BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: DAVOL, INC./C.R. BARD, INC. POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION	))))	**MDL Docket No.: 2846**

RESPONSE OF PLAINTIFFS DOUGLAS LAPCHYNSKI AND MARY FOOS TO THE MOTION FOR TRANSFER AND COORDINATION OF ACTIONS TO A SINGLE DISTRICT FOR CONSOLIDATED AND COORDINATED PRE-TRIAL PROCEEDINGS PURSUANT TO 28 U.S.C. § 1407

I. PRELIMINARY STATEMENT

Plaintiffs Douglas Lapchynski and Mary Foos ("Plaintiffs") submit this Response to the motion for consolidated and coordinated pre-trial procedure of related hernia mesh products liability actions against Defendants C.R. Bard, Inc, and Davol Inc., ("Defendants") under 28 U.S.C. § 1407.

Your undersigned's law firm represents the afore-named Plaintiffs who have a case pending in the United States District Court for the Southern District of Ohio, who are seeking recovery against Defendants for personal injuries and loss of consortium caused by Defendants' hernia mesh device, which Defendants designed, manufactured, marketed, distributed, sold and introduced into the stream of commerce.

For the reasons set forth herein, Plaintiffs support the Motion for §1407 Coordination/Consolidation and Transfer of Related Actions to the Southern District of Ohio filed by Fleming, Nolen & Jez, L.L.P. ("Fleming Motion") and agree that centralization of all hernia mesh products liability actions against Defendants should be transferred to the Southern District of Ohio for centralized pretrial proceedings pursuant to 28 U.S.C. § 1407. Indeed, an MDL would be the most efficient and most appropriate course of action for the Panel because it would: (1)

promote the just and efficient conduct of these actions; (2) prevent inconsistent pretrial rulings and duplicative discovery; and (3) conserve the resources of the judiciary, the parties and their counsel.

Additionally, Plaintiffs agree with the position set forth in the Fleming Motion that the most appropriate venue for this litigation is the United States District Court for the Southern District of Ohio, before the Honorable Chief Judge Edmund A. Sargus. Specifically: (1) the Southern District of Ohio is a convenient and accessible venue; (2) there are currently other actions against Defendants pending in the Southern District of Ohio that have all been consolidated and assigned to Chief Judge Edmund A. Sargus; and (3) Chief Judge Edmund A. Sargus is an experienced jurist with significant mass tort experience.

II. FACTUAL CLAIMS ABOUT DEFENDANTS' HERNIA MESH DEVICES

Defendant C.R. Bard, Inc. is a developer, manufacturer, marketer, and seller of polypropylene hernia mesh devices throughout the U.S. and worldwide. Its subsidiary, Defendant Davol, Inc., is involved with the production and sale of many of the polypropylene hernia mesh devices used in hernia repair surgical procedures that are subject to this litigation.

A hernia occurs when an internal organ such as the bowel protrudes through the muscle wall of the abdomen and/or groin due to a weakness in the muscle and/or connecting tissue. Defendants' hernia mesh devices at issue are designed to serve as a permanent synthetic implantable polypropylene reinforcement used during hernia repair operations.

Plaintiff Lapchynski has brought a products liability action alleging that Defendants' hernia mesh device that was implanted in him was defective and, as a result of receiving a defective product, he had to undergo additional invasive surgical procedures and other treatments to repair the injuries caused by Defendants' defective hernia mesh device. Plaintiff Foos is a consortium

plaintiff whose claims arose as the result of injuries sustained by her husband, Plaintiff Lapchynski.

Plaintiffs assert that Defendants' hernia mesh devices were defective and that the implantations of the defective products caused them severe injuries. Plaintiffs' pleadings allege that after implantation, the defective design and/or manufacture of Defendants' hernia mesh device has caused, and continues to cause, unreasonable risks of severe adverse reactions. Specifically, Plaintiffs' complaint alleges that Defendants' hernia mesh devices often result in post-operative injuries including adhesions, infections, mesh breakage and/or mesh migration, as well as damage to nerves, viscera, and other organs. Moreover, Plaintiffs allege in their Complaint that in promoting and selling their defective mesh devices, Defendants either concealed or failed to adequately warn consumers and/or physicians of the many mesh-related risks. *See Plaintiffs' Complaint*, attached hereto as Exhibit A.

Additionally, Plaintiffs allege that Defendants have neglected to provide sufficient warning of the adverse events associated with their defective hernia mesh devices. Furthermore, Defendants' marketing of these devices as safe and effective devices to be used in hernia repair surgeries is highly irresponsible and misrepresentative given the number of other, less dangerous hernia mesh devices available on the market.

Further, Plaintiffs allege that Defendants' failure to adequately warn of the potential dangers associated with their defective hernia mesh devices has prevented the medical community and/or the general public and consumers from making informed decisions about using these devices in hernia repair operations. Millions of individuals have risked and continue to risk adverse events due to their implanting surgeons' use of Defendants' hernia mesh devices during routine hernia repair operations.

Upon information and belief, Plaintiffs allege that hundreds, if not thousands, of these individuals have experienced serious injuries, including but not limited to adhesions, mesh infection, mesh migration, organ damage, and bowel obstruction as a direct and proximate result of Defendants' defective hernia mesh devices. Many of these injured individuals have filed or will be filing products liability claims against Defendants for injuries they sustained after Defendants' undergoing hernia repair surgeries where Defendants' defective hernia mesh devices were used.

Currently, approximately 50 personal injuries actions have been filed against the Defendants related to their defective mesh devices in at least 21 United States District Courts throughout the country. It is anticipated that this number will likely increase to the thousands. Given the volume of actions filed and the overlapping nature of the facts and issues involved, consolidation and coordination of all of these actions into one MDL is undoubtedly warranted.

To this end, the Southern District of Ohio is the most appropriate venue for this MDL, particularly because the Southern District of Ohio is a convenient and accessible venue for this litigation and Chief Judge Sargus appears to be an interested jurist with exceptional experience to preside over this MDL.

III. ARGUMENT

A. MULTIDISTRICT CONSOLIDATION IS APPROPRIATE FOR THESE CASES

Under 28 U.S.C. § 1407, the multidistrict litigation Panel *may* consolidate numerous cases if the moving party sufficiently demonstrates that (1) the lawsuits contain common questions of fact, (2) consolidation would best serve the convenience of the parties and witnesses, and (3) consolidation promotes just and efficient conduct of such actions. *See* 28 U.S.C. § 1407.

Plaintiffs herein submit that these factors have been demonstrated, and, thus, centralization and coordination of pretrial proceedings against the Defendants is warranted. Specifically, each of the related actions against the Defendants allege highly similar, if not virtually identical, causes of action and contain allegations about Defendants' defective hernia mesh devices and the propensity of these devices to cause serious harm, including but not limited to adhesions, infections, nerve and organ damage, as well bowel obstructions. These actions are based upon the same or substantially similar underlying facts: (1) Defendants' defective hernia mesh devices can cause adhesions, infections, nerve and organ damage, as well bowel obstructions; (2) Defendants unlawfully designed, researched, manufactured, tested, marketed, advertised, promoted and/or sold these hernia mesh devices that caused the alleged injuries; and (3) all plaintiffs suffered grave injuries as a result of Defendants' defective hernia mesh devices.

In response to these common allegations, Defendants commonly deny that their hernia mesh devices can cause the alleged injuries and vehemently disagree with the FDA's safety communications and alerts regarding these injuries. Thus, these actions involve common questions of facts and law that overlap and are common to all plaintiffs and Defendants.

To illustrate, Plaintiffs submit that these related actions will collectively involve common questions against the Defendants, *inter alia*, in the following topic areas:

- whether Defendants' hernia mesh devices pose increased risks of causing the alleged harms over other similar hernia mesh devices;
- whether Defendants knew of these increased risks and/or side effects;
- whether Defendants suppressed, concealed, misrepresented, and/or mischaracterized the known health risks relating to their hernia mesh devices;
- whether Defendants failed to timely and fully disclose the results of the tests and studies on the risks and harms that can be caused by their hernia mesh devices;

- whether Defendants failed to adequately and appropriately test the safety and efficacy of their hernia mesh devices prior to marketing and making representations about these devices;

- whether Defendants failed to disseminate adequate warnings which would have disclosed the nature and extent of the adverse reactions caused by their hernia mesh devices;

- whether Defendants negligently advertised and/or recommended the use of their hernia mesh devices without sufficient knowledge of its dangerous side effects;

- whether Defendants negligently represented that their hernia mesh devices were as safe as other similar hernia mesh devices;

- whether Defendants concealed and/or withheld information from the FDA regarding the safety and efficacy of their hernia mesh devices;

- whether there is available scientific data to support a causal link between Defendants' hernia mesh devices and the alleged adverse events;

- what warnings should the Defendants have included to advise consumers and/or their treating healthcare physicians of the safety risks associated with their hernia mesh devices;

- whether there are design and/or manufacturing defects inherent in the polypropylene used in Defendants' hernia mesh devices;

- whether certain components of Defendants' hernia mesh devices contain manufacturing and/or design defects that can cause severe injury;

- whether Defendants complied with FDA regulations related to the commercialization of medical devices

- whether Defendants knew, or should have known, about the above-referenced defects and their propensity for injury; and

- whether Defendants' business practices and conduct concerning their hernia mesh devices resulted in liability.

Furthermore, consolidation before one MDL court would prevent inconsistent judicial rulings, would eliminate duplicative discovery, would be more convenient to the parties, witnesses and their counsel, and would conserve the resources of the judiciary, the parties and their counsel. Indeed, because the actions alleging injuries as a result of Defendants' hernia mesh devices are

based upon substantially similar allegations, the parties will likely address similar issues in discovery, and in some cases identical issues. *See In re: Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig*., 254 F. Supp. 3d 1381, 1382 (J.P.M.L. 2017) ("All of the actions share common factual questions arising out of allegations that defects in . . . Physiomesh . . . can lead to complications when implanted in patients . . . ."; *see also In re: Atrium Med. Corp. C-Qur Mesh Prods. Liab. Litig.*, 223 F. Supp. 3d 1355, 1356 (J.P.M.L. 2016) (listing common factual questions involving different hernia mesh devices manufactured by the same Defendants); *see also In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F.Supp.3d 1402 (J.P.M.L. 2014) (court granted consolidation where issues concerning the development, manufacture, regulatory approval, labeling and marketing of the pharmaceutical drug were common to all actions; the Court opined that centralization would eliminate duplicative discovery, prevent inconsistent pretrial ruling and conserve resources.)[1]

Lastly, the need for centralization is evidenced by the fact that there are already more than 50 related actions against Defendants on file in at least 21 district courts around the country that will ultimately result in separate scheduling orders should an MDL not be created. It would be inefficient and uneconomical to have any sort of informal coordination of these separate proceedings that are pending in different district courts, before different judges, and/or on different scheduling tracks, in large part because of the sheer number of cases at issue. *See In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II*), 249 F. Supp. 3d 1357 (J.P.M.L. 2017)

[1] Historically, litigations involving implantable mesh products - hernia mesh and pelvic mesh - have received MDL treatment from the JPML. *See eg., In re: Ethicon Physiomesh Flexible Composite Hernia Mesh Products Liability Litigation* (MDL No. 2782); *In re: Atrium Med. Corp. C-Qur Mesh Products Liability Litigation* (MDL No. 2753); *In re: Kugel Mesh Hernia Patch Products Liability Litigation* (MDL No. 1842), *In re: C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation* (MDL No. 2187), *In re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation* (MDL No. 2325), *In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation* (MDL-2326), *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation* (MDL No. 2327*), In re: Coloplast Corp. Pelvic Support Systems Products Liability Litigation* (MDL No. 2387), *In re: Cook Medical, Inc., Pelvic Repair System Products Liability Litigation* (MDL No. 2440).

(plaintiffs argued in their second centralization motion that the litigation has expanded dramatically in terms of the number of actions, districts, and that informal coordination has become impracticable; the court held that centralization was now proper due to the large number of actions, districts, and plaintiffs' and defense counsel which rendered informal coordination impracticable); *see also In re Fluoroquinolone Prods. Liab. Litig*., 122 F. Supp. 3d 1378, 1379-1380 (J.P.M.L. 2015)(rejecting a defendant's argument that informal coordination was superior to consolidation pursuant to 28 U.S.C. § 1407); *see also In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402, 1404 (J.P.M.L. 2014) (rejecting informal coordination argument finding that "the considerable growth in the litigation over the past few months" which included 51 actions pending in 22 districts demonstrated that informal coordination would not be practicable or effective);

Here, it is estimated that there will likely be hundreds, if not thousands, of similar actions against Defendants filed throughout the country. MDL centralization of related actions was instituted precisely for the purpose of avoiding such issues, and in order to promote efficiency and significant financial savings. Thus, for the sake of judicial economy, consistency and efficiency, coordination of all these actions is clearly necessary and warranted.

Moreover, individual case-specific facts in these related actions against Defendants do not deter centralization. To the contrary, the Panel typically orders the transfer of such cases. *See In re: Eliquis (Apixaban) Prods. Liab. Litig.*, 2017 WL 6569794, at *2 (J.P.M.L. May 30, 2017) (holding that "transfer does not require a complete identity of parties or factual issues when, as here, the actions arise from a common factual core".); *see also In re: Roundup Prods. Liab. Litig*., 214 F. Supp. 1346, 1347 (J.P.M.L. 2016) (holding that "differences are not an impediment to centralization when common questions of fact are multiple and complex."); *see also In re: Tylenol (Acetaminophen) Marketing, Sales Practices & Prods. Liab. Litig.*, 936 F. Supp. 2d 1379 (J.P.M.L.

2013) (noting that almost all injury litigation involves questions of causation that is case-specific and varies by plaintiff).

B. THE MOST APPROPRIATE VENUE FOR THIS LITIGATION IS THE SOUTHERN DISTRICT OF OHIO

Assuming centralization is appropriate – which Plaintiffs herein submit that it is – the question presented then becomes one of determining the proper venue for transfer of these cases. To this end, Plaintiffs submit that the most appropriate venue for this litigation is the Southern District of Ohio over any other forum. Defendants do business throughout the United States and market, distribute, promote, and sell their hernia mesh devices in all states. Given those facts, the transfer of Defendants' polypropylene hernia mesh cases to the U.S. District Court for the Southern District of Ohio, is most appropriate due to its geographically centralized location and its ability to handle a large volume of cases. Moreover, Chief Judge Edmund Sargus, is an excellent candidate to serve as the transferee judge due to his experience and proven ability to handle large, complex litigations such as this one.

1. The United States District Court for the Southern District of Ohio is a Proper Transferee Court and Venue

Plaintiffs herein support the Fleming Motion for centralization and respectfully submit that the Southern District of Ohio, before the Honorable Chief Judge Edmund A. Sargus is the most appropriate forum for this MDL.

i) The Southern District of Ohio is Centrally Located and Geographically Ideal

When related actions are pending in various districts throughout the United State, the Panel has held that the geographically central location of a potential transferee district is a very significant factor. *See In re: Epipen (Ephinephrine Injection USP) Marketing, Sales Practices & Antitrust Litig.*, 268 F. Supp. 3d 1356, 1359 (J.P.M.L. 2017) (court transferred a nationwide

litigation to a "geographically central forum"); *see also In re: Genentech Herceptin (trastuzumab) Marketing & Sales Practices Litig.*, 178 F. Supp. 2d 1374, 1376 (J.P.M.L. 2016) (court held that a transfer to "a geographically central forum for this nationwide litigation," was appropriate); *see also In re: Fluoroquinolone Prods. Liab. Litig.*, 122 F. Supp. 2d 1378, 1381 (J.P.M.L. 2015) (the court transferred the actions to a "geographically central and convenient forum.")

Moreover, the Panel has found the Southern District of Ohio to be an appropriate forum in numerous other MDL proceedings. *See eg., In re: American Honda Motor Co., Inc., CR–V Vibration Mktg. and Sales Practices Litig.*, MDL 2661, 140 F. Supp. 3d 1336, 1337 (J.P.M.L. 2015) ("We select the Southern District of Ohio as the transferee district for this litigation… [i]n addition, a majority of plaintiffs support selection of that district…"); *In re: E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 939 F. Supp. 2d 1374, 1375 (J.P.M.L. 2013) ("The Southern District of Ohio is both accessible and convenient for parties and witnesses."); *In re: Porsche Cars N. Am., Inc.*, 787 F. Supp. 2d 1349, 1349 (J.P.M.L. 2011) ("We have selected the Southern District of Ohio as the transferee district for this litigation, because this district is *geographically centrally located* for parties and witnesses in this nationwide litigation and has the capacity to manage this MDL."); *In re: Bill of Lading Transmission & Processing Sys. Patent Litig.*, 626 F. Supp. 2d 1341, 1342 (J.P.M.L. 2009) ("The Southern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation."); *In re Vision Serv. Plan Tax Litig.*, 484 F. Supp. 2d 1356, 1357 (J.P.M.L 2007) ("[C]entralization under Section 1407 in the Southern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation."); *In re: Foundry*, 342 F. Supp. 2d at 1347 ("[T]he Southern District of Ohio will serve the convenience of the parties and witnesses").

Thus, for all the reasons detailed above, the Southern District of Ohio is a geographically convenient location all plaintiffs as well as Defendants.

ii) The Southern District of Ohio is Convenient for All Parties and Witnesses

Pretrial proceedings in a court in a single district will foster the convenience of witnesses and parties in the expanding number of related hernia mesh actions filed against Defendants throughout many districts. To that end, this Panel generally orders centralization when it determines that the statutory requisites are met. *See In re: 21st Century Oncology Customer Data Security Breach Litig.*, 214 F. Supp. 3d 1357, 1358 (J.P.M.L. 2016) ("[W]hile it might inconvenience some parties, transfer of a particular action often is necessary to further the expeditious resolution of the litigation taken as a whole."). Here, centralization is warranted, and Plaintiffs submit the venue should be the Southern District of Ohio.

Although Defendant C.R. Bard is incorporated and based in New Jersey; and Defendant Davol, Inc. is incorporated in Delaware, with its principal place of business in Rhode Island, the Southern District of Ohio is far more convenient than any of those three states. The location of Defendants' corporate headquarters is not dispositive of the convenience factor. To the contrary, it plays a minor part in a convenience analysis. *See, e.g.*, *Bartolucci v. 1-800 Contacts, Inc.*, 245 F. Supp. 3d 38, 48 (D. D.C. 2017) ("While access to proof is still relevant in a motion to transfer inquiry, modern technology has made the location of documents … much less important to a determination of convenience than it once was."); *Republic Techs. (NA), LLC v. BBK Tobacco & Foods, LLC*, 240 F. Supp. 3d 848, 853 (N.D. Ill. 2016) (holding that due to the ease of transfer of digital evidence, the physical location of such evidence has become a lot less important than it was in previous years.) As discussed above, centralization in the Southern District of Ohio, a geographically convenience location, is warranted because it will be easily accessible by litigants

throughout the country and would not inconvenience Defendants even though their principal place of business is elsewhere.

Further, because this litigation will likely involve a large number of cases spread across the country, geographical factors weigh heavily in support of transfer to the Southern District of Ohio. Additionally, the city of Columbus is easily accessible and will be convenient for Plaintiffs and Defendants.

Pertaining to travel to and from the Southern District of Ohio, the courthouse itself is in close proximity to Port Columbus International Airport (which is only 8.3 miles away and, per Google maps, approximately 18 minutes from the courthouse), and is thus a very convenient location for witnesses and parties to convene. Moreover, there are a plethora of local hotels ranging from a Courtyard Marriott, Double Tree Suites, Sheraton, Westin and many more available options, all centrally located in the Uptown and Downtown Districts of Columbus, and within a short distance of the courthouse.

iii) The Southern District of Ohio has Proven Efficacy in Managing a Docket

The Southern District of Ohio has the capacity to handle this MDL. The District has six District Judges, six Senior Judges, and nine Magistrate Judges. The Panel has previously determined that the district is equipped with the resources that a complex docket, such as this one, is likely to require. *See In re: Nat'l Century Fin. Enters., Inc.*, 293 F. Supp. 2d 1375, 1377 (J.P.M.L. 2003). Moreover, the Southern District of Ohio provides a well-staffed and experienced clerks' office with a lot of experience in handling numerous cases, including complex cases such as these, in an efficient manner.

Moreover, in recent MDL's, the Southern District of Ohio has provided an easily accessible state-of-the-art website that has useful information, including attorney contacts and court orders, thereby providing ease of access to information for litigants and attorneys throughout the country.

iv) Chief Judge Edmund A. Sargus Appears Interested in the Litigation and has the Necessary Experience and Knowledge to Oversee this MDL

One factor the Panel looks to in considering the most appropriate transferee court is the interest of the jurist in the proposed MDL, as well as his/her history with and dedication to past MDLs. In this regard, upon information and belief, the Panel looks to interested, experienced jurists to ensure that any given MDL will be managed in an efficient manner that is beneficial to all parties and witnesses involved. To this end, Chief Judge Edmund Sargus, Jr. is an experienced mass tort jurist who appears interested in "steering this MDL on a prudent course," – a proposition expressed by the Panel in prior Orders. *See In re DePuy Orthopaedics, Inc.*, 753 F.Supp. 2d 1378 (J.P.M.L. 2010); *In re Mirena IUD Prods. Liab. Litig.*, 938 F.Supp.2d 1355 (J.P.M.L. 2013); *In re Viagra (Sildenafil Citrate) Prods. Liab. Litig.*, 2016 LEXIS 47256 (J.P.M.L. 2016). Chief Judge Sargus was appointed to the bench in 1996. He is currently serving as Chief Judge for the Southern District of Ohio.

Additionally, this Panel has previously recognized that Judge Sargus is an experienced and knowledgeable judge suitable to oversee an MDL. *See In re: E.I. du Pont de Nemours & Company C-8 Personal injury Litig.*, 939 F. Supp. 2d 1374, 1375 (J.P.M.L. 2013). It is Plaintiffs' position that Chief Judge Sargus is an appropriate judge for transfer and consolidation of this complex hernia mesh litigation. Moreover, Chief Judge Sargus is well suited to ensure proper and efficient case management of these products liability actions.

As noted above, most recently, in *In re: E.I. du Pont de Nemours & Co. C-8 Personal Injury Litig.*, MDL No. 2433, Chief Judge Sargus successfully steered a docket consisting of thousands of litigants who sustained personal injuries and suffered grave illnesses caused by water contaminated by the C-8 chemical. For approximately four years, Chief Judge Sargus oversaw the C-8 litigation through discovery, dispositive motions, complex dispute resolution, bellwether trials, and ultimately settlement.[2]

Moreover, although, as Defendants suggest, other courts may be capable of handling large-scale MDL's such as this one, the Southern District of Ohio is a more appropriate venue for this MDL, not only because of its geographically convenient location but also because Chief Judge Sargus is an experienced jurist who has the necessary expertise to efficiently manage this MDL. Additionally, Chief Judge Sargus is currently assigned to all the hernia mesh cases against Defendants that are pending in the Southern District of Ohio, indicating a general familiarity with this litigation, and a willingness to advance case management principles.

For the multitude of reasons set forth above, Chief Judge Sargus has exceptional experience overseeing mass tort litigations and given his judicial leadership and experience with complex MDL matters, he is an able, competent, and interested jurist, who we respectfully submit, should be permitted to oversee this litigation as a MDL.

[2] It appears that all of the approximately 3,600 cases in that MDL resolved through a global settlement. See *In re: E.I. du Pont de Nemours & Company C-8 Personal Injury Litig., MDL No. 2433*, No. 2:13-md-02433, Doc. No. 5086 ("The parties have informed the Court that they have reached a global resolution of all the cases that make up this MDL.") And it appears that there are less than 35 newly diagnosed injury cases that have been filed, and which the Court is handling essentially as individual cases under his MDL. *See* CMO 24, Management of Newly-Filed Cases, Doc. No. 5140.

III. CONCLUSION

For the foregoing reasons, Plaintiffs herein respectfully request that this Honorable Panel grant the Fleming Motion for consolidation and centralization via a multidistrict litigation to the United States District Court for the Southern District of Ohio before Chief Judge Edmund Sargus and grant such other and further relief as it may deem just and appropriate under the circumstances.

Dated: New York, New York
July 17, 2018

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

DOUGLAS LAPCHYNSKI and MARY FOOS,	)	
	)	**CASE NO. 2:18-cv-637**
Plaintiffs,	)	
v.	)	**JUDGE**
	)	
C.R. BARD, INC. and DAVOL, INC.,	)	**MAGISTRATE JUDGE**
Defendants.	)	
	)	**JURY DEMAND ENDORSED**
	)	**HEREON**

COMPLAINT

Plaintiffs, Douglas Lapchynski and Mary Foos, by and through counsel, brings this Complaint for damages against C.R. Bard, Inc. and Davol, Inc ("Defendants") and in support state the following:

NATURE OF ACTION

1. This products liability action is brought on behalf of the above-named Plaintiffs, arising out of the failure of Defendants' hernia mesh product, the Ventralex Hernia Mesh Patch. As a result, Plaintiffs suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

JURISDICTION AND VENUE

2. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000, exclusive of interest and costs.

3. This Court has personal jurisdiction over Defendants pursuant to the Ohio Long-Arm Statute, Ohio Rev. Code § 2307.382. Defendants transact business within the State of Ohio,

contracted to sell and supply their Ventralex mesh products in the State of Ohio, and committed tortious acts and omissions in Ohio. Defendants' tortious acts and omissions caused injury to Plaintiff Douglas Lapchynski in the State of Ohio. Defendants employ sales representatives in the State of Ohio to sell their Ventralex mesh products throughout the State, including the Ventralex Hernia Mesh that was implanted in Plaintiff Douglas Lapchynski. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, medical devices including the Ventralex Hernia Mesh in Ohio, for which they derived significant and regular income. The Defendants intended and reasonably expected that that their defective mesh products, including the Ventralex Hernia Mesh, would be sold and implanted in Ohio and could cause injury in Ohio.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district.

5. Defendants continue to conduct substantial business in the State of Ohio and in this District, distribute the Ventralex Hernia Mesh in this District, receive substantial compensation and profits from sales of the Ventralex Hernia Mesh in this District, and material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to in personam jurisdiction in this District.

FACTS COMMON TO ALL COUNTS

6. Plaintiffs are citizens and residents of Greene County, Ohio and the United States.

7. Plaintiff Mary Foos is the lawful spouse of Plaintiff Douglas Lapchynski.

8. Defendant Davol Inc. ("Davol") is a corporation that is incorporated under the laws of the State of Delaware. Davol has its principal place of business in the State of Rhode Island. It manufactures the Ventralex Hernia Mesh and is located at 100 Crossings Boulevard, Warwick, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy.

9. Defendant C. R. Bard Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the Ventralex Hernia Mesh. It also manufactures and supplies Davol with material that forms part of the Ventralex Hernia Patch.

10. Upon information and belief, at all relevant times, Defendants transacted, solicited, and conducted business in the State of Rhode Island, New Jersey, and Ohio and derived substantial revenue from such business.

11. The Ventralex Hernia Mesh was designed and is manufactured and distributed by Defendants who own the patent on the device that was inserted into Plaintiff Douglas Lapchynski's body.

12. Defendants designed, manufactures and distributed the Ventralex Hernia Mesh that was inserted into Plaintiff Douglas Lapchynski's body.

13. Defendants, through its agents, servants, and employees, participated in the manufacture and delivery of the Ventralex Hernia Mesh that was inserted into Plaintiff Douglas Lapchynski's body.

14. Defendants submitted a 510(k) Application to the Federal Drug Administration (*hereinafter* "FDA") in May 2002. 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.

15. Under Section 510(k), the Ventralex Hernia Mesh did not undergo clinical study to gain FDA approval. Instead, it was supposed to demonstrate substantial equivalence to a predicate medical device. Following this 510(k) Application, on July 16, 2002, the Ventralex Hernia Mesh was authorized by the FDA as a Class II medical device and found to be "substantially equivalent" to the Bard Composix Kugel Mesh Patch.

16. The Ventralex Hernia Mesh is a multi-layer polypropylene and expanded polytetraflouroethylene patch marketed by Defendants, as a mesh to be used in repairing hernias and to provide extra reinforcement to the hernia defect.

17. Defendants' Ventralex Hernia Mesh product contains two layers of polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving these products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

18. Defendants' statements made to the FDA regarding these devices inadequately relied on predicate devices and not clinical testing or other design verification testing. These statements induced Plaintiff Douglas Lapchynski's implanting surgeon and/or Plaintiffs into relying upon Defendants' judgment.

19. The Ventralex Hernia Mesh is designed, indicated, and utilized for permanent implantation in the human body, in the intraabdominal space between the subcutaneous tissue and intestines.

20. Upon information and belief, Defendants' numerous suppliers, of various forms of polypropylene, cautioned all users in their United States Material Safety Data Sheet (*hereinafter* "MSDS") that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

21. Defendants failed to warn or notify doctors, regulatory agencies, and/or consumers of the severe and life-threatening risks associated with polypropylene.

22. The Ventralex Hernia Mesh contains the following components: 1) a "memory recoil ring" component, 2) a layer of expanded polytetraflouroethylene, and 3) two layers of polypropylene mesh.

23. The Ventralex Hernia Mesh has two layers of polypropylene mesh on one side, and an expanded polytetraflouroethylene ("ePTFE") on the other side. The ePTFE is intended to face the intestines in the intra-abdominal space. The layers of polypropylene are stitched to the ePTFE with polytetraflouroethylene ("PTFE") monofilament. The design also contains a polytetrafluoroethylene ("PET") "memory recoil ring" at its periphery. The stated purpose of this ring is only to facilitate initial placement of the mesh by the surgeon, yet, by design, it is left implanted along with the mesh components. The presence of the ring can directly lead to deformation and buckling of the patch as a result of mesh and/or mesh/wound shrinkage, tissue ingrowth, other mechanical forces acting on the ring, or of plane positioning and repositioning of the patch (noting that the surface to which it is attached is not actually flat even initially), and initial lack of flatness of the ring plane. Additionally, the above-noted forces on the ring can cause the ring to break, causing an array of problems including, but not limited to, bowel perforation.

24. The polypropylene mesh and ePTFE used in the manufacture the Ventralex Hernia Mesh, which was implanted into Plaintiff Douglas Lapchynski is not suited for implantation into

the human body due to its small pore size and weave, high volume of material utilized, selection of polypropylene resin, and other design features. These design aspects lead to adverse tissue reactions in the body, which directly lead to complications.

25. The Ventralex Hernia Mesh implanted in Plaintiff was designed, manufactured, sold and distributed by Defendants to be used by surgeons for hernia repair surgeries and was further represented by Defendants to be an appropriate, cost-effective and suitable product for such purpose.

26. The polypropylene mesh used in the manufacture of the Ventralex Hernia Mesh, which was implanted into Plaintiff Douglas Lapchynski is unreasonably dangerous, defective, and negligently designed in the following ways:

(a) The weave of the mesh produces very small interstices which allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages

(b) Polypropylene is impure: there is no such thing as pure polypropylene (PP). PP contains about 15 additional compounds which are leached from the PP and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis.

(c) Mesh was shown to be not inert in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions.

(d) With loss of PP due to degradation, the surface area is greatly increased, thus providing greater areas for bacterial adherence and more elution of toxic

compounds from the PP, and also the freed toxic PP itself, all of which increases the inflammatory reaction and intensity of fibrosis.

(e) By 1998 polypropylene mesh was known to shrink 30-50%.

(f) Heat begins the process of degradation.

(g) Predominate infection/inflammation was noted at least in 2007 in explanted samples.

(h) Allergic reactions occur with polypropylene after implantation.

(i) Polypropylene is subject to oxidation by acids produced during the inflammatory reaction which caused degradation and loss of compliance.

(j) Mesh porosity is important for tissue ingrowth, with low porosity decreasing tissue incorporation. Porosity also affects the inflammatory and fibrotic reaction. With mechanical stress the porosity of the pores is decreased.

(k) Pore size should be at least 3mm. The Ventralex pore size is much less than this; it has an effective porosity of 1mm.

(l) Observation of mesh under the scanning electron microscope reveals that very small interstices exist between the mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

(m) Polypropylene is known to depolymerize, cross-link, undergo oxidative degradation by free radicals, and stress crack after implantation in the human body.

(n) Polypropylene migrates to lymph nodes when there is a foreign body giant cell reaction.

(o) The large surface area promotes wicking of fluids and bacteria and is a "bacterial super highway" which provides a safe haven for bacteria.

(p) Common complications associated with PP include restriction of abdominal wall mobility and local wound disturbances. Often failures of PP include persistent and active inflammatory processes, irregular or low formation of scar tissue and unsatisfying integration of the mesh in the regenerative tissue area.

(q) Klosterhalfen published a series of 623 explanted mesh samples removed for pain, infection and recurrence. There are also reports of mesh migration and erosion into the sigmoid colon. Reduced mobility of the abdominal wall has also been found. Moreover, the rate of chronic pain after mesh hernia repair ranges from 4-40%. Thus, Defendants should have been aware of these issues with polypropylene.

(r) Fibrotic bridging is often observed in mesh variants with pore sizes of 1mm or less, which is the typical pore size of heavyweight, small pore PP mesh, like the Ventralex Hernia Mesh.

(s) The ePTFE patch shrinkage rates are the largest as a microporous mesh. Due to the microporous design, the ePTFE is embedded entirely in a fibrous capsule, wherein its collagen fibers are arranged parallel to the surface of the ePTFE patches. During wound healing, collagen fibers parallel to the ePTFE surface cause a maximum wound contraction with a reduction of the patch size up to 50%.

27. A malfunction of this device can lead to bowel perforations and/or chronic intestinal fistulae (abdominal connections or passageways between the intestines and other organs), as well as other chronic and debilitating conditions

28. The Ventralex Hernia Mesh implanted into Plaintiff Douglas Lapchynski was manufactured in the same or in a similar manner as recalled Composix Kugel patches. Plaintiff's Ventralex Hernia Mesh contained the same or similar "memory recoil ring," the same or similar polypropylene mesh, and the same or similar ePTFE layer. Plaintiff suffered symptoms and injuries consistent with the symptoms and injuries described by the recall information as suffered by the other individuals affected by the defective Composix Kugel Patches.

29. Upon information and belief Defendants failed to comply with the FDA application and reporting requirements.

30. Upon information and belief Defendants were aware of the high degree of complication and failure rate associated with the Ventralex Hernia Mesh.

31. Upon information and belief Defendants were aware of the defects in the manufacture and design of the Ventralex Hernia Mesh.

32. Upon information and belief, Defendants were and are aware of the defects in the manufacture and design of the Ventralex Hernia Mesh and chose, and continue to choose, not to issue a recall of these products, including the Ventralex Hernia Mesh implanted in Plaintiff Douglas Lapchynski, in the face of a high degree of complication and failure rates.

33. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the Ventralex Hernia Mesh.

34. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the Ventralex Hernia Mesh but did not readily disclose this information.

35. Defendants failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

36. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

37. Defendants marketed the Ventralex Hernia Mesh to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants did not undergo pre-market approval for the Ventralex Hernia Mesh and are, therefore, prohibited by the FDA from asserting superiority claims.

38. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Ventralex Hernia Mesh.

39. Defendants failed to design and establish a safe, effective procedure for removal of the Ventralex Hernia Mesh; therefore, in the event of a failure, injury, or complications it is difficult to safely remove the Ventralex Hernia Mesh.

40. Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using the Ventralex Hernia Mesh for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including Plaintiff Douglas Lapchynski.

41. The Ventralex Hernia Mesh was utilized and implanted in a manner foreseeable to Defendants.

42. The Ventralex Hernia Mesh was implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

43. On or about April 9, 2011 Plaintiff Douglas Lapchynski underwent surgery for repair of an incarcerated incisional hernia. A Ventralex Hernia Mesh Patch**,** Reference number 0010301 and Lot number HUTK0B62 was implanted to repair the hernia defect.

44. At the time of the operation, Plaintiffs were not informed of, and had no knowledge of the complaints, known complications and risks associated with the Ventralex Hernia Mesh.

45. Plaintiffs were never informed by Defendants of the defective and dangerous nature of the Ventralex Hernia Mesh.

46. At the time of the implant, neither Plaintiffs nor Plaintiff Douglas Lapchynski's physicians were aware of the defective and dangerous condition of the Ventralex Hernia Mesh.

47. On or about October 30, 2012, Plaintiff underwent an additional surgery to remove the Ventralex Hernia Mesh.

48. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

49. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

50. Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, which include intentional concealment from Plaintiffs and/or the general public that the Ventralex Hernia Mesh is defective, while continually marketing the product with the effects described in this Complaint.

51. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which Defendants had exclusive control—and because Plaintiffs could not reasonably have known the Ventralex Hernia Mesh was defective, Defendants are estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

52. Despite diligent investigation by Plaintiffs into the cause of Plaintiff Douglas Lapchynski's injuries, including consultations with his medical providers, the nature of the injuries and damages, and their relationship to the Ventralex Hernia Mesh was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

53. Plaintiffs did not learn of Defendants' wrongful conduct until August of 2017. Furthermore, in the existence of due diligence, Plaintiffs could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

54. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

55. Defendants expected and intended the Ventralex Hernia Mesh to reach users such as Plaintiff Douglas Lapchynski in the condition in which the product was sold.

56. The implantation of the Ventralex Hernia Mesh in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

57. When the Ventralex Hernia Mesh was implanted in Plaintiff Douglas Lapchynski's body it was defectively manufactured.

58. Defendants' poor quality control and general non-compliance resulted in the non-conformance of the Ventralex Hernia Mesh implanted in Plaintiff Douglas Lapchynski. The implanted product did not conform to Defendants' intended manufacturing and design specifications.

59. Upon information and belief, Defendants utilized substandard and adulterated polypropylene and raw materials used to make the Ventralex Hernia Mesh, which deviated from Defendants' material and supply specifications.

60. As a direct and proximate result of the defective manufacture of the Ventralex Hernia Mesh, Plaintiffs suffered injuries and damages as summarized in this Complaint.

61. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

62. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

63. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

64. The Ventralex Hernia Mesh was defectively designed and/or manufactured and was not reasonably safe for its intended use in hernia repair; and the risks of the design outweighed any potential benefits associated with it. As a result of the defective design and/or manufacture of the Ventralex Hernia Mesh, there was an unreasonable risk of severe adverse reactions to the mesh or its components including: chronic infections; chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation; allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tumor formation, cancer, tissue damage and/or death; and other complications

65. When affixed to the body's tissue, the impermeable ePTFE layer in the Ventralex Hernia Mesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection or abscess formation and other complications.

66. The smooth surface of the ePTFE layer provides an ideal bacteria breeding ground in which the bacteria cannot be eliminated by the body's immune response, thus allowing bacteria to lie dormant and infection to eventually proliferate.

67. The Ventralex Hernia Mesh is defective in its design in part due to a material mismatch. ePTFE shrinks at a significantly faster rate than polypropylene. This material mismatch results in the Ventralex Hernia Mesh curling after implantation.

68. ePTFE contracts due to the body's inflammatory and foreign body response. Polypropylene incites a greater inflammatory and foreign body response than ePTFE alone. Defendants' ePTFE and polypropylene combination design results in the ePTFE layer shrinking faster than ePTFE would if not in the presence of polypropylene.

69. The multi-layer design of the Ventralex Hernia Mesh results in ineffective sterilization more often than single layer mesh.

70. The Ventralex Hernia Mesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

71. These manufacturing and design defects associated with the product were directly and proximately related to the injuries Plaintiff Douglas Lapchynski suffered.

72. Neither Plaintiff Douglas Lapchynski nor his implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of the product. Moreover, neither Plaintiff Douglas Lapchynski nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the Ventralex Hernia Mesh.

73. The product implanted in Plaintiff Douglas Lapchynski failed to reasonably perform as intended. It caused serious injury and had to be removed via invasive surgery and necessitated additional invasive surgery to repair the hernia that the product was initially implanted to treat.

74. When the Ventralex Hernia Mesh was implanted in Plaintiff Douglas Lapchynski's body, 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.

Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the product's risks.

75. Defendants expected and intended the product to reach users such as Plaintiff Douglas Lapchynski in the condition in which the product was sold.

76. The implantation of the Ventralex Hernia Mesh in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

77. The risks of the product significantly outweigh any benefits that Defendants contend could be associated with it. The Ventralex Hernia Mesh incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable ePTFE layer leads to seroma formation, provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

78. The polypropylene mesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants. The polypropylene material used in the Ventralex Hernia Mesh was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body, further exacerbating the adverse reactions caused by the product. As the ePTFE layer quickly contracts, the Ventralex Hernia Mesh curls, exposing the underlying polypropylene. When implanted adjacent to the bowel and other internal organs, as Defendants intended for the Ventralex Hernia Mesh, polypropylene mesh is unreasonably susceptible to adhesion, perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

79. Bacterial adherence is increased due to the interstitial porosity, surface tension, and electronegativity of ePTFE.

80. ePTFE undergoes irreversible structural changes in the presence of microorganisms. The structural changes ePTFE undergoes provide protection to the microorganisms, allowing them to flourish and necessitating the total removal of the Ventralex Hernia Mesh product.

81. The appropriate treatment for complications associated with the Ventralex Hernia Mesh involves additional invasive surgery in an attempt to remove the mesh from the body, thus eliminating any purported benefit that the product was intended to provide to the patient.

82. When the Ventralex Hernia Mesh was implanted in Plaintiff Douglas Lapchynski, there were safer feasible alternative designs for hernia mesh products available.

83. The Ventralex Hernia Mesh product provides no benefit to consumers over other mesh types and increased the risks to patients implanted with these devices.

84. The Ventralex Hernia Mesh product implanted in Plaintiff Douglas Lapchynski failed to reasonably perform as intended and had to be surgically removed. Thus, further invasive surgery was necessary to repair the very problem that the product was intended to repair, providing only harm and no benefit to him.

85. As a direct and proximate result of the defective and unreasonably dangerous condition of the Ventralex Hernia Mesh, Plaintiffs suffered injuries and damages.

86. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

87. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

88. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. When the Ventralex Hernia Mesh was implanted in Plaintiff Douglas Lapchynski's body, the warnings and instructions provided by Defendants for the product were inadequate and defective. 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.

90. Defendants expected and intended the product to reach users such as Plaintiff Douglas Lapchynski in the condition in which it was sold.

91. Plaintiff and/or Plaintiff's physicians were unaware of the defects and dangers of the Ventralex Hernia Mesh, and were unaware of the frequency, severity and duration of the risks associated with the product.

92. Defendants' Instructions for Use provided with the product expressly understate and misstate the risks known to be associated specifically with it. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Ventralex Hernia Mesh.

93. Defendants' Instructions for Use failed to adequately warn Plaintiff Douglas Lapchynski's physicians of numerous risks, which Defendants knew or should have known were associated with the Ventralex Hernia Mesh, including the following: immunologic response,

infection, pain, dehiscence, encapsulation, rejection, migration, scarification, contraction, erosion through adjacent tissue and viscera, bowel obstruction, and tumor or cancer formation.

94. Defendants' Instructions for Use also failed to instruct physicians how much larger than the hernia defect the product needed to be for an effective repair.

95. As well, the Instructions for Use failed to disclose the extent the Ventralex Hernia Mesh would shrink, or that it would even shrink at all.

96. Defendants failed to adequately warn Plaintiff Douglas Lapchynski and/or his physicians about the need for invasive surgical intervention in the event of complications or inform them of the treatment for such complications when they occurred.

97. Defendants failed to adequately warn Plaintiff Douglas Lapchynski and/or his physicians that the surgical removal of the Ventralex Hernia Mesh, in the event of complications, would leave the hernia unrepaired and the resulting hernia would be much larger than the original. Thus, more complicated medical treatment would be needed to attempt to repair the same hernia that the failed product was intended to treat.

98. Defendants failed to adequately warn Plaintiff Douglas Lapchynski and/or his physicians that in the event of complications, the product is more difficult to fully remove than other feasible hernia meshes that have been available at all material times.

99. Defendants failed to warn Plaintiff Douglas Lapchynski and/or his physicians that as a result of being implanted with the Ventralex Hernia Mesh, he would be at a higher risk of infection for the remainder of his life.

100. With respect to the complications listed in Defendants' warnings, they provided no information or warning regarding the frequency, severity and duration of those complications,

even though the complications associated with the Ventralex Hernia Mesh were more frequent, more severe and longer lasting than those with safer feasible alternative hernia repair treatments.

101. If Plaintiff Douglas Lapchynski and/or his physicians had been properly warned of the defects and dangers of the Ventralex Hernia Mesh, and of the frequency, severity and duration of the risks associated with the product, he would not have consented to allow the product to be implanted, and his physicians would not have implanted it.

102. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiffs suffered injuries and damages as summarized in this Complaint.

103. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

104. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT IV: NEGLIGENCE

105. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

106. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Ventralex Hernia Mesh, but failed to do so.

107. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, creating, and/or designing the Ventralex Hernia Mesh without thoroughly testing it;

(b) Manufacturing, producing, promoting, creating, and/or designing the Ventralex Hernia Mesh without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not the Ventralex Hernia Mesh was safe for use and/or implantation; in that Defendants herein knew or should have known that the Ventralex Hernia Mesh was unsafe and unfit for use and/or implantation by reason of the dangers to its users;

(d) Selling the Ventralex Hernia Mesh without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and the FDA of the dangers of the Ventralex Hernia Mesh;

(f) Negligently advertising and recommending the use of the Ventralex Hernia Mesh without sufficient knowledge as to its dangerous and harmful properties;

(g) Negligently representing that the Ventralex Hernia Mesh was safe for use for its intended purpose, when, in fact, it was unsafe and harmful;

(h) Negligently representing that the Ventralex Hernia Mesh had equivalent safety and efficacy as other types of mesh products used in similar hernia repairs;

(i) Negligently designing the Ventralex Hernia Mesh in a manner which was dangerous to its users;

(j) Negligently manufacturing the Ventralex Hernia Mesh in a manner which was dangerous to its users;

(k) Negligently assembling the Ventralex Hernia Mesh in a manner which was dangerous to its users;

(l) Concealing information from Plaintiffs and/or implanting surgeons in knowing that the Ventralex Hernia Mesh was unsafe and dangerous;

(m) Improperly concealing and/or misrepresenting information from Plaintiffs and/or healthcare professionals, concerning the severity of risks and dangers of the Ventralex Hernia Mesh compared to other hernia mesh devices used in similar hernia repairs.

108. Defendants knew, or in the exercise of reasonable care should have known, that the product was defectively and unreasonably designed and/or manufactured and was unreasonably dangerous and likely to injure patients in whom it was implanted. Defendants knew or should have known that Plaintiff Douglas Lapchynski and/or his physicians were unaware of the dangers and defects inherent in the product.

109. Defendants knew or should have known that the MSDS for the polypropylene used to manufacture the Ventralex Hernia Mesh prohibited permanently implanting the polypropylene into the human body.

110. Defendants utilized non-medical grade polypropylene.

111. Defendants knew or should have known that the polypropylene component is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

112. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

113. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

114. Defendants knew or should have known that the ePTFE component is associated with high rates of severe chronic infections.

115. Defendants knew or should have known that ePTFE degrades in the presence of bacteria.

116. Defendants knew or should have known that once ePTFE is infected, it is nearly impossible to permanently rid the infection and salvage the mesh.

117. Defendants knew or should have known that ePTFE is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

118. Defendants knew or should have known that all subsequent operations carry a greater risk of infection after the patient has been implanted with a Ventralex Hernia Mesh.

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

120. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

121. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT V: BREACH OF IMPLIED WARRANTY

122. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

123. At all material times, Defendants manufactured, distributed, advertised, promoted, and sold their Ventralex Hernia Mesh product.

124. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff Douglas Lapchynski and/or his implanting physician in fact used it; and Defendants impliedly warranted that the product and its component parts was of merchantable quality, safe and fit for such use, and adequately tested.

125. Defendants were aware that consumers, including Plaintiff Douglas Lapchynski and/or his physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff Douglas Lapchynski was a foreseeable user of Defendants' Ventralex Hernia Mesh.

126. Defendants' Ventralex Hernia Mesh was expected to reach, and did in fact reach consumers, including Plaintiff Douglas Lapchynski and/or his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

127. Defendants breached various implied warranties with respect to the Ventralex Hernia Mesh, including the following:

(a) Defendants represented to Plaintiff Douglas Lapchynski and/or his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was safe. But at the same time, they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

(b) Defendants represented to Plaintiff Douglas Lapchynski and/or his physician and healthcare providers that their product was safe and/or

safer than other alternative procedures and devices. But at the same time, they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

(c) Defendants represented to Plaintiff Douglas Lapchynski and/or his physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time, they fraudulently concealed information regarding the true efficacy of the Ventralex Hernia Mesh.

128. In reliance upon Defendants' implied warranties, Plaintiff Douglas Lapchynski, individually, and/or by and through his physician, used the Ventralex Hernia Mesh as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

129. Defendants breached their implied warranties to Plaintiffs in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

130. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiffs were caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

131. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

132. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VI: VIOLATION OF CONSUMER PROTECTION LAWS

133. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

134. Plaintiff Douglas Lapchynski purchased and used the Ventralex Hernia Mesh primarily for personal use, and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

135. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff Douglas Lapchynski would not have purchased and/or paid for the product and would not have incurred related medical costs and injury.

136. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Ventralex Hernia Mesh, which would not have been paid but for Defendants' unfair and deceptive conduct.

137. Unfair methods of competition or deceptive acts or practices proscribed by law include the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

138. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct, directed at patients, physicians and/or

consumers, was to create demand for and sell the Ventralex Hernia Mesh. Each aspect of Defendants' conduct combined to artificially create sales of the product.

139. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Ventralex Hernia Mesh.

140. Had Defendants not engaged in the deceptive conduct described above, Plaintiff Douglas Lapchynski would not have purchased and/or paid for the product and would not have incurred related medical costs.

141. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, and/or physicians and/or consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

142. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes.

143. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of 15 U.S.C. §§ 2301-2312 (1982) and Ohio Rev. Code § 1345, *et. seq*.

144. The statutes listed above were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants are the suppliers, manufacturers, advertisers, and sellers, subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

145. Defendants violated the statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Ventralex Hernia Mesh was fit to be used for the

purpose for which it was intended, when in fact it was defective and dangerous; and by other acts alleged in this Complaint. These representations were made in marketing and promotional materials.

146. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection statutes.

147. Defendants had actual knowledge of the defective and dangerous conditions of the Ventralex Hernia Mesh but failed to take any action to cure those conditions.

148. Plaintiffs and/or the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

149. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and/or consumers, constituted unfair and deceptive acts and practices.

150. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result, Plaintiffs have suffered ascertainable losses and damages.

151. As a direct and proximate result of Defendants' violations of the consumer protection laws, Plaintiffs have sustained economic losses and other damages, and are entitled to statutory and compensatory damages in an amount to be proven at trial.

152. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

153. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VII: GROSS NEGLIGENCE

154. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

155. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs, for which the law would allow, and for which Plaintiffs will seek at the appropriate time, the imposition of exemplary damages. That is because Defendants' conduct, including the failure to comply with applicable federal standards was specifically intended to cause substantial injury to Plaintiffs. Their conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and Defendants were actually, subjectively aware of the risk involved but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included Defendants' false material representations, with their knowledge that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that Plaintiffs would act upon their representation.

156. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

157. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time, in an amount within the jurisdictional limits of the Court.

158. Plaintiffs also allege that Defendants' acts and omissions, whether taken singularly or in combination with others, constitute gross negligence, proximately causing their injuries. In that regard, Plaintiffs will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

159. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

160. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT VIII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

161. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

162. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Ventralex Hernia Mesh to Plaintiffs.

163. Defendants carelessly and negligently concealed the harmful effects of the product from Plaintiff Douglas Lapchynski and/or his physician on multiple occasions and continue to do so to this day.

164. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the Ventralex Hernia Mesh to Plaintiff Douglas Lapchynski and/or his physician on multiple occasions and continue to do so to this day.

165. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that they have sustained, and will continue to sustain, emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Ventralex Hernia Mesh.

166. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the Ventralex Hernia Mesh to Plaintiff Douglas

Lapchynski and/or his physician, after he sustained emotional distress, severe physical injuries, and economic loss.

167. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the product to Plaintiff Douglas Lapchynski and/or his physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

168. As a proximate result of Defendants' conduct, Plaintiffs have been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

169. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

170. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT IX: FRAUDULENT CONCEALMENT

171. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

172. At all material times Defendants knew or should have known that the Ventralex Hernia Mesh caused large numbers of complications. Moreover, they knew or should have known that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of the Ventralex Hernia Mesh had not been proven with respect to, among other things, the product, its components, its performance, and

its method of insertion; and that the product was not safe and effective. Defendants continued to represent that it was safe and effective.

173. Although Defendants knew or should have known about the lack of safety and efficacy of the Ventralex Hernia Mesh, they failed to disclose this information to Plaintiffs, and/or the treating physicians, and/or the public at large.

174. At all material times, Defendants had the duty and obligation to disclose to Plaintiff Douglas Lapchynski and/or his physicians the true facts concerning the Ventralex Hernia Mesh, i.e., its dangerous and defective nature, its lack of efficacy for its purported use and lack of safety in normal use, and its likelihood to cause serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff Douglas Lapchynski was implanted with the Ventralex Hernia Mesh.

175. Defendants were under a duty to Plaintiff Douglas Lapchynski to disclose and warn him of the defective nature of the product because:

(a) Defendants were in a superior position to know the product's true quality, safety, and efficacy;

(b) Defendants knowingly made false claims about the product's safety and quality in documents and marketing materials; and

(c) Defendants fraudulently and affirmatively concealed the defective nature of the product from Plaintiffs.

176. The facts Defendants concealed and/or did not disclose to Plaintiffs were material facts that a reasonable person would have considered important in deciding whether to purchase and/or use the Ventralex Hernia Mesh.

177. At all material times, Defendants willfully, intentionally, and maliciously concealed facts from Plaintiff Douglas Lapchynski and/or his physician, with the intent to defraud.

178. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Ventralex Hernia Mesh so that Plaintiff Douglas Lapchynski would request and purchase the product; and his healthcare providers would dispense, prescribe, and recommend the product. Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

179. At all material times, neither Plaintiff Douglas Lapchynski nor his physician was aware of the facts.

180. Had they been so aware, they would not have reasonably relied upon the representations of safety and efficacy and would not have utilized the Ventralex Hernia Mesh. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physician's selection of the Ventralex Hernia Mesh. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff Douglas Lapchynski, as a patient.

181. As a direct and proximate result of this conduct, Plaintiffs were injured.

182. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

183. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT X: NEGLIGENT MISREPRESENTATION

184. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

185. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff Douglas Lapchynski, and/or the public, that the Ventralex Hernia Mesh had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

186. Defendants failed to exercise ordinary care in their representations concerning the Ventralex Hernia Mesh while involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the product, because they negligently misrepresented the product's risk of unreasonable and dangerous adverse side effects.

187. Defendants breached their duty by representing to Plaintiff Douglas Lapchynski, and/or his physician, and/or the medical community that the Ventralex Hernia Mesh has no serious side effects different from older generations of similar products or procedures.

188. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew, or had reason to know, that the Ventralex Hernia Mesh had been insufficiently tested, or had not been tested at all; and that the product lacked adequate and accurate warnings, and created a high risk—and/or higher than acceptable or reported and represented risk—of adverse side effects, including pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

189. As a direct and proximate result of Defendants' conduct, Plaintiffs have been injured and sustained past and future severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

190. Plaintiffs have suffered and will continue to suffer physical pain and suffering, as well as mental anguish and emotional distress.

191. Plaintiffs have also incurred substantial medical bills and has suffered loss of other monies due to the defective hernia patch that was implanted.

COUNT XI: LOSS OF CONSORTIUM
ON BEHALF OF PLAINTIFF MARY FOOS

192. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

193. Plaintiff Mary Foos was and is the lawful spouse of Plaintiff Douglas Lapchynski, and as such, was and is entitled to the comfort, enjoyment, society and services of her spouse.

194. As a direct and proximate result of the foregoing, Plaintiff Mary Foos was deprived of the comfort and enjoyment of the services and society of her spouse, Plaintiff Douglas Lapchynski, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. The Plaintiffs, Douglas Lapchynski and Mary Foos' injuries and damages are permanent and will continue into the future. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

195. By reason of the foregoing, each Plaintiff has been damaged as against Defendants.

PUNITIVE DAMAGES ALLEGATIONS

196. Plaintiffs repeat, reiterate, and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

197. Defendants failed to adequately test and study the Ventralex Hernia Mesh to determine and ensure that the product was safe and effective prior to releasing it for sale for permanent human implantation; and Defendants continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe.

198. Defendants developed, designed and sold the product, and continue to do so, because it has a significantly higher profit margin than safer hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Ventralex Hernia Mesh, including the risk of failure and serious injury, such as that suffered by Plaintiffs.

199. At all material times, Defendants knew or should have known that the Ventralex Hernia Mesh was inherently more dangerous with respect to the risk of foreign body response, allergic reaction, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, tumor or cancer formation, loss of life's enjoyment, remedial surgeries and treatments to attempt to cure the conditions related to use of the product, as well as the other severe and personal injuries that are permanent and lasting.

200. Defendants' misrepresentations include knowingly withholding material information form the medical community and/or the public, including Plaintiffs, concerning the safety and efficacy of the Ventralex Hernia Mesh, depriving Plaintiff Douglas Lapchynski and/or his implanting physicians of vitally necessary information with which to make a fully informed decision about whether to use the product.

201. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Ventralex Hernia Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

202. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Ventralex Hernia Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of

treatment, and recklessly failed to advise the medical community and/or the general public, including Plaintiffs, of those facts.

203. At all material times, Defendants intentionally misstated and misrepresented data; and continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by the Ventralex Hernia Mesh.

204. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of the Ventralex Hernia Mesh, and its increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and/or to consumers without disclosing the true risk of such complications.

205. When Plaintiff Douglas Lapchynski was implanted with the Ventralex Hernia Mesh, and since then, Defendants have known the product was defective and unreasonably dangerous. But they continued to manufacture, produce, assemble, market, distribute, and sell the product so as to maximize sales and profits at the expense of the health and safety of the public in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Ventralex Hernia Mesh to members of the public, including Plaintiffs.

206. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Ventralex Hernia Mesh, in order to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiffs.

207. Defendants' conduct, acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of

care raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs Douglas Lapchynski and Mary Foos demand judgment against Defendants, individually, jointly, and severally, and in the alternative requests compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiffs Douglas Lapchynski and Mary Foos demand judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. Restitution and disgorgement of profits;

iii. Punitive or enhanced compensatory damages;

iv. Reasonable attorneys' fees as provided by law;

v. Costs of these proceedings, including past and future costs of the suit;

vi. All ascertainable economic damages;

vii. Prejudgment interest on all damages as allowed by law; and

viii. Such other and further relief as this Court deems just and proper.

Dated: June 28, 2018

/s/ David J. Butler
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DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

/s/ David J. Butler
David J. Butler, Esq.