IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case Nos. 3:07-cv-00088 (Parker *et al.*) 3:07-cv-00101 (Stafford *et al.*)
	*	3:07-cv-00102 (Booth *et al.*) 3:07-cv-00130 (Dover *et al.*)
	*	

O R D E R

This multidistrict litigation proceeding includes various product liability actions against Mentor Worldwide LLC ("Mentor") arising from the implantation of Mentor's suburethral sling product, ObTape Transobturator Tape ("ObTape"), to treat Plaintiffs for stress urinary incontinence. In these actions, Plaintiffs assert claims for design and manufacturing defect, breach of implied warranty, and failure to warn.[1] ObTape allegedly caused complications, including infection and erosion of ObTape through Plaintiffs' bodily tissues. In support of their claims, Plaintiffs rely upon the opinion testimony of several expert witnesses, who opine that ObTape had a design and/or manufacturing defect that proximately caused the injuries suffered by these Plaintiffs. These experts also opine that Mentor did not adequately warn Plaintiffs' physicians about the risks associated with ObTape.

[1]This litigation has been divided into phases, and the present Order applies to the Phase I Plaintiffs whose actions originated in Georgia district courts.

Mentor argues that the testimony of Plaintiffs' experts on these issues is unreliable under Federal Rule of Evidence 702 and must be excluded (Doc. 156). Mentor maintains that without that expert testimony, Plaintiffs are unable to create genuine issues of material fact on design defect, manufacturing defect, failure to warn, and causation. Mentor also contends that Plaintiffs' claims for breach of implied warranty fail. Therefore, Mentor moves for summary judgment on all Phase I Georgia Plaintiffs' design defect claims (Doc. 154), as well as their manufacturing defect claims, failure to warn claims, and implied warranty claims (Doc. 140 in 3:07-cv-88 (Parker Plaintiffs); Doc. 142 in 3:07-cv-88 (Olson Plaintiffs); Doc. 114 in 3:07-cv-101 (Plaintiffs Stafford and Pinkney); Doc. 110 in 3:07-cv-102 (Crowther Plaintiffs); Doc. 111 in 3:07-cv-102 (Booth Plaintiffs); Doc. 112 in 3:07-cv-102 (Tucker Plaintiffs); Doc. 105 in 3:07-cv-130 (Plaintiff Mills); Doc. 106 in 3:07-cv-130 (Dover Plaintiffs); Doc. 108 in 3:07-cv-130 (Merritt Plaintiffs); Doc. 109 in 3:07-cv-130 (Looper Plaintiffs); and Doc. 110 in 3:07-cv-130 (Turner Plaintiffs)). Mentor also argues that the claims of Plaintiffs Dover, Merritt, and Olson are time-barred.

For the following reasons, the Court finds that Plaintiffs have produced sufficiently reliable expert testimony to create genuine issues of material fact as to design defect, manufacturing defect, failure to warn, and causation, but the Court finds that Plaintiffs'

claims for breach of implied warranty fail. Mentor's motion to exclude the expert testimony is denied except as noted below. Mentor's motions for summary judgment as to the design defect, manufacturing defect, and failure to warn claims are denied. Mentor's motions for summary judgment as to the implied warranty claims are granted.[2]

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). In determining whether a *genuine* issue of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of

[2]Mentor also seeks summary judgment as to any claims asserted by Plaintiffs that are based upon a "fraud on the U.S. Food and Drug Administration" theory. Plaintiffs explain that they are not asserting any separate cause of action based upon this theory. To the extent their Complaints could be construed to allege any claim of this type, the Court rules that such claims have been abandoned. This ruling should not be interpreted to mean that evidence regarding the FDA application process is therefore irrelevant as to Plaintiffs' remaining claims. That determination will be made through rulings on Mentor's *Daubert* motions and/or motions in limine.

the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

The evidence relevant to the pending motions for summary judgment can be divided into two categories–evidence that relates to all Plaintiffs' claims and individualized evidence that relates with specific particularity to one or more Plaintiffs. The Court will discuss each category of evidence separately, starting with the evidence that is relevant to all Plaintiffs' claims. The record, with all reasonable inferences construed in favor of Plaintiffs, establishes the following.

I. Evidence Relevant to All Plaintiffs' Claims

Mentor developed a suburethral sling called ObTape Transobturator Tape ("ObTape"), which was used to treat women with stress urinary incontinence ("SUI"). ObTape was cleared for sale by the U.S. Food and Drug Administration ("FDA") via the FDA's 510(k) regulatory process. ObTape was a Class II medical device, available only through a prescription from a physician. It was sold to hospitals and physicians, not directly to patients. Every ObTape package included a Product Insert Data Sheet ("PIDS") which contained the following statement regarding "Adverse Reactions":

> No undesirable effects that could be directly attributed to the polypropylene fibers have been reported in the literature. As with all foreign bodies, the ObTape is likely to trigger any existing infection, which can result in fistular formation and/or expulsion of the device. The following events have been reported *very rarely*:
>
> Vaginal Erosion
>
> Urethral Erosion
>
> Infection
>
> Patients should be monitored regularly after the device has been implanted.
>
> No undesirable effects directly attributed to materials used in the Introducer Needles have been reported in the literature.

(Ex. 1 to Mentor's Mot. for Summ. J. as to Design Defect Claims (Doc. 154), Wyatt Decl., Jan. 12, 2010 [hereinafter Wyatt Decl.], Ex. A, ObTape Product Insert Data Sheet 2 (emphasis added) [hereinafter ObTape PIDS].) The PIDS also instructs that patients "should immediately report any onset of bleeding or dysuria." (*Id.*) In addition, the PIDS states: "If explantation is necessary, Mentor will analyze the explanted device[.]" (*Id.*)

As discussed in more detail below, Plaintiffs were implanted with ObTape to treat SUI. Plaintiffs contend that the defective design and/or manufacture of ObTape caused complications that resulted in significant injuries, including serious infections and erosion of the tape through their bodily tissues. In support of their claims, Plaintiffs rely primarily upon the testimony of various

expert witnesses who have had direct clinical experience with ObTape, as well as the expert testimony of a former Mentor employee, Dr. Catherine Ortuno.

Dr. Ortuno is a former employee of Mentor-Porges.[3] She is a medical doctor who received her medical degree from CHU Cochin Port-Royal (University of Paris V). (Attach. A to Ex. 4 to Pls.' Separate Statement of Material Facts, Ortuno Curriculum Vitae.) She began working for Porges in 1996 as a junior project manager for clinical trials, and she was also responsible for device vigilance. (*Id.*) In 2001, she became Senior Project Manager for Women's Health Products, and she also served as Device Vigilance and Clinical Research Officer. In that role, she was in charge of the vigilance database for Mentor-Porges products, including ObTape, and she was also in charge of clinical trials. She received complaints from the field about Mentor's products, including ObTape and its predecessor, Uratape. Her job duties required her to evaluate, investigate, and report adverse events reported to Mentor-Porges regarding ObTape. (Ortuno Dep. 73:24-74:3, Oct. 19, 2009.) With Uratape, Dr. Ortuno "observed an increased rate of vaginal erosions." (Ex. 4 to Pls.' Separate Statement of Material Facts, Ortuno Rule 26 Report 4 [hereinafter Ortuno Rule 26 Report].) Dr. Ortuno believed that the increased rate of erosions was caused either by Uratape's silicone

[3]Mentor-Porges was a subsidiary of Mentor from 2001 until 2006.

patch or by the structure of the Uratape mesh. (*Id.*) According to Dr. Ortuno, ObTape has the same mesh structure as Uratape, but it lacks the silicone patch. (*Id.*; *see also* Ortuno Dep. 29:12-14.) After ObTape was launched, Mentor received reports of serious complications, and Dr. Ortuno concluded: "The cause could no longer be the silicone patch which had been removed from the product. The cause was the structure of ObTape." (Ortuno Rule 26 Report 4; *accord* Ortuno Dep. 300:6-20; *see also id.* at 233:6-25 (noting that ObTape complications were more severe than complications associated with competing product).)

In addition to the opinions of Dr. Ortuno, Plaintiffs also rely upon the opinions of several medical experts. These experts include: Dr. Linda Brubaker, a board-certified obstetrician and gynecologist ("OB/GYN") specializing in urogynecologic surgery; Dr. Suzanne Bush, a surgeon who performs urogynecologic surgery; Dr. Michel Cosson, a professor of gynecology and obstetrics at the Medical University Lille; Dr. John Davis, a physician who treats patients with stress urinary incontinence; Dr. Paul Ducheyne, a bioengineering professor at the University of Pennsylvania; Dr. Ahmed El-Ghannam, a professor of mechanical, biomaterials, and tissue engineering at the University of North Carolina at Charlotte; Dr. James Hiller, a surgeon who performs urogynecologic surgery; Dr. Mickey Karram, a board-certified OB/GYN; Dr. Kenneth Mitchell, a surgeon who performs urogynecologic

surgery; Dr. Donald Ostergard, a board-certified OB/GYN specializing in urogynecologic surgery; Dr. William Porter, a board-certified OB/GYN specializing in urogynecologic surgery; Dr. Andrew Siegel, a board-certified urologist; and Dr. Mark Slack, a urogynecologist who has a urogynecology practice and also a faculty appointment at Cambridge University.[4]

These experts opine that the ObTape design is defective and that this defective design caused the medical complications complained of by the individual Plaintiffs. While each expert's testimony is unique, their scientific and/or medical methodologies used to reach their opinions share common themes. The bioengineering experts—Dr. Ducheyne and Dr. El-Ghannam—examined ObTape samples and performed various tests on the samples. They base their opinions on these tests; their knowledge, skill, training, and experience as bioengineers; and on their review of the relevant scientific literature. The physician experts—Dr. Brubaker, Dr. Bush, Dr. Cosson, Dr. Davis, Dr. Hiller, Dr. Karram, Dr. Mitchell, Dr. Ostergard, Dr. Porter, Dr. Siegel, and Dr. Slack—rely upon their knowledge, experience, training, and skill as physicians; their specific experiences with ObTape and other suburethral sling

[4]The Court recognizes that Mentor has moved to strike Dr. Slack as an expert due to alleged discovery abuses. That motion has not yet been decided. The Court does not rely on Dr. Slack's testimony in ruling on Mentor's motions for summary judgment.

products; their understanding of the differences between the structure of the ObTape polypropylene mesh and the structure of other polypropylene mesh products; and a review of relevant medical literature. In addition, at least two of the physicians—Dr. Siegel and Dr. Slack—published articles in peer-reviewed medical journals regarding ObTape complications.

Viewed in the light most favorable to Plaintiffs, the evidence demonstrates that ObTape is a "non-woven, thermally bonded white polypropylene mesh tape" that contains non-uniform pores, some of which are closed-ended pores and the vast majority of which are smaller than 40 microns. (Ex. 11 to Mentor's Mot. to Exclude Experts, Ducheyne Rule 26 Report 2, 9-10, 13 [hereinafter Ducheyne Rule 26 Report].) The evidence viewed in the light most favorable to Plaintiffs further shows that ObTape's product specifications called for pores measuring between 40 and 100 microns. (Ex. 13 to Pls.' Resps. to Mentor's Mots. for Summ. J. as to Individual Ga. Pls., Mentor's 510(k) Notification to the U.S. Food and Drug Administration at MENTOR/OBTAPE CONFIDENTIAL_00019-20 [hereinafter 510(k) Notification].) The evidence also shows that ObTape degrades under certain circumstances. (*See generally* Exs. 12 & 13 to Mentor's Mot. to Exclude Experts, El-Ghannam Rule 26 Report & Supp.) According to Plaintiffs' experts, these characteristics of ObTape cause ObTape to admit bacteria, hinder immune cells, and fail to achieve tissue in-

growth, which causes complications such as erosion and infection. (*E.g.*, Ducheyne Rule 26 Report 10-11, 15; Ex. 15 to Mentor's Mot. to Exclude Experts, Hiller Rule 26 Report 4 [hereinafter Hiller Rule 26 Report]; Ex. 35 to Mentor's Mot. to Exclude Experts, Mitchell Rule 26 Report 2-3 [hereinafter Mitchell Rule 26 Report]; Ex. 39 to Mentor's Mot. to Exclude Experts, Porter Rule 26 Report 3-4 [hereinafter Porter Rule 26 Report], Ex. 41 to Mentor's Mot. to Exclude Experts, Siegel Rule 26 Report 4-5 [hereinafter Siegel Rule 26 Report].)

In contrast, woven, macroporous mesh products ("Type I mesh products"), such as Gynecare TVT and Mentor's own ARIS product, have a uniform distribution of pores that are generally larger than 75 microns. (Ducheyne Rule 26 Report 13-14.) Plaintiffs assert that Type I mesh products are a safer alternative to ObTape and that two of Mentor's competitors offered Type I mesh products while ObTape was on the market. Eventually, Mentor introduced its own Type I mesh product. Mentor ultimately withdrew ObTape from the market. Mentor's Type I mesh product, along with those of its competitors, are still on the market. While erosion and infection risks exist with Type I mesh products, Plaintiffs' experts maintain that the design of ObTape creates more frequent complications that are more serious than those caused by the Type I mesh products. (*E.g.*, Mitchell Rule 26 Report 3; Porter Rule 26 Report 3; Siegel Rule 26 Report 4-5.) To corroborate their findings, Plaintiffs' experts

point to case reports and case series that show a connection between ObTape and the complications. They also reviewed the medical records of the individual Plaintiffs. (*E.g.*, Siegel Rule 26 Report 5-6.) Finally, Plaintiffs' experts opine that ObTape is capable of causing Plaintiffs' injuries and that ObTape actually did cause those injuries. (*E.g.*, Hiller Rule 26 Report 4, 8-9 (opining that ObTape caused Plaintiff Booth's injuries); Ex. 17 to Mentor's Mot. to Exclude Experts, Karram Rule 26 Report 2-3 (same as to Plaintiff Crowther); Ex. 2 to Mentor's Mot. to Exclude Experts, Brubaker Rule 26 Report re Dover 2, 6-7 (same as to Plaintiff Dover); Ex. 3 to Mentor's Mot. to Exclude Experts, Brubaker Rule 26 Report re Looper 2, 6-7 (same as to Plaintiff Looper); Mitchell Rule 26 Report 4, 8 (same as to Plaintiff Merritt); Ex. 4 to Mentor's Mot. to Exclude Experts, Brubaker Rule 26 Report re Mills 2, 5-6 (same as to Plaintiff Mills); Hiller Rule 26 Report 4, 8-9 (same as to Plaintiff Olson); Ex. 10 to Mentor's Mot. to Exclude Experts, Davis Rule 26 Report re Parker 2 (same as to Plaintiff Parker); Mitchell Rule 26 Report 4, 8 (same as to Plaintiff Stafford); Bush Dep. 186:15-189:5, Nov. 18, 2009 (ruling out doctor errors and contributory factors as alternative causes of Plaintiff Tucker's injuries); Mitchell Rule 26 Report 4, 8 (opining that ObTape caused Plaintiff Turner's injuries).)

Plaintiffs have certainly covered their bases with their proffered expert testimony. That testimony includes the opinion of a former employee of Mentor who opines that the product was defective and that the defective design was capable of causing the complications complained of by Plaintiffs, as confirmed by reports accepted by Mentor's own employees as reliable. They have produced opinions of biomedical scientists who have examined the actual product and its design and explained how the design and/or manufacture is defective and is capable of causing the reported complications to an unreasonable degree. Finally, they rely upon medical doctors who have actual experience with these types of products and who have examined the individual Plaintiffs' medical complications and opine that the most likely cause is the defectively designed and/or manufactured ObTape; these medical doctors also opine that the warnings Mentor gave regarding ObTape did not adequately disclose ObTape's risks. If this testimony is admissible, Plaintiffs have created genuine issues of material fact as to whether ObTape is defectively designed and/or manufactured, whether Mentor's warnings regarding ObTape were adequate, and whether ObTape proximately caused Plaintiffs' injuries. Thus, Mentor's pending motions for summary judgment depend substantially upon the admissibility of these opinions.

II. Evidence Regarding Individual Plaintiffs

To address fully Mentor's motions for summary judgment, it is also necessary to consider certain evidence that pertains to the individual Plaintiffs separately. The record, when construed in favor of Plaintiffs, establishes the following.

A. Plaintiffs Treated by Dr. Thomas Oliver

Dr. Thomas Oliver treated Plaintiffs Valerie Booth, Janice Crowther, Cheryl Olson, Barbara Parker, and Jeannie Tucker for SUI; he implanted each of them with ObTape and treated them for subsequent complications. The parties do not dispute that it was Dr. Oliver's standard practice to review product insert data sheets prior to using an implantable medical device; though he could not specifically recall reading the ObTape PIDS, he would have done so in accordance with his standard practice. Independent of the ObTape PIDS, Dr. Oliver knew that infection and erosions were complications associated with ObTape and that there is a risk that a patient's body may reject an implantable medical device. However, he also stated that neither the PIDS nor anyone from Mentor told him that ObTape had a higher risk of erosion and infection than other tapes and that, in his experience, such complications with ObTape were not "rare." (Oliver Dep. 430:7-433:15, 434:16-436:11, Apr. 20 & 30, 2009, May 29, 2009.) He also stated that he would not have implanted ObTape in his patients if he had known of its increased risks. (*Id.* at 435:9-22.)

1. Valerie Booth

In December 2004, Plaintiff Valerie Booth ("Mrs. Booth") consulted with her physician about her SUI symptoms. Mrs. Booth was referred to Dr. Oliver, who diagnosed Mrs. Booth with SUI. After discussing the benefits of the suburethral sling implantation procedure compared with the risks as Dr. Oliver understood them, Mrs. Booth decided to undergo suburethral sling implantation surgery to treat her SUI. The surgery took place on December 22, 2004, and Dr. Oliver used the ObTape sling. After the surgery, Mrs. Booth was continent for between four and six months, but her incontinence returned, accompanied by discharge and odor. In January of 2006, Dr. Oliver diagnosed an erosion of the ObTape, along with an infection. (*Id.* at 339:13-15, 340:14-341:6.) Dr. Oliver removed a portion of Mrs. Booth's ObTape. Mrs. Booth continued to experience complications, and her symptoms worsened. She underwent three additional surgeries to correct complications she contends were caused by ObTape. Mrs. Booth filed her product liability suit against Mentor on August 14, 2007. Her husband, Phil Booth, asserts a derivative claim for loss of consortium.

2. Janice Crowther

In December of 2004, Plaintiff Janice Crowther ("Mrs. Crowther") consulted her primary care physician about her SUI symptoms. The primary care physician referred Mrs. Crowther to Dr. Oliver. After

discussing the benefits of the suburethral sling implantation procedure compared with the risks as Dr. Oliver understood them, Mrs. Crowther decided to undergo suburethral sling implantation surgery to treat her SUI. Dr. Oliver implanted the ObTape in Mrs. Crowther on March 7, 2005. About five months after the surgery, Mrs. Crowther began to have "really, really bad discharge" with a "terrible odor," as well as a "horrific" pain in her right leg. (Crowther Dep. 149:21-150:5, Mar. 10, 2009.) On August 22, 2005, Mrs. Crowther saw her primary care physician, who diagnosed an abscess and sent Mrs. Crowther to the hospital, where Dr. Oliver removed the right half of the ObTape sling. (*Id.* at 159:2-4.) After that, Mrs. Crowther had two additional surgeries to treat complications she contends were caused by ObTape and to remove the remaining portion of ObTape. Mrs. Crowther filed her product liability suit against Mentor on August 14, 2007. Her husband, Terry Crowther, asserts a derivative claim for loss of consortium.

3. Cheryl Olson

Plaintiff Cheryl Olson ("Mrs. Olson") was diagnosed with SUI in 1995. In April 2004, Mrs. Olson's physician referred her to Dr. Oliver to discuss the possibility of suburethral sling surgery. Mrs. Olson consulted with Dr. Oliver regarding the risks and benefits of the procedure as Dr. Oliver understood them, and Dr. Oliver warned her that there was no guarantee of success and that there was a risk

of erosion and infection. Mrs. Olson elected to go forward with suburethral sling surgery, and Dr. Oliver implanted her with ObTape on September 21, 2004. After the surgery, Mrs. Olson was continent for a while but began to experience leakage of urine, and she also had pelvic discomfort during intercourse; in December of 2004, Dr. Oliver treated her symptoms by giving her a collagen injection. (Olson Dep. 148:6-149:17, Mar. 11, 2009.) At that point, Mrs. Olson believed her sling was not working. (*Id.* at 150:4-151:3.) In February 2005, Mrs. Olson went back to see Dr. Oliver because she "felt something," which Dr. Oliver's physician assistant discovered was a piece of exposed ObTape. (*Id.* at 151:17-152:2.) The physician assistant told Mrs. Olson that the ObTape had eroded. (Lavelle Dep. 139:5-141:19, Sept. 11, 2009.) Dr. Oliver also explained to Mrs. Olson that her ObTape had eroded and explained that it was possible that her body was rejecting the sling or that trauma from intercourse could have thinned the tissue. (Oliver Dep. 305:12-21.) Mrs. Olson realized at that time that the sling "wasn't working like it should" (Olson Dep. 157:6-7), though she also stated she did not realize at that time that there was a problem with the sling (*id.* at 156:6-19). In March of 2005, Dr. Oliver removed a portion of Mrs. Olson's ObTape.

After the March 2005 excision procedure, Mrs. Olson continued to have problems, including brown, bloody discharge and pain during

sexual intercourse. (*Id.* at 158:6-161-15, 168:13-18.) Mrs. Olson went to her gynecologist in June of 2005, and he prescribed a medicated cream for her. (*Id.* at 163:5-164:11.) Between then and November 2006, Mrs. Olson had "constant discharge and bleeding, sometimes worse than others, [and] the horrible smell[, b]ut it didn't seem like anything was actually wrong." (*Id.* at 161:25-162:3.) In November of 2006, however, Mrs. Olson discovered another piece of ObTape hanging out of her vagina. (*Id.* at 161:23-162:11.) She returned to Dr. Oliver, who performed an excision procedure and gave Mrs. Olson another collagen injection in January 2007. (*Id.* at 173:4-20.) During that procedure, Dr. Oliver found "active infection on the mesh," and he attributed it to the sling erosion. (Oliver Dep. 319:5-12.) After that procedure, Mrs. Olson experienced less discharge and was more continent, but she still experienced pain during intercourse. (Olson Dep. 178:16-179:23.) Finally, in September 2007, Mrs. Olson felt more exposed ObTape, and she had a third excision procedure. After that procedure, she stopped having discharge and bleeding, and the infection has not returned. (*Id.* at 182:23-183:5.) At some point after the January 2007 excision but before the final excision, Mrs. Olson had a conversation with Dr. Oliver's physician assistant, who told her there was a problem with the sling; at that time, Mrs. Olson came to believe that her ObTape might be defective. (*Id.* at 134:4-17, 211:1-25.) Mrs. Olson filed

her product liability action against Mentor on July 24, 2007. Her husband, Edwin Olson, asserts a derivative claim for loss of consortium.

4. Barbara Parker

Plaintiff Barbara Parker ("Mrs. Parker") was diagnosed with SUI in 1999. In February 2004, she consulted Dr. Oliver regarding her SUI. After discussing the benefits of the suburethral sling implantation procedure compared with the risks as Dr. Oliver understood them, Mrs. Parker decided to undergo suburethral sling implantation surgery to treat her SUI. The surgery took place on May 12, 2004, and Dr. Oliver used the ObTape sling. After the surgery, Mrs. Parker was pain-free and continent for nine months, but she began to experience heavy bleeding during intercourse. (Parker Dep. 135:16-136:10, Mar. 5, 2009.) She went to her gynecologist in March 2005, and the gynecologist told Mrs. Parker that it appeared the incision from her ObTape surgery had not healed properly. (*Id.* at 137:9-13, 138:12-14.) After receiving treatment from Dr. Oliver and another doctor during March, June, and July 2005, Mrs. Parker's complications improved, but they returned later that year. Dr. Oliver performed surgery on Mrs. Parker in September 2005, and he discovered a piece of exposed ObTape, which he excised. (Oliver Dep. 233:2-9.) Her symptoms worsened, and she saw Dr. John Blankenship, who ultimately performed two additional excision surgeries. Mrs.

Parker filed her product liability action against Mentor on July 24, 2007. Her husband, Richard Parker, asserts a derivative claim for loss of consortium.

5. Jeannie Tucker

Plaintiff Jeannie Tucker's ("Mrs. Tucker") doctor diagnosed her with SUI and referred her to Dr. Oliver, who confirmed the SUI diagnosis. After consulting with Dr. Oliver regarding the risks and benefits of the procedure as Dr. Oliver understood them, Mrs. Tucker elected to go forward with suburethral sling surgery, and Dr. Oliver implanted her with ObTape on March 7, 2005. Although the ObTape surgery cured Mrs. Tucker's SUI, she began to experience complications, including abdominal pressure and vaginal discharge, about a month after the surgery. (Tucker Dep. 192:3-193:5, Feb. 25, 2009.) Mrs. Tucker was treated with antibiotics, though she still experienced intermittent flare-ups of pain and malodorous discharge. (*Id.* at 197:7-17.) She had her first repair surgery in January 2006. Dr. Oliver discovered an erosion of the ObTape, and he excised a portion of the tape. (Oliver Dep. 385:10-19.) In all, Mrs. Tucker has had seven repair surgeries to remove ObTape and treat infections she contends were caused by ObTape. (Tucker Dep. 202:23-203:1.) Mrs. Tucker filed her product liability action against Mentor on August 14, 2007. Her husband, Kenneth Tucker, asserts a derivative claim for loss of consortium.

B. Plaintiffs Treated by Dr. Bruce Kyburz

Dr. Bruce Kyburz, a urologist, treated Plaintiffs Maris Merritt and Cheryl Turner for SUI; he implanted each of them with ObTape and treated them for subsequent complications. It is undisputed that Dr. Kyburz never read the PIDS for ObTape. Dr. Kyburz was in regular contact with a Mentor sales representative, and he believes he received written materials regarding ObTape. (Kyburz Dep. 121:3-124:2, Apr. 21, 2009, May 26, 2009.) It is undisputed that Dr. Kyburz knew that infection and erosions were complications associated with ObTape and that there is a risk that a patient's body may reject an implantable medical device. However, Dr. Kyburz also stated that no Mentor sales representative or written materials from Mentor informed him that ObTape had a higher risk of erosion and infection than other tapes. (*Id.* at 363:2-365:20.) Dr. Kyburz also testified that he would not have recommended ObTape to his patients had he known of its increased risks. (*Id.* at 369:6-17.)

1. Maris Merritt

Plaintiff Maris Merritt ("Mrs. Merritt") was diagnosed with SUI by her urologist, Dr. Kyburz. Dr. Kyburz told Mrs. Merritt about the suburethral sling implantation procedure. He explained that there was a chance the procedure would not work and that there was a risk of infection and a need for additional surgeries to treat complications. After discussing the benefits of the suburethral

sling implantation procedure compared with the risks as Dr. Kyburz understood them, Mrs. Merritt decided to undergo suburethral sling implantation surgery to treat her SUI. The surgery took place on September 19, 2003, and Dr. Kyburz used the ObTape sling. After the surgery, Mrs. Merritt's SUI improved, but she began to suffer from vaginal discharge. At the time, Dr. Kyburz could not determine the cause of the discharge. (Merritt Dep. 189:16-22, Feb. 27, 2009, Apr. 8, 2009.) In January 2005, Mrs. Merritt returned to Dr. Kyburz, complaining of bloody discharge and pain during intercourse. Dr. Kyburz diagnosed "[p]robable excoriation of anterior vaginal wall." (Kyburz Dep. 237:23-238:7.) Dr. Kyburz performed an excision procedure in February 2005, during which he found and removed some exposed ObTape; Dr. Kyburz told Mrs. Merritt that the excision should get rid of her symptoms. (*Id.* at 245:6-246:2.) Mrs. Merritt continued to have bloody discharge. She went back to Dr. Kyburz in May 2005, and Dr. Kyburz did not see or feel any more tape; he told Mrs. Merritt that they could either wait to see if the situation resolved on its own or excise the remainder of the sling. (*Id.* at 258:1-262:15.) In June 2005, however, Dr. Kyburz felt more tape and told Plaintiff it would have to be removed. (*E.g., id.* at 267:19-20.) After Dr. Kyburz performed the excision, Mrs. Merritt's discharge and her SUI symptoms improved. (*Id.* at 276:25-280:9.)

The discharge returned in August 2005, and Mrs. Merritt's primary care physician found polyps on her vaginal wall. (Merritt Dep. 213:3-214:10.) Mrs. Merritt then saw a gynecologist regarding the polyps; she underwent two surgeries to remove the polyps, one in October 2005 and one in January 2006. (*Id.* at 215:18-21, 219:11-13.) The doctors did not give her any theories on what caused the polyps. (*Id.* at 214:2-4, 215:25-216:21, 219:14-17.) In the fall of 2006, Mrs. Merritt developed severe groin pain and was referred to another doctor, who performed a sling excision surgery on January 12, 2007. (*Id.* at 232:2-233:21.) Since that last surgery, Mrs. Merritt has not suffered from bleeding or discharge. (*Id.* at 234:2-3.)

Dr. Kyburz never told Mrs. Merritt that the ObTape may have been defective. (Kyburz Dep. 402:19-403:14.) However, in the summer of 2007, Mrs. Merritt's husband read a newspaper article about product liability suits against Mentor brought by women who experienced problems similar to Mrs. Merritt's. (Merritt Dep. 249:8-21.) Mrs. Merritt filed her product liability action against Mentor on October 19, 2007. Her husband, Glenn Merritt, asserts a derivative claim for loss of consortium.

2. Cheryl Turner

Plaintiff Cheryl Turner ("Mrs. Turner") was diagnosed with SUI in 1995, and in 2003, Plaintiff saw Dr. Kyburz to discuss her SUI symptoms. After consulting with Dr. Kyburz regarding the risks and

benefits of the procedure as Dr. Kyburz understood them, Mrs. Turner elected to go forward with suburethral sling surgery, and Dr. Kyburz implanted her with ObTape on November 18, 2003. In March of 2006, Mrs. Turner began suffering from infections. She had an abscess, and she has undergone three excision procedures to remove eroded ObTape. (Turner Dep. 109:1-115:8, 116:24-117:2, 121:1-6, 125:5-9, Mar. 6, 2009.) Mrs. Turner filed her product liability action against Mentor on October 19, 2007. Her husband, Tommy Turner, asserts a derivative claim for loss of consortium.

C. Gail Dover

In 2002, Plaintiff Gail Dover ("Mrs. Dover") was diagnosed with SUI by her OB/GYN, and she was referred to Dr. Bruce Green, a urologist. Dr. Green does not specifically recall reading the ObTape PIDS, but he testified that he "must have" done so. It is undisputed that Dr. Green knew that infection and erosion are risks of suburethral slings and that he told Mrs. Dover about these risks. However, Dr. Green stated that no one from Mentor ever told him that ObTape had a higher risk of erosion and infection than other tapes. (Green Dep. 184:6-185:14, July 31, 2009.) Dr. Green further testified that he would not have used ObTape if he had known of the increased risks. (*Id.* at 185:15-186:7.)

After consulting with Dr. Green regarding the risks and benefits of the procedure as Dr. Green understood them, Mrs. Dover elected to

go forward with suburethral sling surgery, and Dr. Green implanted her with ObTape on February 11, 2004. Mrs. Dover was continent and pain-free for five months after the implantation surgery. (Dover Dep. 120:25-121:7, Mar. 17, 2009.) She began developing infections by September of 2004, and her doctors performed ultrasounds of her kidneys; at the time, they could not determine the cause of the infections. (*Id.* at 123:8-124:9.) On December 28, 2004, Dr. Green determined that Mrs. Dover's ObTape had eroded through her vagina, and he told her that the tape needed to be removed. (Green Dep. 111:14-112:9; *see also* Dover Dep. 126:1-8.) At the time, Mrs. Dover "was having a lot of infections, a lot of bad odors coming out of [her] body." (Dover Dep. 126:13-15.) She stated, "I understood it might be coming from the sling and that's why he was going to have to remove it." (*Id.* at 126:15-18; *see also* Green Dep. 231:21-232:19 (testifying that he told Mrs. Dover that erosion and infection would be alleviated by removing the ObTape).) It is undisputed that Dr. Green removed a portion of the ObTape on February 4, 2005, and he implanted a SPARC device at that time. The next month, Mrs. Dover presented with a severe infection and an abscess, and she was hospitalized. Dr. Green attributed these complications to the February 2005 procedure, and he removed additional portions of the ObTape. (Green Dep. 123:15-24.) Mrs. Dover's wound closed by July 2005, and she returned to work in the fall of 2005. Mrs. Dover

stated that she did not suspect that her ObTape was defective until sometime in 2006, when she read a newspaper article about a lawsuit regarding ObTape. (Dover Dep. 27:13-28:3, 165:10-167:9.) Mrs. Dover filed her product liability action against Mentor on October 19, 2007. Her husband, Hugh Dover, asserts a derivative claim for loss of consortium.

D. Kellie Looper

In November 2004, Plaintiff Kellie Looper ("Mrs. Looper") consulted with Dr. Thomas Chun regarding her SUI symptoms. It is undisputed that Dr. Chun did not read the ObTape PIDS, but Dr. Chun did receive a brochure regarding ObTape that contained some language regarding potential adverse reactions, and he had a conversation with a Mentor sales representative regarding complication rates associated with ObTape; based on all of this information, Dr. Chun believed that the risks of ObTape were comparable to the risks associated with other suburethral sling products. (Chun Dep. 82:9-84:17, 93:18-94:24, 140:3-11, Apr. 23, 2009, July 15, 2009.) It is undisputed that Dr. Chun knew that infection and erosions were complications associated with ObTape and that there is a risk that a patient's body may reject an implantable medical device. However, he also stated that neither the brochure nor anyone from Mentor told him that ObTape had a higher risk of erosion and infection than other tapes. (*E.g.*, *id.* at 299:3-18.) Dr. Chun further testified that he would not have

used ObTape if he had known of the increased risks. (*Id.* at 302:15-20.)

After discussing the benefits of the suburethral sling implantation procedure compared with the risks as Dr. Chun understood them, Mrs. Looper decided to undergo suburethral sling implantation surgery to treat her SUI. The surgery took place on January 10, 2005, and Dr. Chun used the ObTape sling. Mrs. Looper lived pain-free and continent for about a year, but in early 2006 she and her husband determined that "something wasn't right down there." (Looper Dep. 143:1-5, Apr. 9, 2009.) Dr. Chun performed an excision procedure on March 17, 2006; after that, Mrs. Looper had three additional excision procedures and was treated for an abscess. Mrs. Looper filed her product liability action against Mentor on October 19, 2007. Her husband, Larry Looper, asserts a derivative claim for loss of consortium.

E. Linda Mills

Plaintiff Linda Mills ("Ms. Mills") consulted with her physician regarding her SUI symptoms, and she was referred to Dr. Nikolas Symbas to discuss the possibility of suburethral sling surgery. It is undisputed that Dr. Symbas does not recall whether he read the ObTape PIDS. Dr. Symbas did discuss ObTape with a Mentor sales representative, who represented to Dr. Symbas that the tape was a good material; Dr. Symbas also received an instructional video on how

to implant ObTape, along with materials regarding the safety and efficacy of the procedure, though he did not recall the specifics of those materials. (Symbas Dep. 135:1-17, 142:10-143:22, Apr. 27, 2009, June 4, 2009.) It is undisputed that Dr. Symbas knew that infection and erosions were complications associated with ObTape and that there is a risk that a patient's body may reject an implantable medical device. However, Dr. Symbas stated that no one from Mentor told him that ObTape had a higher risk of erosion and infection than other tapes. (*E.g., id.* at 399:16-402:5.) Dr. Symbas further testified that he would not have used ObTape if he had known of the increased risks. (*Id.* at 403:21-23.)

After consulting with Dr. Symbas regarding the risks and benefits of the procedure as Dr. Symbas understood them, Ms. Mills elected to go forward with suburethral sling surgery, and Dr. Symbas implanted her with ObTape on November 16, 2004. After the surgery, Ms. Mills underwent three excision procedures due to ObTape erosion, and she has suffered from infections. Ms. Mills filed her product liability action against Mentor on October 19, 2007.

F. Shirley Stafford

Plaintiff Shirley Stafford ("Mrs. Stafford") was diagnosed with SUI in 1999. She consulted with a urologist, Dr. John Blankenship, regarding her SUI symptoms in 2004. It is undisputed that Dr. Blankenship reviewed the PIDS for ObTape before he performed any

ObTape surgeries. It is also undisputed that Dr. Blankenship knew that infection and erosions were complications associated with ObTape and that there is a risk that a patient's body may reject an implantable medical device. However, Dr. Blankenship also stated that neither the PIDS nor anyone from Mentor told him that ObTape had a higher risk of erosion and infection than other tapes and the "degree of infections, erosions, and abscess formation was far greater than [he] would have interpreted the [PIDS] as indicating possible." (Blankenship Dep. 359:17-362:8, 369:19-370:5, Apr. 22, 2009, May 1 & 28, 2009.) In fact, the Mentor sales representative told Dr. Blankenship that ObTape had a complication rate equal to that of another suburethral sling product, TVT. (*Id.* at 343:17-25.) Dr. Blankenship stated that he would not have prescribed ObTape for his patients if he had known it was associated with increased risks. (*Id.* at 365:15-366:4.)

After discussing the benefits of the suburethral sling implantation procedure compared with the risks as Dr. Blankenship understood them, Mrs. Stafford decided to undergo suburethral sling implantation surgery to treat her SUI. The surgery took place on September 28, 2004, and Dr. Blankenship used the ObTape sling. After the surgery, Mrs. Stafford was pain-free and continent for six months, but she began to develop complications, including an infection for which Dr. Blankenship could not pinpoint the cause.

Ultimately, Mrs. Stafford underwent several excision surgeries and suffered from severe infections, and Dr. Blankenship stated that "she almost died from complications of the sling." (*Id.* at 284:5-6.) In addition, Mrs. Stafford's husband, Torrence Pinkney, was cut on the penis several times during sexual intercourse with Mrs. Stafford, and he attributes these injuries to ObTape. (Stafford Dep. 147:24-148:6, Mar. 18, 2009.) Mrs. Stafford filed her product liability action against Mentor on August 3, 2007. Her husband, Mr. Pinkney, asserts a claim for personal injury and a claim for loss of consortium.

DISCUSSION

Plaintiffs rely upon four separate legal theories in support of their claims: 1) design defect; 2) manufacturing defect; 3) breach of implied warranty; and 4) failure to warn. Although the evidence relating to these claims overlaps, the Court will address each claim separately.

I. Plaintiffs' Legal Theories and Causes of Action

As previously mentioned, the admissibility of the opinion testimony of Plaintiffs' experts is critical in determining whether sufficient evidence exists to create genuine issues of material fact. Before turning to the admissibility of the opinions of Plaintiffs' experts, it is necessary to understand what Plaintiffs must prove to recover on their various claims.

A. Design Defect

To recover on their design defect claims against Mentor, Plaintiffs must establish that (1) ObTape's design is defective and (2) the defective design caused Plaintiffs' injuries. Under Georgia law, a product design is defective if "the risks inherent in a product design [outweigh] the utility or benefit derived from the product." *E.g., Dean v. Toyota Indus. Equip. Mfg., Inc.*, 246 Ga. App. 255, 259, 540 S.E.2d 233, 237 (2000). The factors relevant to the risk-utility analysis include:

> the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger, i.e., the user's knowledge of the product, publicity surrounding the danger, or the efficacy of warnings, as well as common knowledge and the expectation of danger, and the user's ability to avoid danger; the state of the art at the time the product is manufactured; the manufacturer's ability to eliminate the danger without impairing the product's usefulness or making it too expensive; and the feasibility of spreading the loss in the price or by purchasing insurance.

Id. (footnote omitted). "A manufacturer's proof of compliance with federal regulations is also a factor to be considered. These factors are not exhaustive and do not apply in all cases." *Id.* (footnotes omitted). The most important factor, however, is "whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware"—this factor is the "heart" of design defect cases. *Banks v. ICI Ams., Inc.*, 264 Ga.

732, 736, 450 S.E.2d 671, 674 (1994) (internal quotation marks omitted).

In general, weighing the risk-utility factors is left to the jury. *E.g.*, *Dean*, 246 Ga. App. at 259, 540 S.E.2d at 237. Judgment as a matter of law "will rarely be granted in design defect cases when any of [the] elements is disputed." *Ogletree v. Navistar Int'l Transp. Corp.*, 271 Ga. 644, 646, 522 S.E.2d 467, 470 (1999) (internal quotation marks omitted). To prevail at summary judgment, a defendant must "show plainly and indisputably an absence of *any* evidence that a product as designed is defective." *Id.*

When faced with a summary judgment motion, Plaintiffs have the burden to demonstrate a genuine issue of material fact that ObTape is defectively designed; to do this, they must produce evidence from an expert who is qualified to conduct the risk-utility analysis and to opine that the risks inherent in ObTape's design outweigh the utility or benefit derived from the product. *E.g.*, *Dean*, 246 Ga. App. at 259, 540 S.E.2d at 237.

Once it is established that a product has a defect, the plaintiff must show causation. The parties agree that to prevail on their claims, Plaintiffs must establish both general causation and specific causation. *Guinn v. AstraZeneca Pharms. LP*, No. 09-11104, 2010 WL 1286947, at *2 n.1 (11th Cir. Apr. 6, 2010) (per curiam). In other words, Plaintiffs must prove that ObTape can cause the type

of injury suffered by Plaintiffs (general causation) and that ObTape did in fact cause Plaintiffs' injuries (specific causation). *Id.*

B. Manufacturing Defect

In addition to their design defect theory, Plaintiffs contend that each of their ObTapes had a manufacturing defect. While a design defect claim posits that there is a problem with the entire product line, a "manufacturing defect is a defect that is 'measurable against a built-in objective standard or norm of proper manufacture.'" *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1239 (N.D. Ga. 2002) (quoting *Banks*, 264 Ga. at 734 n.2, 450 S.E.2d at 673 n.2); *see also id.* at 1236 n.7 ("In manufacturing defect cases . . . the standard of comparison is supplied by the designer of the perfectly executed product that is in complete accordance with the intended design."). Therefore, in a manufacturing defect case, the "product's defectiveness is determined by measuring the product in question against the benchmark of the manufacturer's designs." *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, Civil Action No. 1:07-CV-606-TWT, 2008 WL 2229121, at *2 (N.D. Ga. May 28, 2008).

C. Failure to Warn

In addition to their design and manufacturing defect claims, Plaintiffs contend that Mentor failed to provide adequate warnings regarding the risks associated with ObTape and that Plaintiffs were injured as a result of the inadequate warnings. To establish their

failure to warn claims, Plaintiffs must show that (1) Mentor had a duty to warn, (2) Mentor breached that duty, and (3) the breach was the proximate cause of Plaintiffs' injuries. *E.g., Dietz v. SmithKline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (applying Georgia law). Under Georgia's learned intermediary doctrine, a medical device manufacturer "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003). "The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ [a medical device] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." *Id.* (internal quotation marks omitted). The warnings to the doctor "must be adequate or reasonable under the circumstances of the case." *Id.*

In general, the first step of the inquiry is whether the manufacturer provided the learned intermediary with an adequate warning. *Dietz*, 598 F.3d at 816; *see also Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1277-78, 1281 (11th Cir. 2002) (per curiam) (finding that manufacturer adequately warned doctors and nurses of risks of third-party activation of morphine pump because evidence demonstrated

they all had actual knowledge of risk). If the warning is inadequate, the plaintiff must show that the deficient warning proximately caused the alleged injury to prevail; if the learned intermediary "has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided," then the plaintiff cannot establish causation. *Ellis*, 311 F.3d at 1293 n.8 (internal quotation marks omitted).

D. Implied Warranty

Plaintiffs' breach of implied warranty claims can be disposed of summarily. Under Georgia law, a plaintiff must have privity with the seller to recover under a theory of breach of implied warranty of merchantability. *E.g., Gowen v. Cady*, 189 Ga. App. 473, 476, 376 S.E.2d 390, 393 (1988) (finding that lack of privity between patient and medical device manufacturer warranted summary judgment in favor of manufacturer on breach of warranty claim). Plaintiffs Booth, Looper, Merritt, Mills, and Turner concede that their breach of warranty claims fail for lack of privity. (Pls.' Resp. to Mot. for Summ. J. as to Booth 13 n.3; Pls.' Resp. to Mot. for Summ. J. as to Looper 11 n.2; Pls.' Resp. to Mot. for Summ. J. as to Merritt 16 n.3; Pls.' Resp. to Mot. for Summ. J. as to Mills 12 n.2; Pls.' Resp. to Mot. for Summ. J. as to Turner 11 n.2.) Plaintiffs Crowther, Dover, Olson, Parker, Stafford, and Tucker did not respond to this argument.

It is undisputed that Mentor did not sell ObTape directly to any patient; therefore, there is a lack of privity between Mentor and Plaintiffs. Accordingly, Mentor is entitled to summary judgment on all Plaintiffs' implied warranty claims.

With this background in mind, the Court now turns to the expert testimony relied upon by Plaintiffs to prove design defect, manufacturing defect, failure to warn, and causation.

II. Admissibility of Opinions from Plaintiffs' Experts

A. Expert Witness Standards

Under Federal Rule of Evidence 702, "a witness qualified as an expert by knowledge, skill, experience, training, or education" may testify in the form of an opinion "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." The trial court must act as a gatekeeper to ensure the reliability and relevancy of expert testimony; for an expert's testimony to be admitted, the proffered expert must be qualified to render a reliable opinion based on sufficient facts or data and the application of accepted methodologies. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993). The purpose of this gatekeeping function is "to ensure that speculative, unreliable expert testimony does not reach

the jury under the mantle of reliability that accompanies the appellation 'expert testimony.'" *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005) (internal quotation marks omitted).

Scientific expert testimony is admissible when

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusion is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Allison v. McGhan Med. Corp., 184 F.3d 1300, 1309 (11th Cir. 1999) (internal quotation marks omitted). "The party offering the expert has the burden of satisfying each of these three requirements by a preponderance of the evidence." *Rink*, 400 F.3d at 1292. A district court "may not exclude an expert because it believes one expert is more persuasive than another expert." *Id.* at 1293 n.7.

Rule 702 further provides that a witness "may be qualified as an expert by virtue of his or her 'knowledge, skill, experience, training, or education.'" *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003) (quoting Fed. R. Evid. 702). Accordingly, in determining whether a proffered expert is "qualified" to offer an opinion, courts generally look to evidence of the witness's education and experience and ask whether the subject matter of the witness's proposed testimony is sufficiently within the

expert's expertise. *E.g., Maiz v. Virani*, 253 F.3d 641, 665 (11th Cir. 2001).

To ascertain whether proposed expert testimony is "reliable," the courts consider several factors: "(1) whether the expert's methodology can be tested; (2) whether the expert's scientific technique has been subjected to peer review and publication; (3) whether the method has a known rate of error; (4) whether the technique is generally accepted by the scientific community." *Rink*, 400 F.3d at 1292 (citing *Quiet Tech.*, 326 F.3d at 1341). These four factors are not exhaustive, and the district court's primary focus should be "'solely on principles and methodology, not on the conclusions that they generate.'" *Allison*, 184 F.3d at 1312 (quoting *Daubert*, 509 U.S. at 595).

For an expert's testimony to "assist" the trier of fact, "the evidence must have a valid scientific connection to the disputed facts in the case." *Id.* A court "may exclude expert testimony that is imprecise and unspecific, or whose factual basis is not adequately explained." *Cook ex rel. Tessier v. Sheriff of Monroe County, Fla.*, 402 F.3d 1092, 1111 (11th Cir. 2005) (internal quotation marks omitted). Also, expert testimony is generally only admissible "if it concerns matters that are beyond the understanding of the average lay person." *Id.* (internal quotation marks omitted). "Proffered expert testimony generally will not help the trier of fact when it

offers nothing more than what lawyers for the parties can argue in closing arguments." *Id.* (internal quotation marks omitted).

B. Preliminary Matters

Before turning to an analysis of the qualifications of Plaintiffs' experts and the reliability of their opinions, the Court addresses Mentor's argument that the Court should not consider Plaintiffs' submissions of unsworn expert reports, Mentor's internal documents, and journal articles. As to the unsworn expert reports, Mentor contends that they are inadmissible because they are unsworn, and that Plaintiffs should have opposed summary judgment with declarations by the experts. Mentor does not appear to dispute that each of Plaintiffs' experts was examined about his or her report and verified the opinions therein during a deposition. Mentor also does not dispute that the expert reports were exhibits to the experts' depositions. With one exception, Mentor does not contend that any of Plaintiffs' experts retracted or disavowed their opinions.[5] Under

[5]Mentor contends that Dr. Suzanne Bush withdrew her entire specific causation opinion regarding Plaintiff Jeannie Tucker during her deposition. The Court disagrees. Dr. Bush originally concluded that she could rule out that Tucker would have had the same reaction with another sling. (Bush Dep. 195:17-20.) When Mentor's counsel presented Dr. Bush with two articles regarding late-onset complications with a different type of sling, Dr. Bush changed that answer and said she could not "completely" rule out that Tucker would have had the same reaction with another sling. (*Id.* at 201:18-23.) However, viewing her testimony as a whole, Dr. Bush clearly did not disavow her opinion that ObTape caused Tucker's injuries, and she adequately explained the methodology she used to arrive at that opinion. (*Id.* at 186:15-189:5.) The Court rejects Mentor's contention to the contrary.

these circumstances, the Court concludes that it may properly consider the unsworn expert reports. *E.g., Maytag Corp. v. Electrolux Home Prods., Inc.*, 448 F. Supp. 2d 1034, 1064-65 (N.D. Iowa 2006) (finding that unsworn expert reports are properly considered at summary judgment if expert reaffirmed opinions stated in unsworn report during deposition), *aff'd w/o op.*, 224 F. App'x 972 (Fed. Cir. 2007) (per curiam); *see also Medtronic Xomed, Inc. v. Gyrus ENT LLC*, 440 F. Supp. 2d 1300, 1310 n.6 (M.D. Fla. 2006) (concluding that unsworn expert report was properly before court because it was marked as exhibit to expert's deposition and identified by the expert). As to Mentor's internal documents and the journal articles, the Court finds that those items may be relied upon by Plaintffs' experts in reaching their opinions. *See* Fed. R. Evid. 703; *see also United States v. Steed*, 548 F.3d 961, 975 (11th Cir. 2008) (per curiam) (noting that expert may rely on hearsay if such information is of a type reasonably relied upon by experts in the field). Accordingly, the experts' reliance on the journal articles and Mentor's internal documents does not diminish the weight that the Court gives to the experts' opinions, assuming that the opinions are otherwise sufficiently reliable.

C. Plaintiffs' Experts

The first step in the Court's expert testimony gatekeeping function is to evaluate the *qualifications* of Plaintiffs' experts.

Since Mentor does not seriously challenge those qualifications, the Court moves to the second step and evaluates the *reliability* of the expert testimony.

1. Dr. Ortuno

Although the Court finds it unnecessary to examine seriously Dr. Ortuno's professional qualifications, the Court does make the following observations regarding her capacity as an expert in this case. She is not the typical retained litigation expert. Instead, she is a former employee of Mentor. Moreover, her testimony relates to the areas that she oversaw as an employee of Mentor. Her opinions are not based on what others have told her happened, but they are based at least in part on what she actually observed. While these factors do not excuse her from supporting her opinions with reliable scientific methodology, they do give her testimony added credibility.

Dr. Ortuno opines that ObTape caused higher rates of vaginal erosions than a competitor's suburethral sling product did and that the complications associated with ObTape were more severe than those associated with the competing product; according to Dr. Ortuno, ObTape's design structure caused these problems. (Ortuno Rule 26 Report 4; Ortuno Dep. 300:6-20; *see also id.* at 233:6-25 (noting that ObTape complications were more severe than complications associated with competing product).) The bases for Dr. Ortuno's opinions are her experience evaluating, investigating, and reporting adverse

events regarding ObTape (and its predecessor, Uratape), her knowledge of the relevant scientific and medical literature, and her experience as the person in charge of clinical trials for products such as ObTape. Dr. Ortuno's job at Mentor-Porges was to get to the bottom of any reports that ObTape caused complications and to provide Mentor with a suggested course of action. To do that, she collected and studied all of the adverse event reports Mentor received about ObTape; she reviewed clinical studies, animal studies, and case reports regarding ObTape; and she communicated with physicians whose patients experienced complications with ObTape. Based on her prior experience evaluating problems associated with ObTape's predecessor product, Uratape, Dr. Ortuno ruled out Uratape's silicone patch as the cause of the increased risks of the product and concluded that the increased risks were caused by the structure of the polypropylene mesh, which was identical in Uratape and ObTape. The Court finds that Dr. Ortuno's methodology in arriving at those opinions is sufficiently reliable to be considered by a jury. Therefore, her testimony shall be considered in deciding Mentor's summary judgment motions.

2. Doctors with Adverse Clinical Experiences

To support their claims of defect and general causation, Plaintiffs also seek to introduce the opinions of several doctors who had adverse clinical experiences with ObTape: Dr. Linda Brubaker; Dr.

Suzanne Bush; Dr. Michel Cosson; Dr. John Davis; Dr. James Hiller; Dr. Mickey Karram; Dr. Kenneth Mitchell; Dr. Donald Ostergard; Dr. William Porter; and Dr. Andrew Siegel.[6] These doctors opine, among other things, that the degree and frequency of complications caused by ObTape is greater than the degree and frequency of complications caused by other suburethral sling products, Type I mesh products. They opine that ObTape's design accounts for the difference—there is evidence that ObTape is a non-woven, thermally bonded polypropylene mesh tape with non-uniform pores, the majority of which are smaller than 40 microns, while Type I mesh products are woven and have pores larger than 75 microns. They base their opinions on their personal adverse clinical experiences with ObTape, and they maintain that these adverse experiences are confirmed by published scientific literature about ObTape, including case reports and case series.

[6]Several of these experts reviewed a 2003 rabbit study comparing ObTape to another mesh product. Some of them appear to rely on that study to a limited extent in forming their causation opinions, though such reliance is inappropriate. *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1366 (N.D. Ga. 2001) ("Extrapolations from animal studies to human beings generally are not considered reliable in the absence of a credible scientific explanation of why such extrapolation is warranted."), *aff'd sub nom. Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (finding that district court was "within its discretion" in concluding that animal studies were unreliable). Therefore, to the extent any of Plaintiffs' experts intend to testify that the rabbit study is evidence of causation, such testimony is excluded. Nonetheless, the rabbit study is not the sole basis for any of the physicians' causation opinions, and exclusion of such testimony does not affect the testimony that does create genuine issues of material fact. The remaining issues related to the rabbit study are addressed in a separate order on Mentor's *Daubert* motions and are not necessary to resolve for purposes of deciding Mentor's summary judgment motions.

Mentor contends that the doctors' personal clinical experiences, combined with their literature reviews, are insufficient to enable these doctors to opine reliably that ObTape has greater risks than other suburethral slings.

Essentially, Plaintiffs' experts seek to show a connection between ObTape and increased risks of complications by pointing mainly to adverse event data. Adverse event data is generally regarded with caution, particularly in the context of a drug or device that is alleged to cause an injury that might otherwise occur for another reason. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005) (noting that causal attribution based on case studies must be regarded with caution in context of case regarding herbal supplement that allegedly caused injuries that also occur without exposure to the product). However, these experts are not simply parroting published adverse event data. They use that data as confirmation of their own experience using ObTape or treating ObTape patients. It is beyond dispute that experience in a field may provide a sufficient foundation for expert testimony. *United States v. Frazier,* 387 F.3d 1244, 1260-61 (11th Cir. 2004) (en banc). If a witness relies upon experience as a primary qualification for the opinion, the witness must still explain how that experience is reliably applied to the facts. *Id.* at 1261. The Court cannot simply take the expert's "word for it," but must ensure that the opinion

rests on a reliable foundation. *Id.* (internal quotation marks omitted).

The Court finds that Plaintiffs' experts have adequately explained how their experiences with ObTape reliably support their opinions that ObTape was defectively designed and that the defective design causes the kinds of complications suffered by Plaintiffs. That experience consists of implantation of ObTape in and/or explantation of ObTape from their own patients; examining and evaluating those patients after complications arose; exploring the various possible causes of the complications; and then narrowing down that cause to ObTape. Their experience also includes implanting other suburethral slings with a design different than ObTape, including Type I mesh products; learning about the differences between the structure of ObTape and the structure of other designs; and a comparison of the adverse events associated with the different slings. (*E.g.*, Porter Rule 26 Report 1-3 (stating that Dr. Porter implanted more than 1,000 slings, including 17-20 ObTapes, and while he never had a problem with any other sling product, 3-4 of his ObTape patients developed serious complications requiring surgical treatment); Siegel Rule 26 Report 3-5 (stating that Dr. Siegel implanted more than 1,000 slings, the vast majority not ObTape, and that five ObTape patients had serious complications that were "virtually non-existent" with other slings).) To confirm their

experiential conclusions, they also reviewed the scientific literature and case reports, which they opine is part of the scientific methodology for determining causation. That literature supports their conclusion, which Mentor does not dispute, that suburethral slings, including ObTape and Type I mesh products, have inherent risks of erosion and infection. According to Plaintiffs' experts, the literature also supports their conclusion that ObTape posed a higher risk of serious complications than did Type I mesh products. (*E.g.*, Siegel Rule 26 Report 5-7.)

The Court also notes that the general consensus—even among Mentor's experts–is that clinical trials are not as prevalent in the medical device field as they are in other fields because they are not practical. (Ex. 2 to Pls.' Mot. to Exclude, Secrest Rule 26 Report 5 n.4.) Instead, device companies such as Mentor turn to physicians to engage in "evidence based" medicine with a product—the physicians perform a large number of cases, evaluate the results, and share the results with the manufacturer. (*Id.*) Therefore, instead of having a large number of randomized clinical trials, the medical literature related to ObTape is predominately in the form of published case reports or case series, many of which are peer-reviewed and published in medical journals. Thus, according to Plaintiffs' experts, it is an accepted practice to rely upon such case reports and the individual clinical experiences of physicians who have used the

medical device when evaluating causation issues involving the medical device.

The Court finds the methodology used by Drs. Brubaker, Bush, Cosson, Davis, Hiller, Karram, Mitchell, Ostergard, Porter, and Siegel to be reasonably reliable. The Court further finds that they reasonably applied that methodology to the facts of these cases and that their opinions as to defect and general causation would be helpful to the jury. Therefore, they shall be permitted to render an expert opinion regarding whether ObTape had a design defect and whether that defect is generally capable of causing Plaintiffs' injuries.

With regard to specific causation, Mentor seeks to exclude the testimony of Dr. Linda Brubaker; Dr. Suzanne Bush; Dr. John Davis; Dr. James Hiller; Dr. Mickey Karram; Dr. Kenneth Mitchell; and Dr. Mark Slack. All of these physicians reviewed Plaintiffs' implantation and post-implant medical records, as well as the depositions of Plaintiffs and their treating providers. Relying upon that review, their familiarity with the relevant published literature, and their own clinical experiences, they opine that ObTape was a cause of each Plaintiff's complications. This conclusion is based on a differential diagnosis or differential etiology approach. When based on proper scientific groundwork, differential diagnosis or differential etiology is considered a valid

methodology for determining the cause of a plaintiff's injury. *McClain*, 401 F.3d at 1252. "Differential diagnosis involves the determination of which one of two or more diseases or conditions a patient is suffering from, by systemically comparing and contrasting their clinical findings." *Id.* (internal quotation marks omitted). A differential diagnosis leads to a "diagnosis of the patient's condition." *Id.* Differential etiology describes "the investigation and reasoning that leads to the determination of external causation, sometimes more specifically described by the witness or court as a process of identifying external causes by a process of elimination." *Id.* (internal quotation marks omitted).

Mentor argues that, in performing their differential etiology to determine the cause of Plaintiffs' injuries, these physicians did not adequately consider other possible causes of Plaintiffs' complications, including physician error or Plaintiffs' underlying medical conditions, and rule them out as alternative causes.[7] However, the doctors did consider those issues. For example, Dr. Hiller stated in his expert report that the treatment Plaintiffs

[7]Plaintiffs' experts point out that "the only product use 'CONTRAINDICATIONS' Mentor set forth were as to pregnant women, women likely to become pregnant, women desiring to become pregnant in the future and minors." (*E.g.*, Hiller Rule 26 Report 5.) It did not list other preexisting patient contraindications such as "smoking, obesity, diabetes, hormone replacement therapy, post-menopausal women, [and] prior incontinence surgical procedures." (*Id.*) These are some of the "alternate causes" Mentor now suggests caused Plaintiffs' injuries.

Booth and Olson received "preoperatively, perioperatively, and postoperatively in conjunction with ObTape implantation and explantations was within the standards of care of the medical profession generally under like or similar circumstances." (Hiller Rule 26 Report 9; *see* Karram Rule 26 Report 3 (same for Plaintiff Crowther); *see also, e.g.,* Brubaker Rule 26 Report re Mills 3-4 (noting that Plaintiff Mills did not have any contraindications for ObTape and that her physicians performed within the standard of care); Bush Dep. 186:15-189:5 (ruling out doctor errors and contributory factors, such as weight, as alternative causes of Plaintiff Tucker's injuries).) These physicians thus concluded that the injuries suffered by Plaintiffs were caused by "the inappropriate design of ObTape." (*E.g.,* Hiller Rule 26 Report 9; Karram Rule 26 Report 4.) Mentor will certainly be able to argue through its experts that other causes contributed to Plaintiffs' conditions, but those attacks go to the weight of the testimony and not its admissibility.

The Court finds that the experts used a reliable scientific methodology. As discussed above, they included ObTape as a cause of Plaintiffs' injuries, concluding that a defect in ObTape is generally capable of causing Plaintiffs' injuries. Then they ruled out other possible causes based on their review of each individual Plaintiff's medical records and the relevant depositions, as well as their

experience and expertise. After ruling out potential alternative causes such as doctor error and the patient's weight, they opined that to a reasonable degree of medical probability the specific complications suffered by the individual Plaintiffs were caused by a defectively designed product, ObTape, and not by other causes. Whether the experts considered every "possible" alternative cause shall affect the weight of the testimony and not its admissibility.

The Court observes that the methodical approach taken by the experts in this case is a far cry from the haphazard approach taken in cases such as *Guinn v. AstraZeneca Pharmaceuticals LP*. In *Guinn*, the single expert on specific causation opined that the defendant's antipsychotic medication caused the plaintiff to gain weight, which caused her diabetes. 2010 WL 1286947, at *2. The expert relied heavily upon the temporal proximity between the taking of the medication and the weight gain, which progressed over a period of several years until the plaintiff was diagnosed with diabetes. However, the plaintiff's expert failed to rule out the many other obvious causes of weight gain and diabetes in the plaintiff. Moreover, even if the medication had caused some weight gain, the plaintiff's underlying medical condition revealed numerous underlying factors that could have contributed to the onset of diabetes, but the expert never explained why those factors were ruled out or how. *Id.* Those factors were not mere hypothetical possibilities but

represented significant underlying conditions that are frequently associated with diabetes. *Id.* By failing to explain adequately how they could be eliminated as possible alternative causes, the plaintiff failed to show that her expert's methodology was reliable. In contrast, in this case, Plaintiffs' experts considered reasonable, possible alternative causes of Plaintiffs' injuries and explained why, in their opinion, a defect in ObTape was the most likely cause of Plaintiffs' complications.

As the Eleventh Circuit explained in *Guinn*, "a reliable differential diagnosis need not rule out all possible alternative causes, [but] it must at least consider other factors that could have been the sole cause of plaintiff's injury." *Id.* at *6. The expert "must provide a reasonable explanation as to why he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause of the plaintiff's injury." *Id.* (alteration in original) (internal quotation marks omitted). If an expert does this, then a properly conducted differential etiology analysis "can be a reliable methodology under *Daubert*." *Id.* Such an analysis was conducted by Plaintiffs' experts here, unlike the expert in *Guinn*. Thus, the Court concludes that the opinions are sufficiently reliable to be considered in opposition to Mentor's motions for summary judgment.

Based on the foregoing, the Court finds that the testimony of Dr. Brubaker; Dr. Bush; Dr. Davis; Dr. Hiller; Dr. Karram; Dr. Mitchell; and Dr. Slack makes it through the Rule 702 gate. Therefore, their testimony will be considered in deciding Mentor's motions for summary judgment.[8]

3. Dr. George Samaras

Plaintiffs also rely upon the opinions of Dr. George Samaras in support of their contention that ObTape was defectively designed and/or manufactured. Dr. Samaras is a Professional Engineer who has a bachelor's degree in electrical engineering with biomedical emphasis, a master's degree in general physiology, a doctorate in physiology, pharmacology, and biophysiology, and a doctorate in engineering management and industrial and organizational psychology. He was formerly employed as associate director of the FDA's Center for Devices and Radiologic Health, and he has worked and taught in the field of biophysics and engineering for more than thirty years.

Dr. Samaras offers testimony explaining how the physical characteristics of ObTape contribute to the complications (erosion and infection) experienced by Plaintiffs. Mentor seeks to exclude his testimony, arguing that his methodology is flawed because he did not test ObTape, review clinical outcomes regarding ObTape, review

[8]Again, the Court does not consider Dr. Slack's testimony in ruling on the presently pending motions for summary judgment.

medical literature specifically concerning ObTape, or compare ObTape with other slings. Rather, he reviewed a number of Mentor's internal documents regarding ObTape, certain medical literature regarding surgical mesh in general, deposition and trial testimony in a prior case involving ObTape, and deposition testimony given in connection with this litigation. He based the testimony at issue on this review, as well as "first principles," which he described as "fundamental tenets of science." (Samaras Dep. 251:15-19, Nov. 24, 2009.) Thus, it appears that he primarily relies upon his experience as a biomedical engineer as the foundation for his opinions. As previously discussed, experience can certainly be a proper foundation for an expert opinion as long as that experience reliably supports the opinion. *Frazier*, 387 F.3d at 1261. The Court concludes, based on Dr. Samaras's qualifications and background, as well as the review he conducted of documents regarding ObTape and other suburethral sling products, that Dr. Samaras may explain scientifically how the design and construct of ObTape can cause the complications of erosion and infection, which Mentor admits are risks of ObTape. However, since Plaintiffs have not adequately explained the basis for any opinion by Dr. Samaras that connects the

biophysical characteristics of ObTape specifically to any Plaintiffs' individual injuries, he may not opine as to specific causation.[9]

4. Degradation Experts

Plaintiffs offer two expert witnesses to testify about the cause of the degradation of ObTape and about the effects of the degradation on ObTape patients–Dr. Ahmed El-Ghannam and Dr. Paul Ducheyne. Mentor seeks to exclude their opinions under Rule 702.

Dr. El-Ghannam opines that the thermal bonding process by which ObTape fibers are melted together causes ObTape to degrade after implantation. The thrust of Dr. El-Ghannam's opinion is that the degradation he observed in ObTape is unacceptable given its use as a permanent implanted medical device.

To reach his conclusions, Dr. El-Ghannam examined segments of degraded ObTape that had been explanted from several Plaintffs in this MDL proceeding, and he also ran certain tests on ObTape exemplars provided by Mentor. In addition, he reviewed Mentor's internal documents regarding ObTape, as well as a variety of peer-reviewed articles regarding polypropylene mesh products. Dr. El-Ghannam observed degradation of ObTape when he viewed ObTape

[9]In connection with their opposition to Mentor's *Daubert* motion, Plaintiffs submitted an affidavit by Dr. Samaras dated February 10, 2010. (Ex. 67 to Pls.' Resp. to Mentor's Mot. to Exclude.) Mentor asserts that Dr. Samaras's affidavit raises a completely new subject not addressed in his original expert report—a comparison of ObTape to a competitor's sling. Dr. Samaras shall not be permitted to offer opinions on matters he did not address in a Rule 26 report filed within the Court's deadline for doing so.

explanted from certain Plaintiffs with a scanning electron microscope. He also performed differential scanning calorimetry and Fourier transform infrared analyses on ObTape exemplar provided by Mentor. Based on these tests, Dr. El-Ghannam concluded that ObTape had an unacceptable level of degradation, and he opined that ObTape's unique thermal bonding process caused the degradation of the tape *in vivo*. Dr. El-Ghannam also noted that a different process, heat extrusion, is widely used and is not known to cause degradation. Dr. El-Ghannam further opined that any polypropylene that degraded to the same extent as ObTape would be unsuitable for implantation.

Mentor objects that Dr. El-Ghannam's methods were not subjected to peer review but otherwise does not raise challenges to his test methodology. Rather, Mentor argues that all polypropylene mesh products can degrade once implanted inside the body and that Dr. El-Ghannam's testimony cannot establish that ObTape is defective due to its propensity to degrade unless he compared it to a different polypropylene mesh product and found that the other product had a lower degradation rate.[10] The Court concludes that this argument is not a sufficient basis to find that Dr. El-Ghannam's methodology was flawed or that it is not a valid basis for his opinions that ObTape

[10]Dr. El-Ghannam did opine that ObTape's unique thermal bonding process likely caused the degradation, and he points out that a different process, heat extrusion, is widely used and is not known to cause degradation in polypropylene.

actually degraded in Plaintiffs and that ObTape posed an unreasonable risk of degradation. Dr. El-Ghannam's opinion is that any product with a propensity to degrade as ObTape did is too dangerous to be used as a permanent implantable device because of that propensity to degrade. Dr. El-Ghannam stated that implantable material such as ObTape should not degrade inside the body, which, he noted, Mentor's own internal documents confirm. For these reasons, the Court finds Dr. El-Ghannam's opinions to be sufficiently reliable and helpful to be considered by the jury.

Dr. Paul Ducheyne has also been identified as a degradation expert. He opines in his expert report that the thermal bonding step in the manufacture of ObTape "may have caused degradation." (Ducheyne Rule 26 Report 14-15.) The Court cannot find in the record, however, where Dr. Ducheyne opined to a reasonable degree of scientific certainty or probability that, in his opinion, the thermal bonding step causes degradation. Thus, the opinion appears speculative. To the extent Plaintiffs intend to have Dr. Ducheyne testify as to what caused the degradation, that testimony shall not be allowed given the conjectural nature of his testimony. However, to the extent Plaintiffs rely on Dr. Ducheyne's testimony to establish that Mentor should have done more testing on ObTape to determine its propensity to degrade *in vivo* because Mentor knew or should have been aware that the tape could degrade, Mentor points to

no reason why such an opinion is unreliable, and it shall be permitted.

5. Dr. Arnold Lentnek

Finally, Plaintiffs rely upon the expert testimony of Dr. Arnold Lentnek in opposition to Mentor's motions for summary judgment. Mentor seeks to exclude his testimony under Rule 702. Dr. Lentnek is a physician who practices in the fields of internal medicine and infectious disease. He is not a gynecologist or urologist, and he does not implant suburethral slings in patients. Dr. Lentnek opines that there is a more frequent occurrence of erosion or extrusion with ObTape than with other suburethral sling products, and he also opines that ObTape is associated with a heightened risk of erosion and late onset pelvic infection. In reaching this opinion, Dr. Lentnek did not perform any tests, and he did not base his opinion on any clinical experience he had with suburethral sling products. Rather, Dr. Lentnek conducted a literature review in the online database Medline. He then reviewed articles that were referenced in the bibliographies of the articles he found during his initial search.

The Court has concerns about the reliability of Dr. Lentnek's testimony and finds that it is necessary to conduct a *Daubert* hearing regarding his qualifications and the reliability of his methodology. The Court thus does not consider Dr. Lentnek's opinions in ruling on

Mentor's summary judgment motions. The *Daubert* hearing will be held during the pretrial conference.

Dr. Lentnek should be prepared to address the following issues at the hearing:

1. whether he is simply parroting the medical literature regarding ObTape, which the Court finds is not appropriate;
2. whether his methodology and scope of literature review is generally accepted in the medical community as a basis for arriving at opinions such as those he intends to express in this case; and
3. how his opinions that appear to rest primarily upon simply repeating what is contained in the literature are helpful to the jury.

III. Genuine Issues of Material Fact as to Design Defect Claims

As discussed in more detail above, the evidence in the present record, including the expert testimony which the Court has determined satisfies Rule 702, establishes that genuine issues of material fact exist as to whether ObTape is defectively designed and whether it proximately caused the injuries allegedly suffered by Plaintiffs. Accordingly, Mentor's motion for summary judgment as to Plaintiffs' design defect claims is denied.

IV. Genuine Issues of Material Fact as to Manufacturing Defect Claims

In support of their manufacturing defect claims, Plaintiffs point to evidence that ObTape's product specifications called for pores measuring between 40 and 100 microns. (510(k) Notification.) Mentor disputes that the specifications call for pores measuring between 40 and 100 microns. The 510(k) Notification states, "The tape will be manufactured from polypropylene with a pore size of 40 - 100µm to facilitate tissue ingrowth." (510(k) Notification at MENTOR/OBTAPE CONFIDENTIAL_000019; *see also id.* at MENTOR/OBTAPE CONFIDENTIAL_000020 ("Obtape will be manufactured from 100% polypropylene, with a pore size of approximately 40 - 100 µm to facilitate tissue ingrowth.").) Citing this language, Mentor argues that the specifications called for an *average* pore size of 40 to 100 microns and that some pores could be larger and some could be smaller. On its face, however, the 510(k) Notification does not state what the average pore size should be; it appears to state the approximate minimum and maximum pore sizes. Without some evidence that the specifications called for an average pore size rather than a minimum and maximum pore size, the Court cannot conclude as a matter of law that the specifications called for an average pore size. There is also evidence before the Court that tests of ObTape samples reveal that ObTape contains non-uniform pores, some of which

are closed-ended pores and the vast majority of which are smaller than 40 microns.[11] (Ducheyne Rule 26 Report 2, 9-10, 13.) Based on this evidence, the Court finds that a reasonable fact finder could conclude that Plaintiffs' ObTape did not conform to Mentor's specifications.

Mentor argues that there was no manufacturing defect as a matter of law because each lot of ObTape Mentor received from Mentor's contract manufacturer, Analytic Biosurgical Solutions ("ABISS"), was accompanied by a certificate stating that each ObTape contained in the lot conformed to design specifications. (*See* Exs. B-V to Wyatt Decl., Certificates of Conformance.) The certificates state that the products in the particular lot "conform to the specifications according to the supply agreement between Mentor and ABISS." (*E.g.*, Ex. C to Wyatt Decl., Certificate of Conformance as to Lot AE040094.) According to Plaintiffs, however, the tests did not ensure that the ObTape was manufactured to specifications; they were merely visual checks to inspect for dirt and traces and to ensure that a black line marked the center of the tape. (*See* Exs. 19-26 to Pls.' Resps. to Mentor's Mots. for Summ. J., "Controle-Reception" Reports.) Such a visual inspection would not reveal whether the pore size is larger

[11]Though ObTape excised from other patients was tested, along with samples of ObTape that had never been implanted, the ObTape excised from the Phase I Georgia Plaintiffs was not tested for this litigation; either it was not preserved or was not suitable for testing.

or smaller than 40 millionths of a meter. Thus, while the compliance certificates may constitute some evidence that the ObTape implanted in Plaintiffs complied with Mentor's design specifications, there is also evidence from which a fact finder could conclude that the testing performed did not adequately determine whether the ObTape in each lot was, in fact, in compliance with the design specifications. This evidence, combined with the evidence suggesting that ObTape actually did not comply with the specifications, demonstrates that judgment as a matter of law is not warranted on the manufacturing defect issue.[12]

V. Genuine Issues of Material Fact as to Failure to Warn Claims

A. Adequacy of ObTape Warnings

Mentor contends that its warning regarding ObTape was adequate as a matter of law because it listed the complications suffered by Plaintiffs—"erosion" and "infection"—as possible adverse reactions. Mentor argues that a warning is adequate if it lists the specific

[12]To the extent Plaintiffs argue that the failure of ObTape itself is sufficient circumstantial evidence to prove a manufacturing defect, the Court rejects that argument. Where the existence of a manufacturing defect is not the only plausible explanation for a product's failure, the product's failure, standing alone, is not sufficient to establish a manufacturing defect. *Graff v. Baja Marine Corp.*, 310 F. App'x 298, 306 (11th Cir. 2009); *see also Stanley v. Toyota Motor Sales, U.S.A., Inc.*, No. 3:07-CV-08 (CDL), 2008 WL 4664229, at *2 (M.D. Ga. Oct. 20, 2008) ("Georgia courts have squarely rejected the argument that the failure of a mechanical system is itself evidence of an original defect in the product."). Here, it is undisputed that even non-defective suburethral slings can cause complications such as erosion and infection.

injury suffered by the plaintiff. *See Lakey v. Mentor Corp.*, Civil Action No. 1:05-cv-929-TCB, 2007 WL 4811929, at *4 (N.D. Ga. Mar. 30, 2007) (finding that failure to warn claim was barred because plaintiff alleged that product caused infection and product insert sheet warned of risk of infection); *McCombs v. Synthes (U.S.A.)*, 266 Ga. App. 304, 304, 596 S.E.2d 780, 780 (2004) (concluding that warning was adequate and reasonable where warning stated that device could break under certain circumstances and that is what happened in plaintiff's case, where plaintiff presented no evidence to show that warning was inadequate); *see also Trickett v. Advanced Neuromodulation Sys., Inc.*, 542 F. Supp. 2d 1338, 1348 (S.D. Ga. 2008) (concluding that warning regarding medical device was adequate as a matter of law because it warned that there was a risk of certain "undesirable changes" that occurred in plaintiff's case, where there was no evidence suggesting that the warning on that issue was inadequate). Plaintiffs note that Mentor's warnings regarding ObTape were nearly identical to the warnings given for ObTape's competitors, TVT and SPARC.[13] Plaintiffs also observe that the ObTape warning

[13]The TVT warning states:

> Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
>
> As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.

suggests that the adverse reactions of erosion and infection occur "very rarely." (ObTape PIDS 2.) As discussed above, there is a genuine issue of material fact as to whether such complications were indeed "very rare" with ObTape, and there is a fact question as to whether ObTape had a greater propensity to cause erosions and infections than other suburethral sling products. There is also a genuine issue of material fact as to whether ObTape was associated with more severe complications than the other products.[14] Given that evidence, combined with the evidence that Mentor did not inform Plaintiffs' physicians of any increased risks associated with ObTape,

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(Ex. 2 to Pls.' Resps. to Mentor's Mots. for Summ. J., TVT PIDS at MENTOR/OBTAPE CONFIDENTIAL_000067.)

> The SPARC warning states:
>
> > Tissue responses to the implant could include extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, and inflamation. The occurrence of these responses may require removal of the entire sling mesh.
> >
> > Like all foreign bodies, the AMS Polypropylene sling mesh may potentiate an existing infection.

(Ex. 3 to Pls.' Resps. to Mentor's Mots. for Summ. J., SPARC PIDS at MENTOR/OBTAPE CONFIDENTIAL_000079.)

[14]According to Plaintiffs' expert Dr. Hiller, a Mentor sales representative told him that the rare erosion and infection referenced in the ObTape PIDS could be addressed with local excision and medication. (Hiller Rule 26 Report 6.) When he read the ObTape PIDS, Dr. Hiller did not "anticipate the rate, degree or severity" of erosions and infections his patients experienced with ObTape. (*Id.*) Similarly, Plaintiffs' expert Dr. Mitchell believed that Mentor's PIDS addressed minor erosion and infection issues he had experienced with other suburethral sling products that could be treated by removing a small portion of the eroded tape or with medication. (Mitchell Rule 26 Report 6.)

a reasonable fact finder could conclude that the ObTape PIDS did not contain an adequate warning regarding ObTape. *See Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1220 (11th Cir. 1999) (finding genuine issue of material fact on failure to warn claim because jury could conclude that more adequate warning was needed on vehicle that had greater propensity than other vehicles to roll over during an accident). After all, "[w]hat may be an adequate warning for one product is not necessarily adequate for the next." *Id.* For these reasons, under the circumstances presented here, the Court concludes that genuine issues of material fact exist as to whether the ObTape warning was adequate.

B. Actual Knowledge

Similarly, Mentor argues that Plaintiffs' doctors were all aware of the potential risks of erosion and infection. However, as discussed above, even if the physicians were generally aware of the potential risks of erosion and infection, they did not have actual knowledge that there was any increased risk associated with ObTape compared with other products. Therefore, the Court cannot conclude as a matter of law that Plaintiffs' doctors had actual knowledge of the risks of ObTape.

C. Causation

Mentor does not seriously dispute that there is a genuine issue of material fact as to whether Dr. Blankenship, Dr. Green, and Dr.

Oliver would have made the same decision to implant ObTape in Mrs. Booth, Mrs. Crowther, Mrs. Dover, Mrs. Olson, Mrs. Parker, Mrs. Stafford, and Mrs. Tucker had there been a different warning regarding the risks of ObTape. These doctors testified that they read the ObTape PIDS (or believe they did), that they were not told of any increased risks associated with ObTape, and that they would not have implanted the ObTape had they known of any increased risks. Accordingly, the Court concludes that genuine issues of material fact exist as to causation on the failure to warn claims of Mrs. Booth, Mrs. Crowther, Mrs. Dover, Mrs. Olson, Mrs. Parker, Mrs. Stafford, and Mrs. Tucker.

Mentor does contend, however, that there is insufficient evidence to create a genuine issue of material fact as to whether Dr. Chun, Dr. Kyburz, and Dr. Symbas would have made the same decision to implant ObTape in Mrs. Looper, Mrs. Merritt, Ms. Mills, and Mrs. Turner even if the warnings had been different. Mentor contends that because these doctors did not read the ObTape PIDS, a different warning would not have mattered. In general, causation on a failure to warn claim cannot be established unless a plaintiff's doctor did read the product warning *or rely on other statements by the product's manufacturer.* For example, in *Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004), the court affirmed summary judgment in favor of a drug manufacturer because the plaintiff's doctor

"testified that he did not read the warning label that accompanied Zoloft *or rely on information provided by Pfizer's detail men before prescribing the drug*[, so] the adequacy of Pfizer's warnings is irrelevant to the disposition of this case." *Id.* at 661 (emphasis added). Here, there is evidence that Drs. Chun, Kyburz, and Symbas relied on information provided to them by Mentor's sales representatives and/or a Mentor brochure regarding ObTape, and they testified that if they had been provided with information about the increased risks of ObTape, they would not have implanted it in their patients. Therefore, the Court concludes that genuine issues of material fact exist as to whether Dr. Chun, Dr. Kyburz, and Dr. Symbas would have made the same decision to implant ObTape in Mrs. Looper, Mrs. Merritt, Ms. Mills, and Mrs. Turner if the warnings had been different.

VI. Statute of Limitation Issues

Finally, Mentor contends that the claims of Mrs. Dover, Mrs. Merritt, and Mrs. Olson are barred by the statute of limitations. The parties agree that each Plaintiff must have brought her claims within two years after the right of action accrued. O.C.G.A. § 9-3-33. The parties also agree that a personal injury claim accrues for statute of limitations purposes "when a plaintiff discovers, or with reasonable diligence should have discovered, both the injury *and the cause thereof*." *Waters v. Rosenbloom*, 268 Ga. 482, 483, 490 S.E.2d

73, 75 (1997) (emphasis added) (finding that discovery rule barred plaintiff's medical malpractice claim due to husband's prescription drug habit because plaintiff knew that prescription drugs were affecting her husband's mental state twenty years before she filed suit); *see also King v. Seitzingers, Inc.*, 160 Ga. App. 318, 319, 287 S.E.2d 252, 254 (1981) ("A cause of action will not accrue under the discovery rule until the plaintiff discovers or in the exercise of reasonable diligence should have discovered not only that he has been injured but also that his injury may have been caused by the defendant's conduct." (internal quotation marks omitted)). For example, in *Welch v. Celotex Corp.* 951 F.2d 1235, 1237 (11th Cir. 1992), the Eleventh Circuit reversed summary judgment in favor of an asbestos manufacturer because genuine issues of material fact existed as to whether the plaintiff knew of a causal connection between the manufacturer's conduct and his injuries more than two years before he filed suit. In *Welch*, although the plaintiff knew he had asbestosis more than two years before he filed his suit, there was evidence that he did not know of any wrongdoing by the manufacturer until he met with an attorney less than two years before he filed suit. *Id.* Disputed issues of material fact regarding when a cause of action accrued must be decided by a jury. *E.g.*, *King*, 160 Ga. App. at 319, 287 S.E.2d at 255.

Mentor argues that Mrs. Dover, Mrs. Merritt, and Mrs. Olson knew or should have known more than two years before they filed suit that a defect in ObTape caused their injuries. The Court disagrees and finds that genuine issues of material fact exist on this issue.

A. Gail Dover

Mrs. Dover filed her action against Mentor on October 19, 2007. However, Mentor argues that Mrs. Dover knew or should have known that a defect in ObTape caused her injuries by mid-2005, after she suffered severe infections and underwent several excision procedures. But, as Mentor points out, erosion and infection are risks of any suburethral sling product, including ObTape, and Mrs. Dover was warned about those risks. There is no evidence she was warned about any increased risks such that she was put on notice that a possible defect caused her injuries. There is evidence that Mrs. Dover did not suspect that ObTape was defective until sometime in 2006, when she read an article regarding product liability suits concerning ObTape. From this, the Court concludes that genuine issues of material fact exist as to when Mrs. Dover's product liability claims accrued.

B. Maris Merritt

Mrs. Merritt filed her action against Mentor on October 19, 2007. However, Mentor contends that Mrs. Merritt knew or should have known that a defect in ObTape caused her injuries

shortly after her surgery in 2003, when she began to have vaginal discharge, or at least by mid-2005, after she had undergone two excision procedures. The Court concludes that this issue cannot be decided as a matter of law because genuine issues of material fact exist. First, there is no evidence that Mrs. Merritt's doctor diagnosed a cause of the vaginal discharge in 2003 such that Mrs. Merritt was put on notice of a possible defect in ObTape. Second, as Mentor points out, erosion and infection are risks of any suburethral sling product, including ObTape, and Mrs. Merritt was warned about those risks. There is no evidence she was warned about any increased risks such that she was put on notice that a possible defect caused her injuries, and Mrs. Merritt's doctor never told her that the ObTape might be defective. There is evidence that Mrs. Merritt did not suspect that her ObTape might be defective until the summer of 2007, when Mrs. Merritt's husband read an article about product liability lawsuits regarding Mentor. For these reasons, the Court concludes that genuine issues of material fact exist as to when Mrs. Merritt's claims accrued.

C. Cheryl Olson

Mrs. Olson filed her product liability action against Mentor on July 24, 2007, but Mentor contends that she knew or should have known that a defect in ObTape caused her injuries by at least March of 2005, when she had undergone an excision procedure and she believed

the sling was not working like it should. However, as Mentor points out, erosion and infection are risks of any suburethral sling product, including ObTape, and Mrs. Olson was warned about those risks. She was also warned that there was a chance the procedure would not work. Furthermore, her doctor never told her there was a defect in the ObTape; when he told her that the tape had eroded in February 2005, he explained that it was possible that her body was rejecting the sling or that trauma from intercourse could have thinned her tissue. Based on the evidence before the Court, a reasonable fact finder could conclude that Mrs. Olson did not suspect that ObTape might be defective until after the January 2007 excision, when Dr. Oliver found an infection in the mesh and Dr. Oliver's physician assistant told Mrs. Olson that there was a problem with the sling. For these reasons, the Court concludes that genuine issues of material fact exist as to when Mrs. Olson's claims accrued.

CONCLUSION

As discussed above, Mentor's Motion for Summary Judgment (Doc. 154) as to Plaintiffs' design defect claims is denied, and Mentor's summary judgment motions as to Plaintiffs' manufacturing defect claims and failure to warn claims are also denied; but Mentor is granted summary judgment as to Plaintiffs' implied warranty claims (Doc. 140 in 3:07-cv-88 (Parker Plaintiffs); Doc. 142 in 3:07-cv-88 (Olson Plaintiffs); Doc. 114 in 3:07-cv-101 (Plaintiffs Stafford and

Pinkney); Doc. 110 in 3:07-cv-102 (Crowther Plaintiffs); Doc. 111 in 3:07-cv-102 (Booth Plaintiffs); Doc. 112 in 3:07-cv-102 (Tucker Plaintiffs); Doc. 105 in 3:07-cv-130 (Plaintiff Mills); Doc. 106 in 3:07-cv-130 (Dover Plaintiffs); Doc. 108 in 3:07-cv-130 (Merritt Plaintiffs); Doc. 109 in 3:07-cv-130 (Looper Plaintiffs); and Doc. 110 in 3:07-cv-130 (Turner Plaintiffs)).

Mentor's motion to exclude certain testimony of Plaintiffs' experts (Doc. 156) is granted in part and denied in part as explained in this Order.[15]

IT IS SO ORDERED, this 22nd day of April, 2010.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE

[15]The remaining *Daubert* motions contained in Mentor's Motion to Exclude, which were not necessary to resolve for purposes of deciding Mentor's motions for summary judgment, will be addressed in a separate order.