CAUSE NO. DC-12-14349

MARTHA SALAZAR and FELIX SALAZAR,	§	IN THE DISTRICT COURT
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	
JORGE FRANCISCO LOPEZ, M.D., COLUMBIA HOSPITAL AT MEDICAL CITY DALLAS SUBSIDIARY, L.P. D/B/A MEDICAL CITY DALLAS HOSPITAL, and BOSTON SCIENTIFIC CORPORATION,	§	95th JUDICIAL DISTRICT
	§	
Defendants.	§	DALLAS COUNTY, TEXAS

PLAINTIFFS' THIRD AMENDED PETITION AND JURY DEMAND

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Plaintiffs Martha Salazar and Felix Salazar, and file their Third Amended Petition complaining of Defendants Jorge Francisco Lopez, M.D., Columbia Hospital at Medical City Dallas Subsidiary, L.P. d/b/a Medical City Dallas Hospital, and Boston Scientific Corporation, and for cause of action, would respectfully show the Court as follows:

DISCOVERY LEVEL

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

DISCLOSURE PURSUANT TO DALLAS COUNTY LOCAL RULE 1.08

2. Pursuant to Local Rule 1.08, Plaintiffs hereby disclose to the Court that this case is related to the following previously-filed cases: *Michelle Burnside Parsons, et al. v. Baylor Health Care System, et al.*, in the 95th District Court of Dallas County, Texas, Cause No. DC-12-00431; *Sandra Dorsey v. Medical City Dallas Hospital*, in 95th District Court of Dallas County, Texas, Cause No. DC-12-005791; and *Margaret Hightower v. Roy Carrington Mason, D.O., et*

al., in the 95th District Court of Dallas County, Texas, Cause No. DC-12-06105. This case and those cases are so related that a transfer of this case to the 95th District Court would facilitate orderly and efficient disposition of the litigation. Thus, Plaintiffs respectfully request transfer of this case to the 95th District Court pursuant to Local Rule 1.06.

PARTIES AND SERVICE

3. Plaintiff Martha Salazar ("Plaintiff Wife") and Plaintiff Felix Salazar ("Plaintiff Husband") are married individuals and residents of Garland, Dallas County, Texas.

4. Defendant Jorge Francisco Lopez, M.D. ("Defendant Lopez") is an individual and resident of Dallas County who has been served with process in this case.

5. Defendant Columbia Hospital at Medical City Dallas Subsidiary, L.P. d/b/a Medical City Dallas Hospital ("Defendant Medical City") is a Texas limited partnership that has been served with process in this case.

6. Defendant Boston Scientific Corporation ("Defendant BSC") is a Delaware corporation with its principal place of business at One Boston Scientific Place, Natick, Massachusetts 01760-1537. Defendant BSC may be served with process by serving its registered agent, Corporation Service Company, at 211 East 7th Street, Suite 620, Austin, Texas 78701.

VENUE

7. Pursuant to Section 15.002(a)(1)-(3) of the Texas Civil Practice and Remedies Code, venue is proper in Dallas County, Texas because this is the county in which all or a substantial part of the events giving rise to this claim occurred, because this is the county of Defendant Lopez's residence at the time Plaintiffs' cause of action accrued, and because this is the county of Defendant Medical City's principal office in this state.

NO FEDERAL CLAIMS PLEADED

8. Plaintiffs' claims in this action are brought solely under state law. Plaintiffs do not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.

9. Moreover, federal diversity jurisdiction is lacking in this action. Complete diversity does not exist between the parties and therefore the federal courts lack jurisdiction under 28 U.S.C §1332.

10. Furthermore, Boston Scientific Corporation agreed with Plaintiffs on December 9, 2013 that it will not remove this matter to Federal Court in the future.

ALTERNATIVE ALLEGATIONS

11. 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

12. At all times relevant herein, Defendant BSC was 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 Obtryx® Transobturator Mid-Urethral Sling System ("Pelvic Mesh Products"). Proxy Biomedical, Ltd., an Irish company, manufactures the polypropylene mesh component of the 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 Defendant BSC 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.

13. Prior the implantation of the Pelvic Mesh Products at issue in this claim, Defendant BSC 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.

14. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Products is inert, the scientific evidence shows 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.

15. 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.

16. Defendant BSC 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. Defendant BSC also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of these products.

17. Contrary to the representations and marketing of Defendant BSC, 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 Wife. 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.

18. Upon information and belief, Defendant BSC has 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.

19. 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.

20. 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 Defendant BSC is one of the manufacturers of the products that are the subject of the notification.

21. 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.

22. Defendant BSC has 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.

23. Defendant BSC suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff Wife. As a result, Defendant BSC 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.

24. Defendant BSC 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.

25. Defendant BSC 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.

26. 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.

27. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant BSC, as they generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

28. Defendant BSC 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.

29. The Pelvic Mesh Products implanted into Plaintiff Wife were in the same or substantially similar condition as they were when they left the possession of Defendant BSC, as well as being in the condition directed by and expected by this Defendant.

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

31. 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.

32. 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.

33. Defendant BSC 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.

34. At all relevant times herein, Defendant BSC continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

35. At all relevant times herein, Defendant BSC failed to provide sufficient warnings and instructions that would have put Plaintiff Wife and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

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

Medical Care at Issue

37. Defendant Lopez is an individual licensed to practice medicine in the State of Texas.

38. Defendant Medical City is the owner and operator of Medical City Dallas Hospital, a hospital located at 7777 Forest Lane, Dallas, Dallas County, Texas.

39. Upon information and belief, prior to January 17, 2011, Defendants Lopez and Medical City 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.

40. Upon information and belief, the administration and/or the members of a Pharmacy and Therapeutic Committee, or a similar committee, of Defendant Medical City did not conduct a formal review to determine whether polypropylene products, such as the one implanted into Plaintiff Wife, should be removed from Defendant Medical City's inventory.

41. Prior to January 17, 2011, Plaintiff Wife presented to Defendant Lopez for consultation regarding her stress urinary incontinence. During this consultation, Defendant Lopez recommended implantation of the Pelvic Mesh Products but failed to fully disclose to Plaintiff Wife all risks associated with implantation.

42. Upon information and belief, Defendant Lopez failed to fully inform Plaintiff Wife that the use of a polypropylene product, such as the one implanted into her by Defendant Lopez, has risks, including, but not limited to, protrusion into her rectum, vagina, and/or bladder, shrinkage, which would require surgical release or other intervention, persistent and life-long dyspareunia, persistent and life-long painful urination, and that she may experience chronic pain and/or chronic infection due to the polypropylene mesh product's interaction with the body and surrounding tissue, that the mesh may have to be removed in one or more surgeries and that it could be impossible to fully remove the polypropylene mesh implant from her body.

43. Upon information and belief, Defendant Lopez recommended the Pelvic Mesh Products to Plaintiff Wife as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff Wife consented to the implantation of the Pelvic Mesh Products. However, Plaintiff Wife was not fully informed of the risks by either Defendant Medical City or Defendant Lopez, as discussed above, which prevented her from making an informed decision regarding the treatment of her stress urinary incontinence and specifically, prevented her from making an informed decision regarding the use of a polypropylene mesh implant for the treatment of her condition.

44. On January 17, 2011, Defendant Lopez implanted Plaintiff Wife with the Pelvic Mesh Products at Medical City of Dallas Hospital with the intention of treating her for stress urinary incontinence, the use for which Defendant BSC marketed and sold these products.

45. Upon information and belief, Defendant Medical City sold to, distributed to, and/or provided Defendant Lopez with the Pelvic Mesh Products that were implanted in Plaintiff Wife.

46. As a result of the implantation of the Pelvic Mesh Products, Plaintiff Wife 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

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

a. As to Defendant BSC, in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Pelvic Mesh Products; and

b. As to Defendant Lopez:

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

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

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

iv. In implanting the Pelvic Mesh Products in Plaintiff Wife 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

v. In failing to fully inform Plaintiff Wife that the use of polypropylene mesh products has risks, including but not limited to, the product might protrude into her rectum, vagina, and/or bladder, that the product might shrink and require surgical release or other intervention, that the mesh might cause persistent and life-long dyspareunia, that the mesh might cause painful urination, that she may experience chronic pain and/or chronic infection due to the mesh, that the mesh may cause scar tissue that may require additional surgery or treatment, that the mesh may need to be removed in one or more surgeries, and that it might be impossible to remove all of the mesh material from her body.

vi. Defendant Lopez's failure to fully advise and inform Plaintiff Wife of the risks of the polypropylene mesh implant to be used in her body prevented Plaintiff Wife from making an informed decision regarding the use of a polypropylene mesh implant for the treatment of her condition. Had Plaintiff Wife been fully informed of all of the risks associated with the polypropylene mesh implant to be used in her body, she would not have consented to implantation of the mesh.

c. As to Defendant Medical City:

i. In selling and/or distributing the defective Pelvic Mesh Products for use in the treatment of Plaintiff Wife'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;

ii. In failing to perform any review whether to remove polypropylene mesh products from Defendant Medical City's inventory. Had a review been conducted by reasonably prudent administrators or members of a Pharmacy and Therapeutic Committee, or similar Committee, such a review would have resulted in the removal of polypropylene mesh products, such as the one implanted into Plaintiff Wife, from the hospital's inventory. Moreover, such a Committee would have the authority to approve procedures, and upon a review by the Committee, should have instructed physicians that usual approved procedures that could be performed at their hospital do not include the transvaginal implantation of polypropylene mesh products. Had an appropriate committee conducted a proper review at Defendant Medical City, the polypropylene mesh products and the transvaginal implantation of such products, would not have been available to the implanting surgeon, and would not have been implanted into Plaintiff Wife. However, because no such review was performed and because the polypropylene mesh products remained in Defendant Medical City's inventory, and because doctors at Defendant Medical City were allowed to use polypropylene mesh products for the treatment of stress urinary incontinence, a polypropylene mesh implant

was implanted into Plaintiff Wife, resulting in her injuries discussed above and potentially more surgery in the future.

iii. In providing Defendant Lopez with the defective Pelvic Mesh Products for use in the treatment of Plaintiff Wife's stress urinary incontinence.

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

Strict Liability, Design Defect: Defendants Medical City and BSC

49. Upon information and belief, Proxy Biomedical, Ltd., which manufactures the polypropylene mesh component of the Pelvic Mesh Products, is not subject to the jurisdiction of this Court. Thus, pursuant to Chapter 82.003(a)(7)(B) of the Texas Civil Practice and Remedies Code, Defendants Medical City and BSC are not excused from liability for being nonmanufacturing sellers.

50. At the time Defendant Lopez implanted the Pelvic Mesh Products in Plaintiff Wife, Defendant BSC was engaged in the business of selling these products and Proxy Biomedical, Ltd. was engaged in the business of selling the polypropylene mesh component of these products.

51. The Pelvic Mesh Products and their polypropylene mesh component were defectively designed when sold.

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

53. The Pelvic Mesh Products and their polypropylene mesh component reached Defendant Lopez and Plaintiff Wife without substantial change in the condition in which they were sold.

54. The defective and unreasonably dangerous condition of the Pelvic Mesh Products and their polypropylene mesh component was a proximate cause of the damages and injuries to Plaintiff Wife.

55. Thus, Defendants Medical City and BSC are strictly liable to Plaintiffs.

Strict Liability, Manufacturing Defect: Defendants Medical City and BSC

56. Upon information and belief, Proxy Biomedical, Ltd., which manufactures the polypropylene mesh component of the Pelvic Mesh Products, is not subject to the jurisdiction of this Court. Thus, pursuant to Chapter 82.003(a)(7)(B) of the Texas Civil Practice and Remedies Code, Defendants Medical City and BSC are not excused from liability for being nonmanufacturing sellers.

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

58. The defective and unreasonably dangerous condition of the Pelvic Mesh Products and their polypropylene mesh component was a proximate cause of the damages and injuries to Plaintiff Wife.

59. Thus, Defendants Medical City and BSC are strictly liable to Plaintiffs.

Strict Liability, Failure to Warn: Defendants Medical City and BSC

60. Upon information and belief, Proxy Biomedical, Ltd., which manufactures the polypropylene mesh component of the Pelvic Mesh Products, is not subject to the jurisdiction of this Court. Thus, pursuant to Chapter 82.003(a)(7)(B) of the Texas Civil Practice and Remedies Code, Defendants Medical City and BSC are not excused from liability for being nonmanufacturing sellers.

61. Defendants Medical City and BSC manufactured, sold, and/or distributed the Pelvic Mesh Products and their polypropylene mesh component that were implanted in Plaintiff Wife.

62. At all times mentioned herein, the Pelvic Mesh Products and their polypropylene mesh component 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 and their polypropylene mesh component were known or knowable to Proxy Biomedical, Ltd., Defendant Medical City, and Defendant BSC at the time of implantation in Plaintiff Wife, yet Proxy Biomedical, Ltd., Defendant Medical City, and Defendant BSC failed to provide warnings of such risks and dangers to Plaintiff Wife.

64. Ordinary consumers would not have recognized the potential risks and dangers the Pelvic Mesh Products and their polypropylene mesh component 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 and their polypropylene mesh component were used in a way reasonably foreseeable to Proxy Biomedical, Ltd., Defendant Medical City, and Defendant BSC by Plaintiff Wife, particularly given the educational material or instructions given to physicians in regard to these products.

66. Proxy Biomedical, Ltd.'s, Defendant Medical City's, and Defendant BSC's failure to adequately warn about the risks and dangers associated with the Pelvic Mesh Products was a proximate cause of the damages and injuries to Plaintiffs.

67. Thus, Defendants Medical City and BSC are strictly liable to Plaintiffs.

Breach of Implied Warranty: Defendant BSC

68. Defendant BSC 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 Wife to treat her medical conditions, these products were being used for the ordinary purpose for which they were intended.

70. Plaintiff Wife, individually and/or by and through her physicians, relied upon the implied warranty of merchantability of Defendant BSC in consenting to have the Pelvic Mesh Products implanted in her.

71. Defendant BSC breached this implied warranty of merchantability because the Pelvic Mesh Products implanted in Plaintiff Wife 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 Wife's body, placing Plaintiff Wife's health and safety in jeopardy.

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

Breach of Express Warranty: Defendant BSC

74. Defendant BSC 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 Wife and/or her healthcare providers chose the Pelvic Mesh Products based upon the warranties and representations of Defendant BSC regarding the safety and fitness of the Pelvic Mesh Products.

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

77. Defendant BSC breached these express warranties because the Pelvic Mesh Products implanted in Plaintiff Wife were unreasonably dangerous and defective and not as Defendant BSC had represented.

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

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

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.

PLAINTIFFS' DAMAGES

Plaintiff Wife

81. As a direct and proximate result of Defendants' improper acts and/or omissions described herein, Plaintiff Wife 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 Wife will sustain in the future;

c. Loss of earning capacity in the past;

d. Loss of earning capacity that, in reasonable probability, Plaintiff Wife will sustain in the future;

e. Disfigurement sustained in the past;

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

g. Physical impairment sustained in the past;

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

i. Medical care expenses incurred in the past; and

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

Plaintiff Husband

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

a. Loss of household services sustained in the past;

b. Loss of household services that, in reasonable probability, Plaintiff Husband will sustain in the future;

c. Loss of consortium sustained in the past; and

d. Loss of consortium that, in reasonable probability, Plaintiff Husband will sustain in the future.

EXEMPLARY DAMAGES

83. 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, Plaintiffs seek exemplary damages in an amount to be determined by the jury.

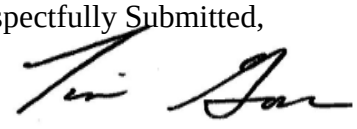
JURY TRIAL DEMAND

84. Plaintiffs hereby respectfully request a trial by jury and have already submitted the appropriate fee.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that Defendants be cited to appear and answer herein, and that upon final hearing hereof, Plaintiffs have judgment against Defendants for all damages to which they are 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 Plaintiffs have shown or will show themselves justly entitled.

Respectfully Submitted,



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CERTIFICATE OF SERVICE

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

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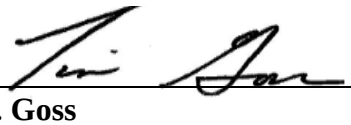
Certified to the 17th day of January, 2014 by:



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