

DOCKET NO.: CV-14-6025333S : **COMPLEX DOCKET**
STAMFORD HEALTH SYSTEM, INC. :
D/B/A STAMFORD HOSPITAL, : **J.D. OF WATERBURY**
:
V. :
: **AT WATERBURY**
ETHICON, INC., ETHICON, LLC, :
JOHNSON & JOHNSON, INC., :
AMERICAN MEDICAL SYSTEMS, INC., :
and AMERICAN MEDICAL SYSTEMS :
HOLDINGS INC., : **May 5, 2016**

REQUEST FOR LEAVE TO AMEND THIRD PARTY COMPLAINT

Pursuant to Connecticut Practice Book §10-60, the third party plaintiff, Stamford Health System, Inc. (“Stamford Hospital”) requests leave to amend its Third Party Complaint. Stamford Hospital respectfully requests that this Court grant her request because the proposed amendment corrects a factual error about one of the Ethicon products used in Ms. Sherwood’s surgery. A copy of the proposed Amended Third Party Complaint is attached hereto. The third party defendants consent to this amendment.

WHEREFORE, the Stamford Hospital respectfully seeks leave to file its Amended Third Party Complaint.

THIRD PARTY PLAINTIFF,
 STAMFORD HEALTH SYSTEM, INC.

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CERTIFICATION

This is to certify that a copy of the foregoing was emailed this 5th day of May, 2016 to

the following counsel of record:

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AMENDED THIRD PARTY COMPLAINT FILED PURSUANT TO C.G.S. § 52-577a(b)

Stamford Health System, Inc. d/b/a Stamford Hospital (hereafter “Stamford Hospital”), as and for its third party complaint filed pursuant to Conn. Gen. Stat. § 52-577a(b) against the third party defendants alleges as follows:

1. Third party plaintiff, Stamford Health System, Inc. d/b/a Stamford Hospital (hereafter “Stamford Hospital”) provides health services to residents of Stamford, Connecticut and surrounding areas through a not-for-profit, 305-bed community medical center called Stamford Hospital.

2. Stamford Hospital is a defendant in an action brought by plaintiffs, Robin Sherwood and Greg Hoelscher. A copy of plaintiffs’ Complaint (“the Complaint”) is attached hereto as Exhibit A.

3. Defendant, Johnson & Johnson (“J&J”) is a corporation, and according to its website, the world’s largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are “Business Units” including the “Ethicon Franchise.” The Ethicon Franchise was charged by J&J with the design, development,

promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

4. Defendant, Ethicon, Inc. (“Ethicon Inc.”), is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

5. Defendant, Ethicon, LLC (“Ethicon LLC”), is a wholly owned subsidiary of Johnson & Johnson Medical, Inc., located in San Lorenzo, Puerto Rico. Ethicon LLC was charged by J&J with the manufacture of Ethicon Inc.’s pelvic floor repair products.

6. Third Party Defendants J&J, Ethicon, Inc. and Ethicon LLC’s (collectively the “J&J Defendants”) product, the Gynecare Prolift kit, were implanted into Ms. Sherwood and are the subject of a products liability action she brought against Stamford Hospital.

7. Defendant American Medical Systems, Inc. (“AMS”) is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc. and a Delaware corporation.

8. Defendant American Medical Systems, Holdings Inc., (“AMS Holdings”) is a Delaware corporation. At all times material to this action, AMS and AMS Holdings have designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products. AMS Holdings controls and directs its wholly owned subsidiary, AMS.

9. Third Party Defendants AMS and AMS Holdings’ (collectively the “AMS Defendants”) product, the Monarc Subfacial Hammock, was implanted into Ms. Sherwood and is the subject of a products liability action she brought against Stamford Hospital.

Count One: Product Liability

10. Stamford Hospital brings this action pursuant to Conn. Gen. Stat. § 52-577a(b).

11. Although hotly disputed by the Hospital, Ms. Sherwood has alleged that Stamford Hospital is a product seller within the meaning of Conn. Gen. Stat. §52- 572m(a).

12. According to the Complaint, plaintiffs allege that Stamford Hospital is also a manufacturer within the meaning of Conn. Gen. Stat. § 52- 572m(e). Stamford Hospital also hotly contests this allegation. As Ms. Sherwood, her husband and their counsel know, the third party defendants have manufactured the products that were implanted into Ms. Sherwood by her physician and Stamford Hospital had nothing to do with manufacturing, patenting, or marketing them. Plaintiffs and their counsel made these allegations against the Hospital knowing that they were false in violation of Practice Book section 10-5.

13. According to the Complaint, in furtherance of their product liability claim, plaintiffs allege that the products implanted into Ms. Sherwood were defective and caused plaintiffs' injuries and damages as set forth in greater detail in her attached Complaint.

14. According to the Complaint, plaintiffs allege that the Pelvic Mesh Products were indicated for the treatment of medical conditions in the female pelvis, pelvic organ prolapse, and stress urinary incontinence.

15. According to the Complaint, plaintiffs allege that Johnson & Johnson, Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare, and American Medical Systems, Inc. are product sellers within the meaning of Conn. Gen. Stat. § 572m(a) and manufacturers within the meaning of Conn. Gen. Stat. § 572m(e). Upon information and belief, all of the third party defendants are product sellers under the statute and have taken steps or participated in developing, patenting, marketing, and selling their respective products that were implanted into Ms. Sherwood.

16. According to the Complaint, plaintiffs allege that Johnson & Johnson, Ethicon, Inc., Ethicon Women's Health and Urology, Gynecare, and American Medical Systems, Inc., inter-alia, marketed and or furthered the marketing of, placed into the stream of commerce, distributed, manufactured, packaged, repackaged, labeled, sold, resold, installed, designed, and/or prepared for implementation and use, some or all of the Pelvic Mesh Products that plaintiff, Robin Sherwood, alleges were implanted in her on or about April 21, 2006, and were defective and caused plaintiffs injuries and damages as set forth in the Complaint. Upon information and belief, all of the third party defendants had a role in performing these actions.

17. According to the repetitive, disorganized and sloppily pled Complaint, the J&J Defendants and the AMS Defendants were engaged in the business of placing medical devices into the stream of commerce by advertising, designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the devices that were implanted into Ms. Sherwood. Stamford Hospital, as plaintiffs and their counsel well know, did none of these things.

18. As alleged in the Complaint, the devices implanted into Ms. Sherwood and described above were designed and sold by the third party defendants for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

19. The third party defendants placed the products implanted into Ms. Sherwood and described above into the stream of commerce and they were purchased by hospitals throughout Connecticut.

20. The products described above were implanted in plaintiff Robin Sherwood on or about April 21, 2006.

21. The Complaint alleges that the products that were implanted into Ms. Sherwood were neither altered or modified before being placed into her, or if they were altered or modified such alteration or modification was in accordance with the instructions or specifications of the third party defendants, and/or the alteration or modification was made with the consent of the third party defendants, and/or the alteration or modification was the result of conduct that reasonably should have been anticipated by the third party defendants.

22. If plaintiffs have been injured and damaged as alleged in the Complaint, and if the Product Liability allegations made by plaintiffs are true, then the third party defendants are liable and legally responsible to plaintiffs by virtue of Conn. Gen. Stat. § 52-572m, et seq., the Connecticut Product Liability Act (the "CPLA"), in one or more of the following ways as alleged in the Complaint:

- a.) The products described herein and implanted into Ms. Sherwood were manufactured and sold in a defective and unreasonably dangerous condition and could not be used without unreasonable risk of injury to plaintiff;
- b.) The products described herein and implanted into Ms. Sherwood contained manufacturing defects in that they were not reasonably safe for their intended use and the third party defendants deviated materially from their design and manufacturing specification and/or such design and manufacture posed an unreasonable risk of harm to Ms. Sherwood in whom these products were implanted; the forgoing products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers; the products create risks to the health and safety of patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the products at issue in this case;
- c.) The products described herein and implanted into Ms. Sherwood contained design defects including, but not limited to: the use of polypropylene material and/or collagen material and the immune reaction that results from such material, causing adverse reactions and injuries; the design of the products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries; biomechanical issues with the

design of the products, including, but not limited to, the propensity of the products to contact or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury; the use and design of arms and anchors in the products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region; the propensity of the products for “creep,” or to gradually elongate and deform when subject to prolonged tension inside the body; the inelasticity of the products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; the propensity of the products for particle loss or “shedding”, which causes a chronic inflammatory response and fibrotic reaction, and results in continuing injury over time; the lack of porosity of the products, which leads to fibrotic bridging and results in continuing injury over time; the design of trocars, as devices to insert the products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries; and the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers’ instructions;

- d.) The products described herein and implanted into Ms. Sherwood are also defective due to the Johnson & Johnson defendants’ failure to adequately warn or instruct plaintiff and/or her health care providers of risks and complications including, but not limited to, the following: The products propensities to contract, retract, and/or shrink inside the body; the products’ propensities for degradation, fragmentation and/or creep; the J&J Pelvic Mesh Products’ inelasticity preventing proper mating with the pelvic floor and vaginal region; the products’ lack of porosity in preventing proper mating with the pelvic floor and vaginal region; the rate and manner of mesh erosion or extrusion; the risk of chronic inflammation resulting from the products; the risk of chronic infections resulting from the products; the risk of permanent vaginal or pelvic scarring as a result of the products; the risk of permanent vaginal shorting as a result of the products; the risk of recurrent, intractable pelvic pain and other pain resulting from the products; that the products were not as safe as other products and procedures available to treat incontinence and/or prolapse; that the products were not as effective as other products and procedures available to treat incontinence and/or prolapsed; that the risk of adverse events with the products was higher than with other products and procedures available to treat incontinence and/or prolapse;
- e.) The third party defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction,

training, selling, marketing, and distribution of the products in one or more of the following respects: failing to design, manufacture, market, distribute, warn, label, study, test and/or sell the products so as to avoid unreasonable risk of harm to women in whom the products were implanted, including plaintiff; in the case of the J&J Defendants and the Prolift product, failing to use reasonable care in seeking and obtaining FDA clearance prior to marketing and selling the device for implantation into the human body; failing to conduct post-market vigilance, or surveillance; failing to report MDRs (Medical Device [adverse event] Reports); and failing to investigate reports of serious adverse events;

- f.) The products described herein and implanted into Ms. Sherwood were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including plaintiff, and the warnings labels, and instructions were deficient;
- g.) The products described herein and implanted into Ms. Sherwood were inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers;
- h.) The products described herein and implanted into Ms. Sherwood defendants breached various express and implied warranties with respect to the J&J Pelvic Mesh Products including the following particulars: The Johnson & Johnson defendants represented to plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products were safe and knowingly withheld and concealed information about the substantial risks of injury and/or death associated with using the products; the third party defendants represented to plaintiff and her physicians and healthcare providers that the products were as safe, and/or safer than other alternative procedures and devices, that complications are rare, and knowingly concealed information, which demonstrated that the products were not safer than alternatives available on the market and that complications were not, in fact, rare; and the third party defendants represented to plaintiff and their physicians and healthcare providers that the products were more efficacious than other alternative medications and knowingly concealed information, regarding the true efficacy of the products;
- i.) The third party defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the products.
- j.) The third party defendants failed to design and establish a safe, effective procedure for removal of the products. Therefore, in the event of a failure,

injury, or complications, it is impossible to easily and safely remove the products described herein and implanted into Ms. Sherwood.

- k.) Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the J&J Pelvic Mesh Products;
- l.) The third party defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the products described herein and implanted into Ms. Sherwood, and thus increase the sales of the products, and also leading to the dissemination of inadequate and misleading information to patients, including plaintiff.

23. The third party defendants are or may be liable for all or part of plaintiffs' claim pursuant to Conn. Gen. Stat. § 52-577(a)b. Stamford Hospital alleges that it is not liable at all for the product liability claims plaintiffs have filed and that if anyone is responsible for plaintiffs' injuries, to the extent she is injured, it is the third party defendants.

WHEREFORE, the third party plaintiff seeks the following:

1. If the Product Liability allegations made by plaintiffs in the Complaint are true, then a determination by the fact finder that the J&J Defendants are liable and legally responsible to plaintiffs by virtue of Conn. Gen. Stat. § 52-572m, et seq., and that the Johnson & Johnson defendants are liable for all or part of plaintiffs' claim pursuant to Conn. Gen. Stat. § 52-577(a)b;

2. If the Product Liability allegations made by plaintiffs in the Complaint are true, then a determination by the fact finder that the AMS Defendants are liable and legally responsible to plaintiffs by virtue of Conn. Gen. Stat. § 52-572m, et seq., and that the AMS Defendants are liable for all or part of plaintiffs' claim pursuant to Conn. Gen. Stat. § 52-577(a)b;

3. Any other relief which this court may deem appropriate at law or in equity.

**DEFENDANT,
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D/B/A STAMFORD HOSPITAL**

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