-18; Snyder v. Ethicon, Inc., et al, Docket No.: MID-L-7053-18; Alguacil v. Ethicon, Inc., et al, Docket No.:

MID-L-7011-18; Perez v. Ethicon, Inc., et al, Docket No.: MID-L-7048-18; Hughey v. Ethicon, Inc., et al, Docket No.: MID-L-7033-18; White v. Ethicon, Inc., et al, Docket No.: MID-L-7061-18; Burns, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7018-18; Spears v. Ethicon, Inc., et al, Docket No.: MID-L-7054-18; Hanson v. Ethicon, Inc., et al, Docket No.: MID-L-5813-18; Pepper, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7723-18; Varner v. Ethicon, Inc., et al, Docket No.: MID-L-5814-18; Reed v. Ethicon, Inc., et al, Docket No.: MID-L-6318-18; Matz v. Ethicon, Inc., et al, Docket No.: MID-L-6331-18; Vernick v. Ethicon, Inc., et al, Docket No.: MID-L-6368-18; Phillips v. Ethicon, Inc., et al, Docket No.: MID-L-6369-18; Eccles, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6370-18; Williams v. Ethicon, Inc., et al, Docket No.: MID-L-6379-18; Favors, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6386-18; Nelson, et al v. Ethicon, Inc., et al, Docket No.: MID-L-6420-18; Bennett v. Ethicon, Inc., et al, Docket No.: MID-L-6426-18; Greenklepper v. Ethicon, Inc., et al, Docket No.: MID-L-6687-18; Landers v. Ethicon, Inc., et al, Docket No.: MID-L-6760-18; Braden v. Ethicon, Inc., et al, Docket No.: MID-L-6805-18; Whipple v. Ethicon, Inc., et al, Docket No.: MID-L-7064-18; Blair v. Ethicon, Inc., et al, Docket No.: MID-L-7085-18; Carlson v. Ethicon, Inc., et al, Docket No.: MID-L-7086-18; Farmer v. Ethicon, Inc., et al, Docket No.: MID-L-7099-18; House v. Ethicon, Inc., et al, Docket No.: MID-L-7132-18; Lujan, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7279-18; Gonzalez, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7280-18; Piper v. Ethicon, Inc., et al, Docket No.: MID-L-7282-18; Oglesby v. Ethicon, Inc., et al, Docket No.: MID-L-7310-18; Kiger v. Ethicon, Inc., et al, Docket No.: MID-L-7325-18; Munoz v. Ethicon, Inc., et al, Docket No.: MID-L-7342-18; Coleman v. Ethicon, Inc., et al, Docket No.: MID-L-7400-18; Dorman v. Ethicon, Inc., et al, Docket No.: MID-L-7547-18; Mullins v. Ethicon, Inc., et al, Docket No.: MID-L-7548-18; Alcantara, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7718-18; Davis, et al v. Ethicon, Inc.,

et al, Docket No.: MID-L-7719-18; Garner v. Ethicon, Inc., et al, Docket No.: MID-L-7720-18; Hickey, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7721-18; Kinder, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7722-18; Espino v. Ethicon, Inc., et al, Docket No.: MID-L-7957-18; Mangan v. Ethicon, Inc., et al, Docket No.: MID-L-7988-18; Cranwell v. Ethicon, Inc., et al, Docket No.: MID-L-7989-18; Ransford v. Ethicon, Inc., et al, Docket No.: MID-L-7990-18; Cashe v. Ethicon, Inc., et al, Docket No.: MID-L-7992-18; Bailey, et al v. Ethicon, Inc., et al, Docket No.: MID-L-7993-18; Martinez v. Ethicon, Inc., et al, Docket No.: MID-L-8025-18; Grayson v. Ethicon, Inc., et al, Docket No.: MID-L-8101-18; Smith v. Ethicon, Inc., et al, Docket No.: MID-L-8102-18; Harris, et al v. Ethicon, Inc., et al, Docket No.: MID-L-8197-18; Holleran v. Ethicon, Inc., et al, Docket No.: MID-L-8198-18; Hooper, et al v. Ethicon, Inc., et al, Docket No.: MID-L-8199-18; and Vautaw v. Ethicon, Inc., et al, Docket No.: MID-L-8313-18. Beyond the Cottle, Bassett, Gold, Noakes, Fowler, Griffin, Linnenbrink, Campbell, Trebolo, Gateley, Redding, Rice, Bean, Alumbaugh, Reynolds, Gaddis, Aaron, Diloreto, Pikulsky, Lang, Gibson, Shackelford, Lindsey, Mack, Schriner, Alexander, Usey, Hart, Galvez, Lindly, Senkel, Maestas, Szaroleta, Krampen-Yerry, Lotridge, Dias, Alvarado, Mountjoy, Fontenot, Anawaty, Capshaw, Briscoe, Smith, Bradford, Johnson, Collier, Williams, Miller, Ward, Shepherd, Scobee, Snyder, Hodge, Trombley, Lloyd, Henley, Benton, Jones, Muniz, Deffenbaugh, Clulee, Johnson, Garrett, Hecker, Hendrix, Hinn, Holman, Wolfe, Booth, Jones, Brooks, Adams, Finotti, Mata, Darnell, Lynch, Parham, Tavian, Banks, Jones, Boston, Rivas, Perez, Austin, Rudenauer, Blackistone, Godfrey, McCutcheon, Soares, Woods, Perez, Chavira, Guidry, Newburn, Cordova, Lecza, Taylor, Lowrey, Wilson, Tyler, Whitfield, Smith, Moskowitz, Strauss, Masingo, Vinas, Morrone, Newman, Strawser, Johnson, Harding, Brown, Green, Bolyard, Bovino, Payne, Clements, Mosby, Mathews, Lowe, Gonzales, Abhold, Warr, Ishii, Jacuzzi, McNally, McCutcheon, Newland, Johnson,

Vaughan, Shaw, Asturi, Brawley, Guy, Mahne, Pierce, Classen, Murphy, Thibodaux, Nomikos, Corgan, Falcon, Frank, Moore, Hall, Lyon, Holland, Palka, Austin, Wetch, Waterfield, Dill, Blocker, Delph, Rigney, Henry, Skiba, Snyder, Alguacil, Perez, Hughey, White, Burns, Spears, Hanson, Pepper, Varner, Reed, Matz, Vernick, Phillips, Eccles, Williams, Favors, Nelson, Bennett, Greenklepper, Landers, Braden, Whipple, Blair, Carlson, Farmer, House, Lujan, Gonzalez, Piper, Oglesby, Kiger, Munoz, Coleman, Dorman, Mullins, Alcantara, Garner, Hickey, Kinder, Espino, Mangan, Cranwell, Ransford, Cashe, Bailey, Martinez, Grayson, Smith, Harris, Holleran, Hooper, and Vautaw cases, I am not aware of any other civil proceedings either pending or contemplated with respect to the matter in controversy herein, and that there are no other parties who shall be joined in this action at this time.

CERTIFICATION PURSUANT TO R. :38-7(c)

I hereby certify that confidential personal identifiers have been redacted from documents now submitted to the Court and will be redacted from all documents in the future in accordance with R. 1:38-8(b).

TRIAL COUNSEL DESIGNATION

Please take notice that pursuant to the provisions of R. 4:25-4, JOSHUA S. KINCANNON, ESQUIRE, is hereby designated as trial counsel on behalf of PLAINTIFF Jennifer Wilson.

LOMURRO, MUNSON, COMER, BROWN & SCHOTTLAND, LLC
Attorneys for Plaintiff

/s JOSHUA S. KINCANNON
JOSHUA S. KINCANNON, ESQ.

Dated: December 20, 2018

Civil Case Information Statement

Case Details: MIDDLESEX | Civil Part Docket# L-008497-18

Case Caption: WILSON JENNIFER VS ETHICON, INC.
Case Initiation Date: 12/20/2018
Attorney Name: JOSHUA S KINCANNON
Firm Name: LOMURRO MUNSON COMER BROWN & SCHOTTLAND LLC
Address: 4 PARAGON WAY SUITE 100
FREEHOLD TWP NJ 07728
Phone:
Name of Party: PLAINTIFF : Wilson, Jennifer
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 12 JURORS
Hurricane Sandy related? NO
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: Per Ravi at eCourts Help, please refer to the Notice of Other Actions paragraph for related actions
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE
CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

12/20/2018
Dated

/s/ JOSHUA S KINCANNON
Signed

MIDDLESEX VICINAGE CIVIL DIVISION
P O BOX 2633
56 PATERSON STREET
NEW BRUNSWICK NJ 08903-2633

TRACK ASSIGNMENT NOTICE

COURT TELEPHONE NO. (732) 645-4300
COURT HOURS 8:30 AM - 4:30 PM

DATE: DECEMBER 20, 2018
RE: WILSON JENNIFER VS ETHICON, INC.
DOCKET: MID L -008497 18

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACK 3.

DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS FROM SERVICE ON THE FIRST DEFENDANT, WHICHEVER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED IS: HON CHRISTOPH RAFANO

IF YOU HAVE ANY QUESTIONS, CONTACT TEAM 004 AT: (732) 645-4300.

IF YOU BELIEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.
PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE WITH R.4:5A-2.

ATTENTION:

ATT: JOSHUA S. KINCANNON
LOMURRO MUNSON COMER BROWN &
4 PARAGON WAY
SUITE 100
FREEHOLD TWP NJ 07728

ECOURTS

EXHIBIT J

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: AMERICAN-MANUFACTURED DRYWALL PRODUCTS LIABILITY LITIGATION

MDL No. 2160

ORDER DENYING TRANSFER

Before the entire Panel: Before the Panel is a motion encompassing three actions in the Southern District of Florida and one action in the District of Arizona as listed on Schedule A.[1] Plaintiffs in one of the Southern District of Florida actions move, pursuant to 28 U.S.C. § 1407, to centralize this litigation in the Southern District of Florida.

Plaintiffs in another Southern District of Florida action support the motion. Plaintiff in the District of Arizona action initially opposed the motion, but later withdrew his opposition with respect to the issue of centralization, while still opposing the Southern District of Florida as the prospective transferee district.

Common defendant New NGC, Inc., d/b/a National Gypsum Company (National Gypsum) opposes the motion. In the event the Panel orders centralization over its objections, National Gypsum (1) requests that any centralized proceedings be limited to lawsuits seeking recovery for allegedly defective drywall manufactured by National Gypsum, and (2) supports centralization in the District of Arizona or the Western District of North Carolina. Defendants 84 Lumber Co. and Lowe's HIW, Inc., also oppose the motion. The remaining defendants in the actions before the Panel – Banner Supply Co. and Pennyworth Homes, Inc. – did not respond to the motion.

The moving plaintiffs subsequently notified the Panel of four additional actions brought against National Gypsum in the Southern District of Florida and eight actions, brought against drywall manufacturers other than National Gypsum, in the Southern District of Mississippi. Plaintiffs in one of the Southern District of Mississippi actions supports the motion for centralization in the Southern District of Florida and proposes centralization in the Southern District of Mississippi in the alternative. Lafarge North America, Inc., Georgia-Pacific Gypsum LLC, and United States Gypsum Co., each of which is a defendant in two Southern District of Mississippi actions, oppose centralization of the actions against them with the actions against National Gypsum.

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[1] The motion initially encompassed an action in the Middle District of Florida; however, that action was dismissed pursuant to a stipulation of dismissal by the parties.

On the basis of the papers filed and hearing session held, we are not persuaded that Section 1407 centralization would serve the convenience of the parties and witnesses or further the just and efficient conduct of this litigation at the present time. All actions identified by the moving plaintiffs have some commonality as to whether the drywall in the homes of the plaintiffs and putative class members has caused the damages and injuries alleged; however, the different manufacturer defendants produced the drywall using different, proprietary techniques and different sources.

The proponents of centralization have not convinced us that any efficiencies from centralization would outweigh the multiple individualized issues, including ones of liability and causation, that these actions appear to present. The parties can avail themselves of alternatives to transfer under Section 1407 to achieve efficiencies in the pretrial proceedings. *See, e.g., In re Eli Lilly and Co. (Cephalexin Monohydrate) Patent Litigation*, 446 F.Supp. 242, 244 (J.P.M.L. 1978); *see also Manual for Complex Litigation, Fourth*, § 20.14 (2004). Also, with only one exception, the actions against each manufacturer are already pending in the same district, and plaintiffs in many of the actions share counsel, which should further facilitate cooperation among the parties and coordination of the actions.

IT IS THEREFORE ORDERED that the motion for transfer, pursuant to 28 U.S.C. § 1407, is denied.

PANEL ON MULTIDISTRICT LITIGATION

John G. Heyburn II
Chairman

Robert L. Miller, Jr.	Kathryn H. Vratil
David R. Hansen	W. Royal Furgeson, Jr.
Frank C. Damrell, Jr.	Barbara S. Jones

IN RE: AMERICAN-MANUFACTURED DRYWALL PRODUCTS LIABILITY LITIGATION MDL No. 2160

SCHEDULE A

District of Arizona

Raymond Yee v. Lowe's HIW, Inc., et al., C.A. No. 3:09-8189

Southern District of Florida

Adolfo Cotilla, et al. v. New NGC, Inc., C.A. No. 0:10-60172
James Paige Visintin, et al. v. National Gypsum Co., et al., C.A. No. 0:10-60266
George Brincku, et al. v. National Gypsum Co., et al., C.A. No. 1:10-20109