IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

GARY GOODSON,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No.: 3:17-cv-00540**
	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

COMPLAINT

COMES NOW Plaintiff Gary Goodson (hereinafter "Plaintiff"), by and through undersigned counsel, and brings this action against Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants"), and alleges as follows:

Parties

1. Plaintiff is, and was, at all relevant times, a citizen and resident of Illinois and the United States.

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

3. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. There are

three sectors within J&J: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostics sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution, and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon, Inc.

4. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon, Inc. is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is a citizen of New Jersey.

5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion, and/or sale of medical devices including Physiomesh (hereinafter may be referred to as the "product").

6. J&J, directly and/or through the actions of Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.

7. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff Gary Goodson arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale, and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees

and/or owners, all acting within the course and scope of their representative agencies, services, employment and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

Jurisdiction and Venue

9. 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.

10. This Court has personal jurisdiction over each of the Defendants pursuant to the Illinois Long-Arm Statute, 735 ILCS 5/2-209. Defendants transact business within the State of Illinois, and Defendants committed tortious acts and omissions in Illinois and elsewhere. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of Illinois. Defendants have purposefully and persistently engaged in a course of conduct in the State of Illinois including developing, manufacturing, publishing information, marketing, distributing, promoting, and/or selling, either directly or indirectly, medical devices including Physiomesh mesh products in Illinois, from which they derived significant and regular income. Defendants reasonably expected that that their defective mesh products, including Physiomesh, would be sold and implanted in Illinois.

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

Facts Common To All Counts

12. Plaintiff Gary Goodson was implanted with a Physiomesh (25CM x 20CM) device at Anderson Hospital in Maryville, Marion County, Illinois to attempt repair of a recurrent ventral incisional hernia.

13. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff, through his doctors, to be used for treatment of hernia repair.

14. Due to continuous complications with Plaintiff's implanted Physiomesh device, Plaintiff requires revision surgery to correct the dangerous and defective Physiomesh.

15. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Physiomesh, including providing the warnings and instructions concerning the product.

16. Among the intended purposes for which Defendants designed, manufactured, and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff Gary Goodson.

17. Defendants represented to Plaintiff and Plaintiff's physicians that Physiomesh was a safe and effective product for hernia repair.

18. Defendants' Physiomesh was defectively designed, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic

pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

19. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

20. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

21. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

22. The multi-layer coating of Defendants' Physiomesh 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.

23. The polypropylene mesh portion of the Physiomesh was insufficient to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

24. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

25. These design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Gary Goodson.

26. Neither Plaintiff Gary Goodson nor his implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff Gary Goodson nor his implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

27. The Physiomesh implanted in Plaintiff Gary Goodson failed to reasonably perform as intended. The mesh failed, caused serious injury requiring surgical removal via invasive surgery and necessitating additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.

28. Plaintiff Gary Goodson's severe adverse reaction and the necessity for surgical removal of the Physiomesh and repair of the hernia the Physiomesh failed to treat, directly and

proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Gary Goodson has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

29. Plaintiff did not know or have reason to know that his injuries were caused by any conduct of the Defendants or any defect in the Defendants' product until less than two years before this Complaint was filed.

COUNT I
Strict Product Liability: Defective Design

30. Plaintiff incorporates herein by reference the allegations in paragraphs 12 through 29 as if fully set forth herein.

31. At the time the Physiomesh that was implanted in Plaintiff Gary Goodson's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

32. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

33. The implantation of Physiomesh in Plaintiff's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

34. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the product's design. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

35. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

36. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended

by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

37. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient.

38. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

39. At the time the Physiomesh was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries he suffered.

40. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

41. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended and requires removal, necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to him.

42. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized herein.

COUNT II
Strict Product Liability: Failure to Warn

43. Plaintiff incorporates herein by reference the allegations in paragraphs 12 through 42 as if fully set forth herein.

44. At the time the Physiomesh was implanted in Plaintiff's body, the warnings and instructions provided by Defendants for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

45. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

46. Plaintiff and his physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

47. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Physiomesh. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, adhesion formation, immunologic response, increased risk for infection, and increased

inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

48. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiff's physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, or hernia incarceration or strangulation.

49. Defendants failed to adequately train or warn Plaintiff or his physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

50. Defendants failed to adequately warn Plaintiff or his physicians that the necessary future surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

51. Defendants represented to physicians, including Plaintiff's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore

at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

52. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

53. If Plaintiff and/or his physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Plaintiff would not have consented to allow the Physiomesh to be implanted in his body, and his physicians would not have implanted the Physiomesh in Plaintiff.

54. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized herein.

COUNT III
Negligence

55. Plaintiff incorporates herein by reference the allegations of paragraphs 12 through 54 as if fully set forth herein.

56. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, but failed to do so.

57. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted.

Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Physiomesh.

58. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, Plaintiff suffered injuries and damages as summarized herein.

COUNT IV
Punitive Damages

59. Plaintiff incorporates herein by reference the allegations in paragraphs 12 through 58 as if fully set forth herein.

60. Defendants failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants had other hernia repair mesh devices that do not present the same risks as the Physiomesh, Defendants developed, designed and sold Physiomesh because the Physiomesh has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff, justifying the imposition of punitive damages.

Prayer for Relief

WHEREFORE, Plaintiff demands judgment in their favor and seeks the following relief against Defendants:

A. Compensatory damages in excess of $75,000, exclusive of interest and costs;

B. Costs of suit;

C. Pre-judgment and post-judgment interest;

D. Punitive damages; and

E. Such other relief as this Court deems just and proper under the circumstances.

Jury Demand

Plaintiff demands a trial by jury on all issues so triable .

Dated: May 22, 2017

Respectfully submitted,

CAREY DANIS & LOWE

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