D. N. UWY-CV14-6025333-S	**:**	**SUPERIOR COURT: CLD**
ROBIN SHERWOOD, et al	**:**	**J.D. OF WATERBURY**
V.	**:**	**AT WATERBURY**
STAMFORD HEALTH SYSTEM, INC. D/B/A STAMFORD HOSPITAL	**:**	**SEPTEMBER 23, 2016**

REQUEST FOR LEAVE TO AMEND

Pursuant to Connecticut Practice Book § 10-60, the Plaintiff requests leave to amend the Complaint in order to add alternative legal theories versus Stamford Hospital and to fully set forth and clarify the allegations within the Amended Complaint. A typographical error in the date was corrected in Paragraph 44.

THE PLAINTIFFS,

BY: __/s/ *Jacqueline E. Fusco*

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Juris No. 106151

CERTIFICATION

This is to certify that a copy of the foregoing was Emailed this date, to all counsel of record.

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AMENDED COMPLAINT

FIRST COUNT: (Product Liability Claim v. Stamford Health System, Inc. D/B/A Stamford Hospital)

1. Plaintiff Robin Sherwood, is an individual married to the Co-Plaintiff Greg Hoelscher, with an address at 1 Clapboard Ridge Road, Greenwich, Connecticut.

2. Defendant, Stamford Health System, Inc. d/b/a Stamford Hospital is a hospital located at 30 Shelburne Road, Stamford, Connecticut 06902 which sells various medical products to patients, including the mesh products at issue in this lawsuit.

3. Stamford Hospital and its agents, servants and/or employees marketed and/or furthered the marketing of various medical products to patients, including the pelvic mesh products implanted into Plaintiff Robin Sherwood, the end user.

4. Stamford Hospital its agents, servants and/or employees including the Director of Urogynecology and Pelvic Reconstructive Surgery at Stamford Hospital furthered the marketing of various medical products to patients, including the pelvic mesh products implanted into the end user Plaintiff Robin

Sherwood and specifically recommended specific mesh products to Ms. Sherwood that were subsequently implanted into her.

II. BACKGROUND OF PELVIC MESH PRODUCTS SOLD, DISTRIBUTED AND/OR MANUFACTURED BY THE DEFENDANT STAMFORD HOSPITAL

A. Johnson & Johnson

5. Johnson & Johnson is a corporation, and according to its website, the world's largest and most diverse medical devices and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

6. Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson with an address at PO Box 151, Somerville, New Jersey 08876-0151.

7. Ethicon Women's Health and Urology is a division of Ethicon, Inc. located at the same address in Somerville, New Jersey.

8. Gynecare is a division of Ethicon, Inc. located at the same address in Somerville, New Jersey. Defendants Johnson & Johnson, Ethicon Women's Health and Urology, Ethicon, Inc. and Gynecare are collectively referred to herein as the Johnson & Johnson Defendants.

9. On or about October, 2002, the Johnson & Johnson Defendants began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary

incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

10. Gynemesh was derived from a product known as Prolene Mesh which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Johnson & Johnson's prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft.

11. On or about March, 2005, Johnson & Johnson began to market and sell a product known as Prolift, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was offered as an anterior, posterior, or total repair system, and all references to the Prolift include by reference all variations. Johnson & Johnson pulled the Prolift from the market in 2012.

12. When Johnson & Johnson began marketing the Prolift it did so without clearance or approval from the FDA. Johnson & Johnson bypassed the FDA process (501(k) clearance) by concluding that it was substantially similar to a different product, the Gynemesh PS. Johnson & Johnson determined that the Prolift was an "in-line extension" of the Gynemesh PS device and, therefore, was covered under that existing approval.

13. The Prolift product was, in fact, a newly shaped mesh product that utilized new surgical tools and new surgical techniques including but not limited to blindly passing large trocars through a woman's pelvis.

14. Johnson & Johnson marketed the Prolift to physicians and hospitals as a new and innovative device with a new surgical procedure and surgical tools.

15. On or about May, 2008, Johnson & Johnson began to market and sell a product known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M was offered as an anterior, posterior, or total repair system, and all references to the Prolift+M include by reference all variations. Johnson & Johnson pulled the Prolift +M from the market in 2012.

16. During the FDA clearance/premarket notification process for the Prolift +M product in 2007, Johnson & Johnson was notified by FDA that one of its claimed substantially similar products, the Prolift, itself was not substantially similar to the Gynemesh PS and that Johnson & Johnson should have sought clearance or approval from the FDA. On or about August 24, 2007, the FDA warned Johnson & Johnson that, until it obtained clearance from the FDA it could not market the Prolift, but *may distribute* the Prolift for investigational purposes to obtain clinical data. The FDA warned that clinical investigations of the Prolift must be conducted in accordance with the investigational device exemption (IDE) regulations.

17. Johnson & Johnson disregarded the FDA's directive and continued to market the Prolift until May 15, 2008 when it received FDA clearance.

18. The products known as Prolene Mesh, Gynemesh, Prolift and Prolift+M as well as any unnamed pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendant's Pelvic Mesh Products.

B. STAMFORD HOSPITAL

19. "Product seller" means any person or entity, including a manufacturer, wholesaler, distributor or retailer who is engaged in the business of selling such products whether the sale is for resale or for use or consumption. Connecticut General Statutes §52-572m(a).

20. At all times relevant herein, Defendant Stamford Hospital was engaged in the business of placing medical devices into the stream of commerce for resale, use and/or consumption by distributing, manufacturing, marketing, packaging, repackaging, labeling, selling and/or reselling, installing or otherwise preparing the product for implantation and use, including the pelvic mesh products that were implanted into the Plaintiff, Robin Sherwood.

21. The pelvic mesh products are products targeted at women who suffer from pelvic organ prolapse, pain, discomfort, and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina.

22. Stamford Hospital furthered the marketing of the Johnson & Johnson pelvic mesh products that were implanted into Plaintiff from their original place of manufacture to a physician, who was an agent, servant and/or employee of Stamford Hospital, who made the final delivery of the product to the end user, Plaintiff Robin Sherwood.

23. Defendant Stamford Hospital is a distributor, final distributor and/or manufacturer of products according to the Food and Drug Administration ("FDA") regulations. 21 C.F.R. 821.3. Stamford Hospital is a mandatory reporter of adverse events associated with medical devices.

24. Stamford Hospital purchased pelvic mesh products without any review, oversight or verification of whether said products were approved/cleared by the FDA or branded as investigational and subject to additional regulatory guidelines. Stamford Hospital also purchased pelvic mesh products without any verification of the safety and efficacy of the products resulting in investigational products being marketed by Stamford Hospital to unsuspecting women as FDA approved safe and effective.

25. Stamford Hospital purchased the Prolift product, which included new tools and new procedures, from Johnson & Johnson without knowledge or awareness of FDA clearance or approval.

26. Stamford Hospital implanted pelvic mesh products into patients at least 200-250 times since approximately 2000, including between 2004-2008 when the Prolift was not approved by the FDA.

III. FACTUAL BACKGROUND

27. The Defendant's Pelvic Mesh Products were sold, resold, distributed, marketed, designed, patented, manufactured and/or labeled by the Defendant, at all times relevant herein.

28. Moreover, these products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, scientific evidence suggests that this material is biologically incompatible with human tissue and specifically should not be used in the pelvic region. Additionally, polypropylene promotes an immune response in a large subset of the population receiving the Defendant's Pelvic Mesh Products. The body's natural responses to pelvic mesh can promote degradation of the pelvic tissue and/or degradation of the mesh itself, and can contribute to other severe adverse reactions.

29. Defendant's Pelvic Mesh Products were represented and/or marketed as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for

treatment, and other competing pelvic mesh products. Stamford Hospital did not monitor or verify the safety and effectiveness of the pelvic mesh products or the new surgical technique used to implant the products that it purchased and then sold to end users such as the Plaintiff.

30. The Defendant's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff. In a study published based on a multi-center randomized controlled trial in August, 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion rate with the Prolift, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs."

31. Stamford Hospital has consistently underreported, failed to report and withheld information about the propensity of the Defendant's Pelvic Mesh Products to fail and cause injury and complications and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

32. The Defendant has known and continues to know-that disclosures to the FDA were and are incomplete and misleading and that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. Stamford Hospital failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, Stamford Hospital actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the pelvic mesh products that it purchased and resold to patients were safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff and others.

33. Despite the chronic underreporting of adverse events associated with Stamford Hospital's Pelvic Mesh Products and the underreporting of events associated with similarly designed competitor products, enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

34. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE

database indicates that Johnson & Johnson was one of the sellers of the products that are the subject of the notification.

35. The Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendant's Pelvic Mesh Products.

36. The Defendant failed to verify a safe and effective design of the pelvic mesh products and failed to establish a safe, effective procedure for removal of the Defendant's Pelvic Mesh Products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendant's Pelvic Mesh Products that it sold and implanted into patients such as Robin Sherwood.

37. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendant's Pelvic Mesh Products.

38. The Defendant's Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendant.

39. The Defendant has at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase

the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

40. The Pelvic Mesh Products implanted into the Plaintiffs were in the same or substantially similar condition as they were when they left the possession of the Defendant, and in the condition directed by and expected by the Defendant.

41. The injuries, conditions, and complications suffered due to the Defendant's Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiffs' intimate partners.

42. Despite Stamford Hospital's knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, the Defendant has continued to market, manufacture and sell and/or resell the Products, while continuing to fail to adequately warn, label, instruct, and

disseminate information with regard to the Defendant's Pelvic Mesh Products, both prior to and after the marketing and sale of the Products.

43. Contrary to the Defendant's representations and marketing to the medical community and to the patients themselves, the Defendant's Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law. The defects stem from any or all of the following:

a. the use of polypropylene material in the Mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Device to be inserted transvaginally, into an area of the body with high levels of bacteria, yeast, and fungus that adhere to mesh causing immune reactions, mesh degradation, as well as subsequent tissue breakdown and adverse reactions and injuries;

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

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

e. degradation of the mesh itself over time which does not allow for appropriate incorporation or fixation of the mesh, which results in injury;

f. the welding and/or manufacturing process extremes that degrade the mesh prior to implantation;

g. the design and inclusion of trocars with pelvic mesh products, to aid with inserting Defendant's Pelvic Mesh Products into the vagina, are defective because these devices require tissue penetration in nerve rich environments which results in the destruction of nerve endings causing pain and other injuries; and/or

h. the product lacked adequate warnings and instructions that would have informed the consumer or user of these dangerous propensities and how to avoid them.

44. On or about April 12, 2006, various of the Defendant's Pelvic Mesh Products were implanted in the Plaintiff by an agent, servant and/or employee of Stamford Hospital, at a time when it was not legal to implant such a device under Federal law.

45. Thereafter, as a result of the defective nature of said products, the Plaintiff suffered numerous, painful and permanent consequences.

46. As a result of the defective product, the Plaintiff received and suffered painful, permanent, severe and disabling injuries which were caused, aggravated, accelerated or lighted up by said occurrence, including mesh erosion, mesh

extrusion, mesh contraction, inflammation, scar tissue, dyspareunia, vaginal shortening, blood loss, muscle damage, rectal laceration made while passing the right trocar through an incision, urinary frequency, urinary urgency, ulceration and ischemia of the vaginal wall, recurrent infections and severe shock to the Plaintiff's entire nervous system, requiring the Plaintiff to undergo intensive medical treatment, including additional operations to locate and remove mesh.

47. As a further result, the Plaintiff has suffered severe physical and emotional distress, extreme pain and suffering, embarrassment, limitation of activities, scarring, inconvenience, disability, and has been unable to perform the work, household, recreational; parental and normal duties, activities, and functions as the Plaintiff did before said occurrence.

48. As a result of said injuries, the Plaintiff was required to expend substantial sums of money and may be required to expend additional sums of money in the future for:

a) Medical care and treatment;

b) Psychological care and treatment;

c) Pharmaceutical expenses;

d) Medical devices; and

e) Diagnostic treatment.

49. As a further result of the conduct of the Defendant, the Plaintiff is apprehensive and fearful of future medical complications resulting from the aforesaid injuries.

50. At all times material, the Defendant owed the Plaintiff the duty to design, manufacture, assemble, inspect and/or test the subject product in such a manner and with the exercise of reasonable care, so as to prevent exposing the Plaintiff to the harms enumerated herein.

51. At all times material, the Defendant had a duty to warn consumers or intended users of the subject product of defects which it knew or should have known in the exercise of ordinary care existed in the subject products, which defects rendered the subject product unreasonably dangerous to use.

52. At all times material hereto, the dangerous, hazardous and defective condition described above in connection with the propensity of the subject product to activate was latent, and the Plaintiff was not capable of realizing the dangerous condition and could not have discovered the dangerous condition with a reasonable inspection.

53. Prior to the sale of the products at issue herein, the Defendant knew of the extreme dangers presented by the aforementioned product due to its design.

54. Prior to the sale of the products at issue herein, the Defendant was notified of injuries sustained by numerous other individuals utilizing the aforementioned products due to their defective and unsafe nature.

55. At the time the Defendant sold the subject product, as well as on April 12, 2006, the product was designed, tested, manufactured and labeled in a defective condition, unreasonably dangerous when put to a reasonably anticipated use by its ordinary users, including Plaintiff.

56. The Defendant at all material times, was, or in the exercise of reasonable care should have been aware of the evidence of the Defects enumerated herein, but nevertheless maintain a practice of not disclosing to customers all of its research data or information on the Defects. Defendant was aware that preventable and foreseeable injuries have been caused by the Defects for a number of years. This awareness comes from studies conducted by the Defendant's supplying companies and others; from specific reports of similar incidents from a range of products; and from prior lawsuits all of which was either actually known or available to the Defendants.

57. The Plaintiff's injuries either would not have occurred, or would have been substantially less severe, had the product not had the defects described herein.

58. At the time of design, manufacture, distribution, marketing, advertising, distribution, sale and continuing thereafter, the product was in a defective, dangerous and unreasonable condition for use by the Plaintiff in that the Defendant:

a. improperly and/or inadequately distributed the product;

b. improperly and/or inadequately manufactured, promoted, and/or sold the product;

c. failed to properly inspect and/or test the product;

d. failed to properly warn and/or install warnings or instructions to the user, dealer, purchaser, seller and/or agents of the user about the hazards and dangers associated with the product, either before or after the sale;

e. failed to establish proper and adequate safety design, risk management, and failure mode and effects analysis to the design and manufacturing of the product; and

f. advertised, marketed and/or promoted its product when it knew or should have known of its unsafe and dangerous propensities.

59. The above described conditions were a substantial factor in producing the Plaintiff's injuries and damages hereinbefore alleged.

60. The Defendant and/or its agents, servants or employees expressly warranted, by way of, among other things, advertising, promotional campaigns, brochures, literature, marketing plans, trade name, and goodwill that said product was among other things:

a. safe and fit for its intended purposes and/or uses;

b. safe and fit for its particular purpose;

c. safe and fit for use by persons such as the Plaintiff; and

d. safe and fit for reasonable and expected uses such as that utilized by the Plaintiff.

61. The Defendant breached these express warranties as described above in providing a product that was not safe and fit as warranted.

62. The breach of these express warranties was a substantial factor in producing and causing the Plaintiff's injuries and damages as alleged.

63. The Defendant impliedly warranted that the product was:

a. fit for its particular purpose for which it was intended; and/or

b. of merchantable quality.

64. The Defendant breached these implied warranties as described above in providing a product that was not fit for its particular purpose or of merchantable quality as impliedly warranted due to the Defects described herein.

65. The breach of these implied warranties was a substantial factor in producing and causing the Plaintiff's injuries and damages as alleged.

66. The Defendant and/or its agents, servants or employees were negligent and careless in one or more of the following ways in that the Defendant:

a. improperly and/or inadequately distributed the product;

b. improperly and/or inadequately manufactured, promoted and/or sold the product;

c. failed to properly inspect and/or test the product;

d. failed to properly warn and/or install warnings or instructions to the user, dealer, purchaser, seller and/or agents of the user about the hazards and dangers associated with the product, either before or after the sale;

e. failed to establish proper and adequate safety design, risk management, and failure mode and effects analysis to the design and manufacturing of the product; and

f. advertised, marketed and/or promoted its product when it knew or should have known of its unsafe and dangerous propensities.

67. The above described negligence of the Defendant was a substantial factor in producing and causing the Plaintiff’s injuries and damages hereinbefore alleged.

68. The Defendant violated Connecticut General Statutes §52-240b by acting with reckless disregard for the safety of product users such as the Plaintiff, in at least one or more of the following ways in that the Defendant:

a. improperly and/or inadequately distributed the product;

b. improperly and/or inadequately manufactured, promoted and/or sold the product;

c. failed to properly inspect and/or test the product;

d. failed to properly warn and/or install warnings or instructions to the user, dealer, purchaser, seller and/or agents of the user about the hazards and dangers associated with the product, either before or after the sale;

e. failed to establish proper and adequate safety design, risk management, and failure mode and effects analysis to the design and manufacturing of the product; and

f. advertised, marketed and/or promoted its product when it knew or should have known of its unsafe and dangerous propensities.

69. The harm, injuries and damages suffered by the Plaintiff was a result of the heedless and reckless disregard for the safety of product users such as the Plaintiff thereby creating an unreasonable risk of bodily injury to the Plaintiff.

70. The Defendant, at all material times, has been engaged in the business of selling products such as the product sold to the Plaintiff.

71. The Defendant, and/or its agents, servants or employees through oral and written representations, represented to the Plaintiff that the product was perfectly safe and well designed.

72. When making the representations described above, the Defendant actually knew, or in the exercise of reasonable care should have known, of the dangerous and defective condition of the product.

73. The Plaintiff relied on the knowledge, experience and expertise of the Defendants and/or their agents, servants or employees and was deceived by its representations.

74. The Defendant has specifically violated CONN. AGENCIES REGS. §42-110B-

18(B), by misrepresenting the standard of its merchandise or services as described above.

75. The Defendant has specifically violated CONN. AGENCIES REGS. §42-110B-18(E), by misrepresenting the nature, characteristics, uses, benefits, and qualities of its merchandise or services as described above.

76. As a result of the above described defective condition of the product, the Defendants are liable and legally responsible to the plaintiffs for their injuries and losses as set forth herein by virtue of Connecticut General Statutes § 52-572m, et seq.

77. The Co-Plaintiff, Greg Hoelscher, is the husband of the Plaintiff.

78. As a further result of the Defendant's conduct, the Co-Plaintiff, has suffered mental and emotional distress, has had to render care and attention to the his spouse and has lost marital consortium, which may include a loss of companionship, care, support, society, aid and comfort all to his loss and damage.

SECOND COUNT: (Negligence v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Second Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes negligence.

THIRD COUNT: (Breach of Express Warranty v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78of the Third Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the

scope of the Products Liability Act, the same constitutes breach of express warranty.

<u>FOURTH COUNT</u>: (Breach of Implied Warranty v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Fourth Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes breach of implied warranty.

<u>FIFTH COUNT</u>: (Recklessness v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Fifth Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes recklessness.

<u>SIXTH COUNT</u>: (Civil Conspiracy v. Stamford Hospital)

1-78. Paragraphs 1- 78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Sixth Count.

79. The Defendant, acting in concert with others, conspired to allow, promote, market and sell the Defendant's pelvic mesh products with known issues that were not disclosed to patients or the FDA.

80. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes Civil Conspiracy.

<u>SEVENTH COUNT</u>: (Lack of Informed Consent v. Stamford Hospital)

1-78. Paragraphs 1- 78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Seventh Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes lack of informed consent.

<u>EIGHTH COUNT</u>: (Innocent Misrepresentation v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Eighth Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes innocent misrepresentation.

<u>NINTH COUNT</u>: (Negligent Misrepresentation v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Ninth Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes negligent misrepresentation.

<u>TENTH COUNT</u>: (Intentional Misrepresentation v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Tenth Count.

81. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes intentional misrepresentation.

<u>ELEVENTH COUNT</u>: (CUTPA v. Stamford Hospital)

1-78. Paragraphs 1-78 of the First Count are incorporated by reference and hereby made Paragraphs 1-78 of the Eleventh Count.

79. To the extent Stamford Hospital's conduct described herein is deemed not within the scope of the Products Liability Act, the same constitutes violations of CUTPA.

THE PLAINTIFFS,

BY: __/s/ *Jacqueline E. Fusco*

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STAMFORD HEALTH SYSTEM, INC. D/B/A STAMFORD HOSPITAL	**:**	**SEPTEMBER 23, 2016**

STATEMENT OF AMOUNT IN DEMAND

The amount in demand is in excess of FIFTEEN THOUSAND ($15,000.00) DOLLARS, exclusive of interest and costs.

THE PLAINTIFFS,

BY: __/s/ *Jacqueline E. Fusco*

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PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs claim:

1. Monetary damages;

2. Attorney fees pursuant to Connecticut General Statutes §52-240a;

3. Punitive damages pursuant to Connecticut General Statutes §52-240B and the common law; and

4. Any other further relief in law or equity which may appertain.

THE PLAINTIFFS,

BY: __/s/ *Jacqueline E. Fusco*

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