IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

DEBORAH SMITH AND MICHAEL SMITH **PLAINTIFFS**

VS. **CIVIL ACTION NO. 3:08CV245 HTW-LRA**

JOHNSON & JOHNSON and
ETHICON, INC. **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

Before the court are seven motions. Defendants Johnson & Johnson, Inc., and Ethicon, Inc., have brought the following five motions: a motion for summary judgment on the Learned Intermediary Doctrine **[docket no. 93]**; a motion to strike the affidavit of William A. Hyman, Sc. D. **[docket no. 114]**; a motion to strike expert reports attached to plaintiffs' response in opposition to defendants' motion for summary judgment **[docket no. 117]**; a motion to strike the affidavit of Stuart Hart, M.D. **[docket no. 118]**; and a motion to strike exhibits H, I, J, L, M, N, O, Q, R, S, S-1, and T to plaintiffs' response in opposition to defendants' motion for summary judgment **[docket no. 120]**.

Plaintiffs Deborah Smith and Michael Smith have submitted the following two motions: a motion for discovery **[docket no. 141]** and a motion **[docket no. 145]** for review of magistrate judge order [docket no. 140] (1), granting defendants' motion to stay 30(b)(6) deposition [docket no. 83]; (2), granting defendants' motion to strike first requests for admission [docket no. 124] ; and (3), denying plaintiffs' motion to strike defendants' motions [docket no. 130].

I. Background

This is a medical device product liability action. In 2001, plaintiff Deborah Smith underwent a total abdominal hysterectomy. In 2002, Smith was diagnosed with vaginal vault prolapse, a condition whereby a portion of her upper vagina fell, protruding from the vaginal opening. Smith elected to undergo an abdominal sacrocolpopexy performed by Dr. Philip Barksdale. An abdominal sacrocolpopexy consists of making a surgical incision in the abdomen and then using mesh to attach the vagina to the front of the sacrum, i.e., backbone. Dr. Barskdale used Mersilene mesh, a sterile synthetic nonabsorbable surgical material. On April 1, 2002, Dr. Barksdale performed said surgery on Smith at the Women's Hospital in Baton Rouge, Louisiana.

In July 2006, Smith presented at Northside Hospital in Atlanta, Georgia, with complaints of worsening severe vaginal pain. Smith was diagnosed with vaginal mesh erosion, among other things, and chose to have the mesh surgically removed. Smith claims the mesh removal led to several serious complications and injuries.

Deborah Smith and Michael Smith, husband and wife, filed their complaint on October 16, 2007, in this court against Johnson & Johnson and Ethicon, Inc., a Johnson & Johnson company which manufactures, markets and distributes the Mersilene mesh. The complaint raises claims of negligence, strict liability, breach of implied warranty of merchantability, breach of express warranty, and loss of consortium. Plaintiffs request compensatory damages in the amount of ten (10) million dollars plus punitive damages in the amount of ten (10) million dollars.

On March 9, 2010, this court held a hearing on five of the motions presently before the court, namely: the motion for summary judgment **[docket no. 93]**; the motion to strike the affidavit of William A. Hyman, Sc.D. **[docket no. 114]**; the motion to strike the expert reports attached to plaintiffs' response in opposition to defendants' motion for summary judgment **[docket no. 117]**; the motion to strike the affidavit of Stuart Hart, M.D. **[docket no. 118]**; and the motion to strike various exhibits to plaintiffs' response in opposition to defendants' motion for summary judgment **[docket no. 120]**. The court did not rule on any of those motions at that time as the court was awaiting a ruling from Magistrate Judge Linda Anderson on the defendants' pending first motion to strike plaintiffs' expert designation [docket no. 58]. The court informed the parties that if the Magistrate Judge denied that motion, the court would then contact the parties to schedule a hearing date for oral arguments on the remaining pending motions. On March 16, 2010, the Magistrate Judge denied defendants' motion to strike [docket no. 58] plaintiffs' expert designation. Consequently, the five aforementioned motions are again before this court, along with two motions filed since the last hearing.

This court has diversity jurisdiction over this matter under Title 28 U.S.C. § 1332(a)(1) since it is alleged in the complaint and undisputed that "[t]he matter in controversy exceeds the sum or value of $ 75,000, exclusive of interest and costs, and is between citizens of different States . . ."[1]

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[1]Section 1332(a)(1) provides:
(a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $ 75,000, exclusive of interest and costs, and is between--
(1) Citizens of different States. . .

II. Discussion

A. Motions to Strike

Before addressing the merits of the defendants' motions for summary judgment, this court must decide the defendants' various motions to strike. Defendants have filed four motions to strike, all of which deal with the exhibits submitted in support of, or attached to, plaintiffs' response to defendants' motion for summary judgment.

1. Motion to Strike the Affidavit of William A. Hyman, Sc. D. and Motion to Designate Dr. Hyman as an Expert

Defendants move to strike the affidavit of William A. Hyman, Sc. D. **[docket no. 114]**. This court will simultaneously consider plaintiffs' motion to designate Dr. Hyman as an expert **[docket no. 141]** since both motions require this court to determine whether to allow Dr. Hyman's testimony as an expert.

The Magistrate Judge initially set April 24, 2009, as the deadline for plaintiffs to designate experts [docket no. 27]. Defendants filed a motion for extension of deadlines [docket no. 39], and the Magistrate Judge granted that motion. The Magistrate Judge entered an agreed amended scheduling order [docket no. 39] which set August 3, 2009, as the new plaintiffs' deadline to designate experts and serve any supplemental reports. On August 6, 2009, the parties filed a joint motion for continuance [docket no. 45]. On August 18, 2009, the Magistrate Judge granted the motion and entered a new scheduling order, setting September 11, 2009, as the deadline for plaintiffs to designate experts.

On September 11, 2009, plaintiffs emailed defendants a cover letter and the curricula vitae of three purported expert witnesses - Dr. Kyle Wohlrab, Dr. Stuart Hart,

and Dr. Robert Lloyd Goldstein. On October 20, 2009, defendants moved to strike plaintiffs' purported expert designations [docket no. 58].

One week later, on October 27, 2009, without leave of court and without filing a motion for extension of time, plaintiffs served two purported expert reports [docket no. 61]. One report was from Dr. Wohlrab and the other from Dr. Goldstein. On November 12, 2009, again without leave of court and without filing a motion for extension of time, plaintiffs served the expert report of Dr. Hart [docket no. 73]. On November 20, 2009, plaintiffs filed a motion for extension of time to complete discovery to serve expert reports [docket no. 77], requesting that the court find the expert reports from Dr. Wohlrab, Dr. Goldstein and Dr. Hart as timely filed.

On December 11, 2009, defendants filed their motion for summary judgment **[docket no. 93]**. On December 28, 2009, plaintiffs filed a motion for extension of time to respond to defendants' motion [docket no. 101], requesting that this court allow them until January 15, 2010, to file a response. On December 29, 2009, this court granted plaintiffs' unopposed motion. On January 15, 2010, plaintiffs filed their response. They filed, as an attachment to their response, the affidavit of Dr. William H. Hyman [docket no. 112], a biomedical engineer, and relied heavily on that affidavit for the argument in their response that the Mersilene mesh package insert was not adequate. This affidavit, filed on January 15, 2010, more than four months after plaintiff's deadline to designate experts, is the first time plaintiffs mentioned Dr. Hyman in this case.

On March 16, 2010, despite finding that "there was no good cause or explanation for [plaintiffs' failure] to complete the expert designations before the scheduling date,"

the Magistrate Judge entered an order [docket no. 139] granting plaintiffs' motion for extension of time to complete discovery to serve expert reports [docket no.77]. The order awarded defendants costs incurred in relation to plaintiffs' untimely expert designations and directed defendants to submit an affidavit of costs. Defendants submitted an affidavit of costs as ordered [docket no. 143]. Plaintiffs, as of the parties' last appearance before this court on September 23, 2010, had not yet paid the defendants' costs.

On March 19, 2010, three days after the Magistrate Judge's order allowing plaintiffs to serve late reports of Dr. Wohlrab, Dr. Goldstein and Dr. Hart, plaintiffs filed a motion to designate Dr. Hyman as an expert **[docket no. 141]**.

Defendants first argue in their motion to strike that plaintiffs should not be allowed to rely on Dr. Hyman's opinion that the insert was inadequate since in submitting Dr. Hyman's opinion, they failed to comply with Federal Rule of Civil Procedure 26(a)(2). Rule 26(a)(2) states in pertinent part:

> (A) In General. In addition to the disclosures required by Rule 26(a)(1), a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705.
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> (B) Written Report. Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report--prepared and signed by the witness--if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain:
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> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
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> (ii) the data or other information considered by the witness in forming them;
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> (iii) any exhibits that will be used to summarize or support them;

(iv) the witness's qualifications, including a list of all publications authored in the previous ten years;

(v) a list of all other cases in which, during the previous four years, the witness testified as an expert at trial or by deposition; and

(vi) a statement of the compensation to be paid for the study and testimony in the case.

The submission of Hyman's opinion [docket no. 112] did not contain all the required items listed in Rule 26(a)(2)(B).

Rule 37(c)(1) instructs that "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless."

In determining whether to exclude expert testimony under Rule 37, courts analyze four factors: (1) the explanation given for the failure to identify the witness; (2) the importance of the witness' testimony; (3) potential prejudice to the opposing party in allowing the witness' testimony; and (4) the possibility that a continuance would cure such prejudice. *Betzel v. State Farm Lloyds*, 480 F.3d 704 (5th Cir. 2007) (citing *Campbell v. Keystone Aerial Surveys*, 138 F.3d 996, 1000 (5th Cir. 1998)).

First, plaintiffs have not offered a satisfactory explanation to the district court for their failure to timely designate Dr. Hyman. Plaintiffs for the first time submitted information from Dr. Hyman on January 2010, well past September 11, 2009, the deadline for designation of experts and the date on which plaintiffs identified Dr. Wohlrab, Dr. Hart and Dr. Goldstein as their designated experts.[2]

[2]Plaintiffs blame defendants for the delay, contending that the defendants withheld discovery. This statement is not considered an explanation since plaintiffs have not clarified how the lack of discovery was a hindrance to identifying Dr. Hyman when: (1) they were able to

Also, defendants note that much of the materials upon which Dr. Hyman relied in arriving at his opinion were available prior to the September 11, 2009, deadline for plaintiffs' expert designation. These materials include Smith's medical records associated with her 2002 and 2006 surgical procedures; 2002 consent and authorization forms; 2002 Mersilene mesh package insert; portions of "Wound Care Manuals" authored by Ethicon that are dated 1985, 1994, 2002 and 2004; various journal articles published before Smith's 2002 surgery; and various information on the website of the Food and Drug Administration ("FDA"). The other materials upon which Dr. Hyman relied are the deposition testimony of Dr. Barksdale, which was taken on November 16, 2009; the deposition testimony of Smith, which was taken on October 27, 2009; documents produced by Ethicon during discovery; the expert disclosure of Dr. Wohlrab; and the expert disclosure of Dr. Hart.

Returning to the four-factor test enunciated by *Betzel* and *Campbell*, *supra*, this court finds that the first factor weighs in favor of striking the affidavit. That first factor mentions "the explanation given for the failure to identify the witness."

The second consideration, the importance of the testimony to be offered, also weighs in favor of striking the affidavit. Plaintiffs' case will not fail solely as a result of the exclusion of Dr. Hyman's expert testimony. *See CQ Inc. v. TXU Mining Co. LP*, 565 F.3d 268, 280 n.7 (5th Cir. 2009) (in considering the importance of an expert's testimony, the testimony is not essential where exclusion of the testimony does not

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designate other experts without the information they supposedly needed and (2) they still had not received the discovery they claim they needed by the time they identified and submitted an opinion from Dr. Hyman.

constitute dismissal of the case). Further, plaintiffs state in their response to defendants' motion to strike that "each and every one of the opinions attested to by [Dr. Hyman] may . . . be elicited from other competent witnesses previously designated, i.e., Dr. Wohlrab and Dr. Hart . . ." Plaintiffs' own statement suggests that Dr. Hyman's testimony is not essential.

Thirdly, this court finds that defendants would be prejudiced by the late designation of Hyman in that the late designation might significantly impact their trial preparation, possibly causing the need to designate additional experts and take additional depositions. Defendants timely retained their two experts, medical doctors Dr. John Morrison and Dr. Brooks Griffin, and provided expert reports for each. Defendants argue that if Dr. Hyman is allowed to be designated at this late date, they will have to revamp their case strategy, which includes possibly retaining a biomedical engineer. The third factor, too, weighs in favor of striking the affidavit.

Finally, this court finds that a continuance would not cure the prejudice to defendants and is not appropriate. This is a vintage case which should proceed apace to resolution where the parties have had ample time to contemplate these issues. Plaintiffs earlier were granted an extension of time to complete discovery to serve expert reports, even though plaintiffs had failed to show good cause for needing the extra time. Accordingly, the fourth factor also weighs in favor of striking the affidavit.

The four *Betzel* factors weigh in favor of striking the affidavit of Dr. Hyman. Defendants' motion to strike **[docket no. 114]** is granted. Plaintiffs' motion to designate Dr. Hyman as an expert **[docket no. 141]** is denied. Dr. Hyman will not be permitted to

testify, and the parties shall not reference any opinions he has offered in his affidavit.

2. Motion to Strike Expert Reports Attached to Plaintiffs' Response

Defendants have also filed a motion to strike the expert reports attached to plaintiffs' response in opposition to defendants' motion for summary judgment **[docket no. 117]**. Plaintiffs attached the expert disclosures of Dr. Wohlrab, a licensed physician[3] [docket no. 111, Exh. G], and Dr. Hart, a physician board-certified in obstetrics and gynecology, [docket no. 111, Exh. P] to their response. Defendants contend that these reports are untimely because they were filed after the expert designation deadline. This argument fails because this court already decided that issue and allowed the late designation of these experts in its March 16, 2010, order [docket no. 139].

Defendants also argue that these reports are not proper summary judgment evidence because they are inadmissible. On a motion for summary judgment, the court may consider expert testimony only if it would be admissible at trial. *See* F.R.C.P. 56(c).[4] The admissibility of expert testimony is governed by Rule 702 of the Federal

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[3]Dr. Wohlrab's curriculum vitae is not clear as to whether he is board certified in certain practice areas. He did a residency in obstetrics and gynecology and a fellowship in urogynecology and has served at times as an instructor in gynecology, obstetrics and urogynecology.

[4]Rule 56(c) states:

> (c) Procedures.
> (1) Supporting Factual Positions. A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:
> (A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or

Rules of Evidence and the guiding principles declared in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). Rule 702 gives trial courts a "gatekeeping role" to ensure that expert opinions presented to a jury are based on an adequate factual foundation and are the product of reliable methodology. *See Daubert*, 509 U.S. at 597.

The Rule 702 standard consists of five requirements: (1) the witness must be qualified as an expert by knowledge, skill, experience, training, or education; (2) the offered testimony or opinion must be based upon sufficient facts or data; (3) the offered testimony or opinion must be derived from reliable principles and methods; (4) the expert witness must have applied the principles and methods reliably to the facts of the case; and (5) expert or specialized knowledge must be helpful in assisting the trier of fact to understand the evidence or to determine a fact in issue. Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. *Michaels v. Avitech*, Inc., 202 F.3d 746, 754 (5th Cir. 2000). "[A] trial court may exclude

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> (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce *admissible* evidence to support the fact.
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> (2) Objection That a Fact Is Not Supported by Admissible Evidence. A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be *admissible* in evidence.
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> (3) Materials Not Cited. The court need consider only the cited materials, but it may consider other materials in the record.
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> (4) Affidavits or Declarations. An affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be *admissible* in evidence, and show that the affiant or declarant is competent to testify on the matters stated.

(emphasis added).

expert testimony that is imprecise and unspecific or whose factual basis is not adequately explained." *S. Grouts & Mortars v. 3m Co.*, 575 F.3d 1235, 1245 (11th Cir. 2009) (finding a report inadmissible that consisted primarily of conclusory statements and claimed to rely on the record as a basis for its opinion but provided no specific citation to the record).

Dr. Hart's report [docket no. 111-17] provides some credentials and states that "[a]s a physician specializing in Urogynecology and Pelvic Reconstructive Surgery, [he is] very familiar with the use of mesh in pelvic surgery." He concludes that "there is a causal relationship between the use of the Mersilene mesh and erosion and sinus tract formation in this case . . . the eroded mesh contributed to Mrs. Smith's medical course." He says he relied on his training and experience and his review of Smith's medical records and the Mersilene mesh insert. He did not use any additional documents about the product from Ethicon or any medical studies or literature.

Dr. Hart's report is simply credentials and a conclusion without factual basis. *See Yaquinto v. Segerstrom*, 247 F.3d 218, 227 (5th Cir. 2001) (rejecting expert evidence that consisted of a conclusive allegation as to cause) and *Boyd v. State Farm Ins.*, 158 F.3d 326, 331 (5th Cir. 1998) ("It is a well established rule that without more than his credentials and a subjective opinion, an expert's testimony that a medical condition simply 'is so' is not admissible."). Dr. Hart's opinion is not based upon sufficient facts or data derived from reliable principles and methods. Thus, his naked opinion is insufficient for summary judgment purposes.

Dr. Wohlrab provides credentials and gives the opinion [docket no. 111-8] that

"the Mersilene mesh inserted in Deborah Smith in 2002 caused vaginal erosion, infection, peritonitis and numerous complications in Smith. The pelvic abscess, colostomy, and hernias are direct adverse sequelae before that period from surgery following the mesh removal." Dr. Wohlrab states that he relied on his training and experience as a medical doctor and on Smith's medical records to reach the conclusion that the Mersilene mesh caused the injuries plaintiff suffered; however, he also states that while he used Mersilene mesh in training, he does not use it in his practice. Dr. Wohlrab does not state how long or how extensively he used the Mersilene mesh during his training. He does not state whether he uses any type of mesh with any type of regularity in his own practice. Yet he claims to rely on his training and experience in reaching his opinion. Dr. Wohlrab puts forth statistics, which he says in his report are drawn from studies, as to the erosion rate of Mersilene mesh. No specific study is cited in, or attached to, his report. Dr. Wohlrab explains that, at the time of giving his opinion, he had "not yet had the opportunity to review documents from Ethicon including product packaging and inserts, medical studies and literature, and instructions on Mersilene mesh use. . ."

The record, including Dr. Wohlrab's own statements, indicates that Dr. Wohlrab simply looked at Smith's medical records and concluded that Mersilene mesh was the cause of her claimed injuries. His conclusion lacks: (1) sufficient facts or data in support, (2) explanation of utilization of reliable principles and methods, and (3) application of principles and methods reliably to the facts of the case. This report, too, is inadmissible.

Therefore, defendants' motion to strike the expert reports of Dr. Hart and Dr. Wohlrab **[docket no. 117]** is granted.

3. Motion to Strike Affidavit of Stuart Hart, M.D.

Defendants filed a motion to strike the affidavit of Stuart Hart, M.D. **[docket no. 118]** on the grounds of untimeliness. This argument is rejected. The affidavit [docket no. 116] in question was filed before this court's March 16, 2010, order [docket no. 139]; thus, the problem of untimeliness is cured by the March 16, 2010, order.

Defendants further argue that the affidavit is not admissible under Rule 56 because it is conclusory. This court agrees.

Dr. Hart's affidavit states that based upon medical literature and adverse event data, "it would appear that the warnings contained in the Mersilene Mesh product may not have been adequate to apprise Dr. Barksdale of the problems with Mersilene mesh at the time he performed the plaintiff's surgery." Dr. Hart's affidavit states that he based this conclusion on published literature. No particular medical article or study or report upon which Stuart relies is cited or attached to his affidavit. The affidavit provides no basis for how either of these sources was used in arriving at his conclusion.

The affidavit merely sets out a variety of conclusory allegations that are opinions devoid of an underlying factual basis and explanation. Expert affidavits may not be used in this way to create issues of material fact at the summary judgment stage. *See, e.g., Hayter v. City of Mt. Vernon*, 154 F.3d 269, 274 (5th Cir. 1998) (holding that "affidavits setting forth 'ultimate or conclusory facts and conclusions of law' are insufficient to either support or defeat a motion for summary judgment[,]" and that

"[w]ithout more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible.") (quoting *Orthopedic & Sports Injury Clinic v. Wang Lab., Inc.*, 922 F.2d 220, 225 (5th Cir. 1991)). As the affidavit fails to provide any factual support for its conclusion that Dr. Barksdale was adequately warned about the dangers of Mersilene mesh, it is insufficient for use on summary judgment and shall be stricken. Defendant's motion to strike **[docket no. 118]** is granted.

4. Motion to Strike Various Other Exhibits in Plaintiffs' Response

Defendants' fourth motion to strike **[docket no. 120]** seeks to exclude exhibits H, I, J, L, M, N, O, Q, R, S, S-1, and T to plaintiffs' response in opposition to defendants' motion for summary judgment. Defendants argue that these exhibits are replete with hearsay, are not properly dated, signed, sworn, or verified and, therefore, are not admissible hearsay.

Exhibits H, I, J are pre-2002 studies on mesh erosion to which Dr. Hyman refers in his affidavit. Defendants say they are hearsay. Plaintiffs reply that they are not hearsay under Federal Rule of Evidence 803(18) which lists learned treatises as a hearsay exception.

Rule 803(18) states that statements contained in published medical treatises are not hearsay when relied upon by an expert witness and established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. Since Dr. Hyman's affidavit has been stricken, and since Dr. Hyman is the only expert to even mention these studies, the studies are stricken and will not be considered by this court on summary judgment.

Exhibits L-O are copies of medical records, including photographs, associated with plaintiff's mesh removal procedure. Exhibits M, N, and O state "[t]his is a preliminary report until authenticated by a physician," and all of the exhibits – L, M, N and O – have a signature line for the purported author but are unsigned. The plaintiffs' exhibits are not competent summary judgment evidence because the plaintiffs' medical records are not authenticated by an affidavit or other means. *See Alleman v. Louisiana*, 698 F. Supp. 2d 644, 667 (M.D. La. 2010) (medical records offered by plaintiff to show that she received medical treatment because of the actions of the defendant are not competent summary judgment evidence because the medical records are not authenticated by an affidavit or other means).

Exhibit Q is composed of photographs of plaintiff, some showing her lying in a hospital bed and some showing her standing in a room at what appears to be a house. Plaintiffs have neither authenticated nor explained the relevance of these photographs. They are stricken.

Exhibit R is a list of entries from the Food and Drug Administration's ("FDA") Medical Device Databases. Exhibit S is an article from the FDA website about the dangers of Mersilene mesh. Information "retrieved from government websites… has been treated as self-authenticating, subject only to proof that the webpage does exist at the governmental web location." *Schaghticoke Tribal Nation v. Kempthorne*, 587 F. Supp. 2d 389, 397 (D. Conn. 2008) (citing 2 McCormick On Evid. § 227 (6th ed. 2006)). Plaintiff may rely on these items in support of their summary judgment response.

Exhibit S-1 is a series of emails. In the first an employee of plaintiffs' counsel

requests more information about an FDA article concerning complications with the use of mesh, and the FDA employee replies with a link to adverse reports received by the FDA. The email correspondence has not been properly authenticated. This exhibit is stricken.

"E-mails (like letters and other documents) must be properly authenticated or shown to be self-authenticating." *Recursion Software, Inc. v. Interactive Intelligence*, Inc., 425 F. Supp. 2d 756, 772 (N.D. Tex. 2006). Electronic communications or "[e]-mails can be authenticated by their authorship. . . . [Also,] [a]dditional data such as the address that an e-mail bears, the use of the "reply" function to generate the address of the original sender, the content of the information included in the e-mail and other circumstances can suffice." Kenneth S. Broun, McCormick on Evidence, § 227 (6th ed. 2006) (footnote omitted).

There appears to be no question that the e-mail messages are authentic. The defendants neither question the authenticity nor identify the portions of the emails that would constitute hearsay. Accordingly, the court will consider the e-mails on this motion for summary judgment.

Exhibit T is a 2008 study on mersilene mesh erosion. This study has not been relied upon by any expert. This study is stricken.

For the foregoing reasons, defendants' motion to strike the abovementioned exhibits **[docket no. 118]** is granted in part and denied in part.

B. Motion for Summary Judgment

1. Standard

Federal Rule of Civil Procedure 56 states in pertinent part:

> (a) Motion for Summary Judgment or Partial Summary Judgment. A party may move for summary judgment, identifying each claim or defense - or the part of each claim or defense--on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.
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> . . . .
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> (c) Procedures.
> (1) Supporting Factual Positions. A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:
> (A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or
> (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

The party moving for summary judgment bears the initial responsibility of informing the district court of the basis for its motion and identifying those portions of the record it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). The non-moving party must then go beyond the pleadings and designate "specific facts showing that there is a genuine issue for trial." *Id.* at 324. Conclusory allegations, speculation, unsubstantiated assertions, and legalistic arguments are not an adequate substitute for specific facts showing a genuine issue for trial. *TIG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002); *Little v. Liquid Air Corp.*, 37 F.3d

1069, 1075 (5th Cir. 1994) (en banc). In reviewing the evidence, factual controversies are to be resolved in favor of the nonmovant, "but only when . . . both parties have submitted evidence of contradictory facts." *Liquid Air,* 37 F.3d at 1075. When such contradictory facts exist, the court may "not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000).

2. Inadequate Warning Argument

All of plaintiffs' claims – negligence, strict liability and breach of warranty – concern the failure to warn of risks associated with use of Mersilene mesh; therefore, all of the claims merge into one inquiry: the adequacy of the Mersilene mesh warnings. Under principles of strict liability, defendants' product is "unreasonably dangerous" if not accompanied by adequate warnings. Similarly, under negligence principles, the reasonableness of defendants' conduct in this case also depends upon the adequacy of their warning. The breach of warranty claims are contingent on the implied and express representations defendants made about risks of the product in the warning.

If the warnings defendants provided to health care practitioners through the package insert were adequate, then the product was not unreasonably dangerous, and defendants' conduct was neither unreasonable nor negligent. *See Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464, 467 (5th Cir. 1987). Plaintiffs' allegations of negligence and strict liability both require proof of a causal connection between the defective product and the plaintiffs' injuries. *Liquid Air*, 37 F.3d at 1076 (citing *Daniels v. GNB, Inc.*, 629 So. 2d 595, 600 (Miss. 1993)(strict liability); *Ford Motor Co. v.*

Matthews, 291 So. 2d 169 (Miss. 1974)(negligence)). Because the instant summary judgment analysis focuses on this common element of causation, this court will consider all of plaintiffs' claims simultaneously. *Liquid Air*, 37 F.3d at 1076 (citing *Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464, 467 & n.3 (5th Cir. 1987)).

Defendants argue that plaintiffs' claims fail as a matter of law under the learned intermediary doctrine. The learned intermediary doctrine is codified in the Mississippi Products Liability Act ("MPLA"). Mississippi Code Annotated § 11-1-63(c)(ii) states:

> An adequate product warning or instruction is one. . . in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

See Wyeth Laboratories, Inc. v. Fortenberry, 530 So. 2d 688 (Miss. 1988) (holding that the manufacturer had a duty to warn the prescribing physician as the learned intermediary, and not the patient himself, of any known adverse side effects that might result from the use of its prescription drugs). The defendants *sub judice* argue that under the learned intermediary doctrine, Ethicon's duty was to warn Dr. Barksdale through the package insert, and that the undisputed evidence demonstrates that Ethicon properly discharged that duty.

Under Mississippi law, in a medical device failure to warn case, the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff. *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992). To satisfy the burden of establishing warning causation, a plaintiff may introduce either objective evidence of how a reasonable physician would have

responded to an adequate warning, or subjective evidence of how the treating physician would have responded. *Id.* Mississippi law requires a manufacturer to give a reasonable warning. *Id.* at 815. To be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product. *Id.* at 815.

The failure to warn of a known risk entitles the plaintiff to a rebuttable presumption that the learned intermediary would have read and heeded a proper warning. *Id.* at 814. But "heed" in this context means only that the learned intermediary would have incorporated the "additional" risk into his decisional calculus. *Id.* The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff. *Id.*

In summary, in a failure to warn case involving a medical device, Mississippi law requires a plaintiff to establish that an adequate warning would have prevented the plaintiff's injury. *Id.* To establish that element, at trial, the plaintiff must establish, by the preponderance of the evidence, both: (1) that an adequate warning would have prevented the treating physician from using the device; and (2) that the injury would not have occurred had the device not been used. *Id.* This court’s analysis here touches solely on the first prong.

In order to survive summary judgment, plaintiffs must establish a genuine issue of material fact as to whether an adequate warning would have convinced Dr. Barksdale not to provide an abdominal sacrocolpopexy with Mersilene mesh as an

option for Smith. Plaintiffs contend that had Dr. Barksdale been privy to proper information concerning the Mersilene mesh before April 1, 2002, that he would either have proceeded differently, i.e., not utilized the mesh and/or recommended the surgery, or that he would have provided relevant and meaningful information to the plaintiff that would have dissuaded her from choosing to undergo the surgery in light of the greater incidences of mesh erosion with defendants' product and the problems being encountered in using the mesh for urogynecologic surgery. Plaintiffs argue that despite the package insert suggesting that no significant adverse reactions had been reported, mesh erosion was a recognized complication associated with abdominal sacrocopoplexy. Plaintiffs assert that had the warning included that information, Dr. Barksdale would still have advocated the abdominal sacrocolpopexy because of the misinformation contained in the "Adverse Reactions" section.

The "Adverse Reactions" section of the package insert provides:

> No significant adverse clinical reactions to Mersilene mesh have been reported. The use of nonabsorbable Mersilene mesh in a wound that is contaminated or infected could lead to fistula formation and/or extrusion of the mesh.

Defendants agree that the "Adverse Reactions" section of the package insert misrepresented the fact that no significant adverse reactions were known at the time of Smith's surgery. This mistake here is harmless, say defendants. Dr. Barksdale testified that he remembered seeing the above statement in the "Adverse Reactions" section declaring that no significant adverse clinical reactions to Mersilene mesh had been reported, and that he did not agree with it, explaining that he knew of adverse events, namely "issues of extrusion, et cetera." Dr. Barksdale also testified that he

would categorize erosion as an adverse clinical reaction. (Barksdale deposition, pp. 82-84). Dr. Barksdale also testified that while he continued to use synthetic materials to correct a prolapse, such as the plaintiff's, some time subsequent to Smith's surgery, he had discontinued use of Mersilene mesh because of adverse events that he had experienced with Mersilene mesh. (deposition, pp.81-82). Plaintiffs argue that the fact that Dr. Barksdale eventually discontinued use of Mersilene mesh due to adverse reactions suggests that he would not have used it during Smith's procedure had the warning apprised him that erosion was an adverse reaction.

This is not so. Most telling is Dr. Barksdale's testimony that he understood the warnings in the package insert and that they adequately informed him of the risks and benefits of using Mersilene mesh. (deposition, pp.72-73). Defense counsel asked Dr. Barksdale if in April 2002 Mersilene mesh was an appropriate product to use in the treatment of Mrs. Smith's vaginal vault prolapse. Dr. Barksdale replied affirmatively. Defense counsel asked if Dr. Barksdale continued to hold that opinion on the date of the deposition, and Dr. Barksdale again replied affirmatively. (deposition, pp.77-78). Defense counsel asked Dr. Barksdale if he was abreast of the current medical literature when he used the Mersilene mesh in April 2002, and if Mersilene mesh was the best synthetic mesh product to use for Mrs. Smith. Dr. Barksdale replied in the affirmative to both questions. (deposition, p.97).

Defendants direct the court to Dr. Barksdale's testimony concerning the "Contraindications" section. The "Contraindications" section of the package insert states:

> Mersilene polyester fiber mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

[docket no. 111-12]. Dr. Barskdale testified that he understood that section as a much stronger warning than the "Adverse Reactions" section and that he considered the Contraindications section applicable in this case because an open vaginal cavity is a contaminated wound of the type that the insert warns may incur subsequent infection requiring mesh removal. (Barskdale deposition, pp.96-99).

From his deposition testimony, one immediately sees that there is no question that Dr. Barksdale was aware that mesh erosion was a known adverse reaction and considered that before he prescribed the procedure for Smith. The record also demonstrates he was aware of what he considered a stronger warning, i.e., that infection might occur. Having considering all those possibilities, Dr. Barksdale testified that Mersilene mesh was in his opinion the best option for Smith in 2002.

Plaintiffs submit data in an attempt to show that Dr. Barksdale was unaware of how high the risk of erosion was and that had he known that risk he would not have recommended the use of Mersilene mesh. Plaintiffs have submitted an October 21, 2008, article from the FDA website titled "Information on Surgical Mesh for Pelvic Organ Prolapse." The article states that:

> [the] FDA has received reports of complications associated with the placement of mesh through an incision made in the wall of the vagina. Although rare, these complications can have serious consequences. The reports have not been linked to a single brand or model of mesh.
>
> The most frequent complications included erosion through the vagina, infection, pain, urinary problems and recurrence of the prolapse and/or incontinence.

While the article states that erosion, like the other listed complications, happens most frequently, it precedes that statement by noting that all of the complications associated with mesh placement are rare. Plaintiffs have also submitted eight adverse event reports submitted prior to 2002 from an FDA database listing serious injuries incurred in association with Mersilene mesh placement. Three of those reports are associated with tears of the mesh. Dr. Barksdale testified that in his own experience of mesh placement, he had between three and six patients other than Smith to experience erosion. So, these reports provide no evidence that had Dr. Barksdale known of these adverse event reports, he would not have chosen to use Mersilene mesh in Smith's procedure.

The failure to warn is a producing cause of the injury if the alleged inadequacy caused the doctor to prescribe the drug for the patient." *Ebel v. Eli Lilly & Co*, 321 Fed. Appx. 350, 356 (5th Cir. 2009) (citations omitted) (internal quotation marks omitted). "If, however, the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury and the plaintiff's recovery must be denied." *Id.* (citations omitted) (internal quotation marks omitted). "Even if the physician is not aware of a risk, the plaintiff must show that proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product." *Id.* (internal quotation marks omitted). Clearly, Dr. Barksdale was aware of the risk of erosion, considered it, decided to recommend use of the product despite the risks and warned Smith of the risk of erosion.

As the moving party, defendants bore the initial burden of "informing the district court of the basis for its motion, and identifying the portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which [they believe] demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986) (quotation marks omitted). By submitting Dr. Barksdale's testimony with his conclusion that the warnings in the Mersilene mesh product insert adequately advised him of the risks and benefits of the product, defendants satisfactorily met their preliminary burden of establishing the absence of a fact issue.

The burden then shifted to plaintiffs to "go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial." *Liquid Air*, 37 F.3d at 1075. Plaintiffs have presented no evidence to suggest that Dr. Barksdale was unaware of the risks engendered by the use of Mersilene mesh at the time he recommended the procedure or that an alternative warning would have changed Dr. Barksdale's decision to use the product. The evidence before the court demonstrates that Dr. Barksdale was aware of the risk of Mersilene mesh erosion and that he communicated these risks to Smith. Dr. Barksdale did not indicate that had he been made aware of additional information regarding the product his risk-benefit analysis of whether to use Mersilene mesh would have changed. Plaintiffs bear the burden of establishing that the allegedly inadequate warning was the producing cause of the harm. Plaintiffs have failed to do so in that they have offered no admissible evidence to show that the mention of mesh erosion as a complication in the product insert would

have changed Dr. Barksdale's course of treatment with Mersilene mesh. As such, this court grants summary judgment.

3. Outstanding Discovery Argument

Plaintiffs contend that defendants' motion for summary judgment is premature in that defendants have not cooperated with their discovery requests; thus, they have not had the opportunity to make full discovery on pertinent issues. Rule 56(d) provides:

> (d) When Facts Are Unavailable to the Nonmovant. If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
> (1) defer considering the motion or deny it;
> (2) allow time to obtain affidavits or declarations or to take discovery; or
> (3) issue any other appropriate order.

Plaintiffs' argument is not well taken. Plaintiffs have generally asserted that additional documents would allow them to show that the warning defendants provided was inadequate. Plaintiffs have not indicated what specific information they seek or how the materials they seek would create a genuine issue of material fact in light of the evidence before the court. This court finds the issues raised on summary judgment ripe for review and the evidence presented sufficient to make a determination. Accordingly, the court has ruled as abovementioned.

C. Motion for Review of Magistrate Judge Order

Lastly, plaintiffs have filed a motion **[docket no. 145]** for review of two orders [docket no.s 139, 140] entered by the Magistrate Judge on March 16, 2010.[5] Under

[5]The first order [docket no. 139] denied defendants' motion to strike plaintiffs' purported designation of expert witnesses [docket no. 58]; granted plaintiffs' motion to extend time to serve expert reports [docket no. 77]; and granted in part plaintiffs' motion for extension of discovery [docket no. 122]. The second order [docket no. 140] granted defendants' motion to stay 30(b)(6) deposition [docket no. 86]; granted defendants' motion to strike first requests for

Federal Rule of Civil Procedure 72(a),[6] a district judge has the authority to review a magistrate judge's order. If the contents of the order are found to be clearly erroneous or contrary to the law, the order may be modified or set aside. *Buie v. Epps*, 271 F. Supp. 2d 922, 923 (S.D. Miss. 2003). This court finds nothing clearly erroneous or contrary to the law in the Magistrate Judge's two March 16, 2010 orders.

III. Conclusion

For the foregoing reasons, the court rules as follows. As for defendants' first three motions to strike, this court GRANTS: the motion to strike the affidavit of Dr. Hyman **[docket no. 114]**; the motion to strike expert reports attached to plaintiffs' response **[docket no. 117]**; and the motion to strike the affidavit of Dr. Hart **[docket no. 118]**. This court GRANTS IN PART AND DENIES IN PART defendants' fourth motion, seeking to strike various other exhibits attached to plaintiffs' response **[docket no. 120]**. This court GRANTS defendants' motion for summary judgment **[docket no. 93]**.

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admission [docket no. 124]; and denied plaintiffs' motion to strike defendants' motions [docket no. 130].

[6]Rule 72(a) states:

> When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge to hear and decide, the magistrate judge must promptly conduct the required proceedings and, when appropriate, issue a written order stating the decision. A party may serve and file objections to the order within 14 days after being served with a copy. A party may not assign as error a defect in the order not timely objected to. The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.

This court DENIES plaintiffs' motion to designate Dr. Hyman as an expert **[docket no. 141]** and motion for review of the Magistrate Judge's two March 16, 2010, orders **[docket no. 145]**.

No issues remain for this court to consider. This court will enter a final judgment in accordance with the local rules.

SO ORDERED this the 31st day of August, 2011.

s/ HENRY T. WINGATE
UNITED STATES DISTRICT JUDGE

Civil Action No. 3:08cv245 HTW-LRA
Order Granting Motions to Strike Affidavit
Order Denying Motion for Discovery
Order Granting Motions to Strike Expert Reports
Order Granting in Part and Denying in Part Motion to Strike Exhibits
Order Granting Motion for Summary Judgment
Order Denying Motion for Review of Magistrate Judge Order