CAUSE NO. D-1-GN-13-002039

JOSEPHINE MARIE RABIOLA,	§	IN THE DISTRICT COURT
	§	
Plaintiff,	§	
	§	
v.	§	
	§	
TOMAS G. ANTONINI, M.D., LONE STAR UROGYNECOLOGY AND CONTINENCE CENTER, PLLC, SETON HEALTHCARE FAMILY, SETON FAMILY OF HOSPITALS, D/B/A SETON MEDICAL CENTER WILLIAMSON, JOHNSON & JOHNSON, and ETHICON, INC.,	§	53rd JUDICIAL DISTRICT
	§	
Defendants.	§	TRAVIS COUNTY, TEXAS

PLAINTIFF'S FIRST AMENDED PETITION AND JURY DEMAND

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiff Josephine Marie Rabiola, and files her First Amended Petition complaining of Defendants Tomas G. Antonini, M.D., Lone Star Urogynecology & Continence Center, PLLC, Seton Healthcare Family, Seton Family of Hospitals, d/b/a, Seton Medical Center Williamson, Johnson & Johnson, and Ethicon, Inc., and for cause of action, would respectfully show the Court as follows:

DISCOVERY LEVEL

1. Plaintiff intends that discovery be conducted under Level 3 pursuant to Rule 190.4 of the Texas Rules of Civil Procedure.

PARTIES AND SERVICE

2. Plaintiff Josephine Marie Rabiola is an individual and resident of Austin, Travis County, Texas.

3. Defendant Tomas G. Antonini, M.D. ("Defendant Antonini") is an individual and resident of Travis County who has been served with process and appeared in this case.

4. Defendant Lone Star Urogynecology & Continence Center, PLLC ("Defendant LSUCC") is a Texas professional limited liability company that has been served with process and appeared in this case.

5. Defendant Seton Healthcare Family ("Defendant Seton Healthcare") is a Texas corporation that has been served with process and appeared in this case.

6. Defendant Seton Family of Hospitals, d/b/a, Seton Medical Center Williamson ("Defendant Seton Williamson") is a Texas corporation that has been served with process and appeared in this case.

7. Defendant Johnson & Johnson ("Defendant J&J") is a foreign corporation organized and existing under the laws of the New Jersey that has been served with process and appeared in this case.

8. Defendant Ethicon, Inc. ("Defendant Ethicon") is a New Jersey corporation that has been served with process and appeared in this case.

JURISDICTION AND VENUE

9. The Court has jurisdiction over the lawsuit because the amount in controversy exceeds this Court's minimum jurisdictional requirements.

10. Pursuant to Section 15.002(a)(1), (2), and (3) of the Texas Civil Practice and Remedies Code, venue is proper in Travis County, Texas because (i) this is the county in which all or a substantial part of the events or omissions giving rise to this claim occurred, (ii) this is the county of Defendant Antonini's residence at the time Plaintiff's cause of action accrued, and (iii) this is the county of Defendant Seton Healthcare's principal office in this state.

RULE 47 CLAIMS FOR RELIEF

11. Pursuant to Rule 47 of the Texas Rules of Civil Procedure, Plaintiff hereby seeks monetary relief over $1,000,000.00 and demands judgment for all the other relief to which she is entitled.

ALTERNATIVE ALLEGATIONS

12. To the extent any allegation in the FACTS or CAUSES OF ACTION sections that follow are inconsistent with any other allegation, such inconsistent allegations are pleaded in the alternative pursuant to Texas Rule of Civil Procedure 48. TEX. R. CIV. P. 48; *see Horizon Offshore Contractors, Inc. v. Aon Risk Servs.*, 283 S.W.3d 53, 59 (Tex.App.—Houston [14th Dist.] 2009, pet. denied) ("[A] a party may assert inconsistent facts or remedies simultaneously against different defendants, settle with one defendant, and still recover judgment against the other defendant even though the facts or remedies alleged against the second defendant are inconsistent with the facts or remedies alleged against the settling defendant.").

FACTS

The Pelvic Mesh Products

13. At all times relevant herein, Defendants J&J and Ethicon were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the GYNECARE TVT™ Secur System and the GYNECARE PROSIMA™ Pelvic Floor System ("Pelvic Mesh Products"). The Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the walls of the vagina. The Pelvic Mesh Products are represented by Defendants J&J and Ethicon to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by

two arms that extend up through the buttocks. They are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence and pelvic organ prolapse.

14. Prior the implantation of the Pelvic Mesh Products at issue in this claim, Defendants J&J and Ethicon sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

15. Despite claims that the polypropylene mesh in the Pelvic Mesh Products is inert, the scientific evidence and literature show that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers and physicians should have been aware of this literature, including the following:

a. Shrinkage and bacteria lead to an evolving process and increased erosion. (Klinge U. Eur J Surg 1998;164:965, Jacquetin B. Int Urogyn J 2009;20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007;29:449).

b. Polypropylene mesh has long been known to shrink. This is well supported by the literature. (Klinge U. Eur J Surg 1998;164:965, Jacquetin B. Int Urogyn J 2009;20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007;29:449). By 1998,

polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007. (Klinge U. Eur J Surg 1998;164:965, Jacquetin B. Int Urogyn J 2009;20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007;29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples. (Yahi Y. Int Urogyn J 2007;18(Suppll):Sl49).

c. The weave of the mesh produces very small interstices which allow bacteria to enter and to 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. (Osterberg B. ActaChirScand l979;145:431, Merritt K. J BiomatAppl 1991;5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998;43:338).

d. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process. (Mahmoud W. J Biomat Sci Polymer Ed 1996;7:751, Klinge U. J Biomed Mater Res 2002;63:765, Vollebregt A. Int Urogyn J 2009;20:1345).

e. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses. (Mahmoud W. J Biomat Sci Polymer Ed 1996;7:751, Klinge U. J Biomed Mater Res 2002;63:765, Vollebregt A. Int Urogyn J 2009;20: 1345).

f. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory

reaction and the intensity of fibrosis. (Sternschuss G. J Urol 2012;May 12 epub, Frostling H. Scand J Work Environ Health 1984;10:163).

g. Prolene™ (polypropylene) was shown to be not inert in 1986 and again 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. (Coda A. Hernia 2003;7:29, Jongebloed WL. Doc Ophthalmol 1986;64: 143-52).

h. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis. (Jongebloed W. Doc Ophth 1986;64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010;21:261).

16. The Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

17. Defendants J&J and Ethicon marketed and sold the Pelvic Mesh Products through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants J&J and Ethicon also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of these products.

18. Contrary to the representations and marketing of Defendants J&J and Ethicon, the Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;

b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Pelvic Mesh Products into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

19. Upon information and belief, Defendants J&J and Ethicon have consistently underreported and withheld information about the propensity of its Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

20. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

21. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants J&J and Ethicon are some of the manufacturers of the products that are the subject of the notification.

22. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of "**continuing serious concern**." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse

were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendants and was not disclosed in any manner.

23. Defendants J&J and Ethicon have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

24. Defendants J&J and Ethicon suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendants J&J and Ethicon actively and intentionally misled and continues to mislead the public into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

25. Defendants J&J and Ethicon failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

26. Defendants J&J and Ethicon failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

27. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter.

28. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants J&J and Ethicon, as they generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

29. Defendants J&J and Ethicon provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

30. The Pelvic Mesh Products implanted into Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants J&J and Ethicon, as well as being in the condition directed by and expected by these Defendants.

31. Plaintiff and her physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse or alter these products in an unforeseeable manner.

32. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

33. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

34. Defendants J&J and Ethicon knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

35. At all relevant times herein, Defendants J&J and Ethicon continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

36. At all relevant times herein, Defendants J&J and Ethicon failed to provide sufficient warnings and instructions that would have put Plaintiff and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

37. The Pelvic Mesh Products were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

Medical Care at Issue

38. On May 24, 2010, Chris Hart, M.D. implanted Plaintiff with the Pelvic Mesh Products, specifically the GYNECARE TVT™ Secur System, at Seton Southwest Hospital in Austin, Travis County, Texas for the treatment of stress urinary incontinence. This product failed because of its defectiveness and caused injuries to Plaintiff.

39. Defendant Antonini is an individual licensed to practice medicine in the State of Texas.

40. Defendant LSUCC is a medical group of which Defendant Antonini is an owner and principal.

41. Defendants Seton Healthcare and Seton Williamson own and operate Seton Medical Center Williamson, a healthcare facility located in Round Rock, Williamson County, Texas.

42. Upon information and belief, prior to November 2, 2011, Defendants Antonini, LSUCC, Seton Healthcare, and Seton Williamson knew the Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating additional surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women.

43. Prior to November 2, 2011, Plaintiff presented to Defendant Antonini for consultation regarding her injuries from the defective GYNECARE TVT™ Secur System and her stress urinary incontinence and pelvic organ prolapse. During this consultation, Defendant Antonini recommended implantation of the Pelvic Mesh Products, specifically the GYNECARE PROSIMA™ Pelvic Floor System and another product, but failed to fully disclose to Plaintiff all risks associated with implantation and alternatives available to the Pelvic Mesh Products. He made this recommendation despite the existing literature and FDA warnings referred to above. Plaintiff was not advised of these issues or risks and thus was unable to give informed consent. Plaintiff would not have consented to implantation of the Pelvic Mesh Products had she been fully advised.

44. Upon information and belief, Defendant Antonini recommended the Pelvic Mesh Products to Plaintiff as appropriate and safe for the treatment of stress urinary incontinence and pelvic organ prolapse. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Products.

45. On November 2, 2011, Defendant Antonini implanted Plaintiff with the Pelvic Mesh Products at Seton Medical Center Williamson with the intention of treating her for stress urinary incontinence and pelvic organ prolapse.

46. Upon information and belief, Defendants LSUCC, Seton Healthcare, and/or Seton Williamson sold, distributed, and/or provided Defendant Antonini with the Pelvic Mesh Products that were implanted in Plaintiff.

47. Upon information and belief, Defendants LSUCC, Seton Healthcare, and/or Seton Williamson allowed and/or encouraged Defendant Antonini to implant Plaintiff with the Pelvic Mesh Products.

48. Upon information and belief, Defendant Antonini was acting with the full authority of Defendant LSUCC at the time of the implantation.

49. As a result of the implantation of the Pelvic Mesh Products, Plaintiff suffered and will continue to suffer serious bodily injuries, including pain, discomfort, pressure, difficulty voiding urine, continued incontinence, discharge, scarring, infection, odor, and bleeding.

CAUSES OF ACTION

Negligence: All Defendants

50. On the occasion in question, the injuries and damages sustained by Plaintiff were proximately caused by the negligence of Defendants in at least the following particulars:

a. As to Defendants J&J and Ethicon, in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Pelvic Mesh Products;

b. As to Defendants Antonini and LSUCC:

i. In failing to select and implant the proper medical device to treat Plaintiff's stress urinary incontinence and pelvic organ prolapse;

ii. In failing to select and perform the proper medical procedure for treating Plaintiff's stress urinary incontinence and pelvic organ prolapse;

iii. In improperly selecting Plaintiff as an appropriate candidate for implantation of the Pelvic Mesh Products;

i. In implanting the Pelvic Mesh Products in Plaintiff despite the fact that these products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating additional

surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women; and

iv. In failing to disclose or adequately disclose the risks and hazards involved in the implantation of the Pelvic Mesh Products;

c. As to Defendants LSUCC, Seton Healthcare, and Seton Williamson:

i. In selling and/or distributing the defective Pelvic Mesh Products for use in the treatment of Plaintiff's stress urinary incontinence when it knew or should have known before such sale or distribution that these products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating additional surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women; and

ii. In providing Defendant Antonini with the defective Pelvic Mesh Products for use in the treatment of Plaintiff's stress urinary incontinence and pelvic organ prolapse.

51. Each act or omission of negligence, acting separately or in combination, was a proximate cause of the damages and injuries to Plaintiff.

Strict Liability, Design Defect: Defendants J&J and Ethicon

52. At the time Chris Hart, M.D. and Defendant Antonini implanted the Pelvic Mesh Products in Plaintiff, Defendants J&J and Ethicon were engaged in the business of supplying these products.

53. The Pelvic Mesh Products were defectively designed when sold.

54. The Pelvic Mesh Products were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

55. The Pelvic Mesh Products reached Chris Hart, M.D., Defendant Antonini, and Plaintiff without substantial change in the condition in which they were sold.

56. The defective and unreasonably dangerous condition of the Pelvic Mesh Products was a proximate cause of the damages and injuries to Plaintiff.

57. Thus, Defendants J&J and Ethicon are strictly liable to Plaintiff.

Strict Liability, Manufacturing Defect: Defendants J&J and Ethicon

58. The Pelvic Mesh Products that were implanted in Plaintiff were unreasonably dangerous, not reasonably safe for their intended use, and were defective as a matter of law with respect to their manufacture.

59. The defective and unreasonably dangerous condition of the Pelvic Mesh Products was a proximate cause of the damages and injuries to Plaintiff.

60. Thus, Defendants J&J and Ethicon are strictly liable to Plaintiff.

Strict Liability, Failure to Warn: Defendants J&J and Ethicon

61. Defendants J&J and Ethicon supplied the Pelvic Mesh Products that were implanted in Plaintiff.

62. At all times mentioned herein, the Pelvic Mesh Products were dangerous and presented a substantial danger to patients who were implanted with them.

63. The risks and dangers associated with the Pelvic Mesh Products were known to Defendants J&J and Ethicon at the time of implantation in Plaintiff, yet these Defendants failed to provide warnings of such risks and dangers to Plaintiff.

64. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products posed because their uses were specifically promoted to improve the health of such patients while the nature and prevalence of such risks were either downplayed or not provided to consumers and their physicians.

65. The Pelvic Mesh Products were used in a way reasonably foreseeable to Defendants J&J and Ethicon by Plaintiff, particularly given the educational material or instructions given to physicians in regard to these products.

66. The failure of Defendants J&J and Ethicon to adequately warn about the risks and dangers associated with the Pelvic Mesh Products was a proximate cause of the damages and injuries to Plaintiff.

67. Thus, Defendants J&J and Ethicon are strictly liable to Plaintiff.

Breach of Implied Warranty: Defendants J&J and Ethicon

68. Defendants J&J and Ethicon impliedly warranted that the Pelvic Mesh Products were merchantable and were fit for the ordinary purpose for which they were intended.

69. When the Pelvic Mesh Products were implanted in Plaintiff to treat her medical conditions, these products were being used for the ordinary purpose for which they were intended.

70. Plaintiff, individually and/or by and through her physicians, relied upon the implied warranty of merchantability of Defendants J&J and Ethicon in consenting to have the Pelvic Mesh Products implanted in her.

71. Defendants J&J and Ethicon breached this implied warranty of merchantability because the Pelvic Mesh Products implanted in Plaintiff were neither merchantable nor suited for their intended use as warranted.

72. These breaches of implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

73. The breaches of the aforementioned implied warranties were a proximate cause of the damages and injuries to Plaintiff.

Breach of Express Warranty: Defendants J&J and Ethicon

74. Defendants J&J and Ethicon made assurances to the general public, hospitals, and health care professionals that the Pelvic Mesh Products were safe and reasonably fit for their intended purpose.

75. Plaintiff and/or her healthcare providers chose the Pelvic Mesh Products based upon the warranties and representations of Defendants J&J and Ethicon regarding the safety and fitness of the Pelvic Mesh Products.

76. Plaintiff, individually, and/or by and through her physicians, reasonably relied upon the express warranties and guarantees of Defendants J&J and Ethicon that the Pelvic Mesh Products were safe, merchantable, and reasonably fit for their intended purpose.

77. Defendants J&J and Ethicon breached these express warranties because the Pelvic Mesh Products implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants J&J and Ethicon had represented.

78. These breaches of express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

79. The breaches of the aforementioned express warranties were a proximate cause of the damages and injuries to Plaintiff.

VICARIOUS LIABILITY

80. Whenever in this Petition it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, or representatives.

PLAINTIFF'S DAMAGES

81. As a direct and proximate result of Defendants' improper acts and/or omissions described herein, Plaintiff was caused to suffer severe injuries and damages, including the following:

a. Physical pain and mental anguish sustained in the past;

b. Physical pain and mental anguish that, in reasonable probability, Plaintiff will sustain in the future;

c. Disfigurement sustained in the past;

d. Disfigurement that, in reasonable probability, Plaintiff will sustain in the future;

e. Physical impairment sustained in the past;

f. Physical impairment that, in reasonable probability, Plaintiff will sustain in the future;

g. Medical care expenses incurred in the past; and

h. Medical care expenses that, in reasonable probability, Plaintiff will incur in the future.

EXEMPLARY DAMAGES

82. Defendants' conduct described herein, when viewed objectively from the standpoint of Defendants at the time of the occurrence, involved an extreme degree of risk, considering the

probability and magnitude of the potential harm to others. Moreover, Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Thus, Plaintiff seeks exemplary damages in an amount to be determined by the jury.

JURY TRIAL DEMAND

83. Plaintiff has requested a trial by jury and submitted the appropriate fee.

PRAYER

84. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants be cited to appear and answer herein, and that upon final hearing hereof, Plaintiff have judgment against Defendants for all damages to which she is entitled under the laws of the State of Texas, which amount exceeds the minimum jurisdictional limits of this Court; for pre-judgment interest in accordance with law and/or at the highest legal rate; for interest on the judgment; for costs of suit; for exemplary damages; and for such other and further relief, either at law or in equity, to which Plaintiff has shown or will show herself justly entitled.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

This will certify that a true and correct copy of the foregoing discovery was served on all counsel of record in accordance with the Texas Rules of Civil Procedure as follows:

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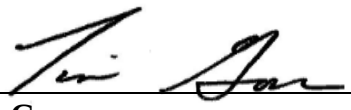
Certified to the 22nd day of August, 2014 by:



Tim K. Goss