2014 WL 505234
Only the Westlaw citation is currently available.
United States District Court, S.D. West Virginia.

In re ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION.
This Document Relates to
Carolyn Lewis et al.
v.
Ethicon, Inc. et al.

MDL No. 2327.
|
Nos. 2:12–MD–02327, 2:12–cv–4301.
|
Feb. 5, 2014.

MEMORANDUM OPINION AND ORDER

(Motions in Limine)

JOSEPH R. GOODWIN, District Judge.

***1** Pending before the court are the Plaintiffs' Motions in Limine [Docket 206] and the Defendants' Omnibus Motion in Limine [Docket 207]. For the reasons stated below, the Plaintiffs' Motions in Limine [Docket 206] are **GRANTED in part** and **DENIED in part,** and the Defendants' Omnibus Motion in Limine [Docket 207] is **GRANTED in part** and **DENIED in part.**

I. Background

This case is one of over 40,000 assigned to me by the Judicial Panel on Multidistrict Litigation. It arises out of injuries allegedly sustained from the implantation of a pelvic mesh product, Ethicon's TVT, to treat stress urinary incontinence. [1] I have resolved the parties' motions for summary judgment, and the following claims remain for trial: strict liability for defective design, negligent design, and punitive damages. (*See* Mem. Op. & Order [Docket 194]). In the instant motions, the parties seek to limit or preclude arguments or evidence on various topics. The plaintiffs have filed seven motions in limine and Ethicon has filed twenty-two.

1 References to Ethicon refer both to the defendant Ethicon, Inc. and to the defendant Johnson & Johnson.

II. The Plaintiffs' Motions

—Motion in Limine No. 1: Motion to Exclude Statements Regarding the Number of Randomized Controlled Trials That Allegedly Support the Safety of the TVT and Similar Products

The plaintiffs move to preclude Ethicon from stating that a certain number of randomized controlled trials support the safety and efficacy of the TVT. (Pls.' Mot. in Limine ("Pls.' Mot.") [Docket 206], at 2). Ethicon's medical director, Piet Hinoul, "testified that as of November 2012, there were 104 randomized clinical trials supporting the safety and efficacy of TVT." (Resp. in Opp. to Pls.' Mots. in Limine ("Ethicon's Resp.") [Docket 220], at 2–3). The plaintiffs contend that this statement should be excluded under Federal Rule of Evidence 801 as inadmissible hearsay because it is testimony regarding the conclusions of studies. Hearsay is an out of court statement offered to prove the truth of the matter asserted. Fed.R.Evid. 801(c). To the extent that Dr. Hinoul testifies that Ethicon relied on these studies, the statement is not hearsay. Without knowing precisely how Ethicon intends to use this statement, the plaintiffs' motion is **DENIED without prejudice.**

—Motion in Limine No. 2: Motion to Exclude TVT "Complication Rates"

The plaintiffs seek to preclude any argument or evidence regarding the TVT's complication rates. According to the plaintiffs, it is impossible for Ethicon to calculate complications accurately because they are unreported and because Ethicon does not know how many TVT devices have been implanted. (*See* Pls.' Mot. [Docket 206], at 5–6). Therefore, the plaintiffs argue that complication rates should be excluded under Rule 403 because they have little probative value and they are highly prejudicial. I agree in part. I will not admit anecdotal evidence of complication rates because that evidence has little probative value and it is highly misleading. However,

evidence of complication rates may be admitted where it is based on reliable, scientific statistics, peer-reviewed literature, or where it has been or may be tested. At this stage, I cannot determine which particular complication rate evidence Ethicon seeks to introduce. Accordingly, the plaintiffs' motion on this issue is **DENIED without prejudice.**

—Motion in Limine No. 3: Motion to Exclude Claims that Certain Alternatives to Surgical Mesh for SUI Treatment Are Not Taught, or Are Rarely Taught, in Medical Schools

***2** The plaintiffs move to bar Ethicon from asserting that the Burch procedure and other surgical alternatives for the treatment of stress urinary incontinence ("SUI") are not taught, or are rarely taught, at medical schools. The plaintiffs believe that these statements are purely speculative and are contradicted by the evidence. Ethicon has proffered witnesses, Dr. Jordan Mitchell and Dr. Brian Feagins, to testify from their personal knowledge that the Burch procedure is not taught, or is rarely taught, at medical schools. (See Ethicon's Resp. [Docket 220], at 5–6). Whether there are safer alternatives to the TVT is highly probative, and the prevalence of this procedure is relevant to whether it is a safer alternative to the TVT. The plaintiffs are free to cross-examine Ethicon's witnesses about the prevalence of alternative surgical procedures and how they came to their conclusions. Therefore, the plaintiffs' motion on this issue is **DENIED.**

—Motion in Limine No. 4: Motion to Exclude Statements by Physician Trade Associations or Organizations

The plaintiffs move to exclude any argument or evidence based on statements by physician trade associations or organizations pursuant to Rules 403 and 801. For instance, the American Urogynecologic Society ("AUGS") recently stated that the TVT "is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence" and "is safe and effective as a surgical implant." (AUGS Position Statement [Docket 206–13], at 1–2). First, to the extent that these statements are relied upon by expert witnesses, they are admissible under the learned treatise exception of Rule 803(18). Second, under Rule 703, experts are permitted to rely on otherwise inadmissible information provided that they "would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed.R.Evid. 703. Third, Ethicon's state of mind is relevant to the punitive damages claim, and "[a]n out-of-court statement that is offered to show its effect on the hearer's state of mind is not hearsay under Rule 801(c)." *United States v. Thompson,* 279 F.3d 1043, 1047 (D.C.Cir.2002). Provided that Ethicon properly introduces this evidence, the plaintiffs' motion on this issue is **DENIED.**

—Motion in Limine No. 5: Motion to Exclude Statements About Counsel

The plaintiffs assert that Ethicon may contend "that this lawsuit or the transvaginal mesh litigation is attorney-driven; that Ms. Lewis saw a television commercial regarding transvaginal mesh litigation before filing suit; or that Ms. Lewis's attorney gave her the name of the surgeon who ultimately performed a revision procedure on her." (Pls.' Mot. [Docket 206], at 14). The plaintiffs argue that these statements have no probative value and are unfairly prejudicial.

As to the first statement—that these lawsuits are "attorney-driven,"—Ethicon represents that it does not intend to mention the existence of other transvaginal mesh lawsuits. Accordingly, the plaintiffs' motion with respect to this statement is **GRANTED.**

***3** As to the second statement—that Ms. Lewis was prompted by a television commercial to file suit—this statement is probative of her credibility regarding her injuries. Accordingly, the plaintiffs' motion with respect to this statement is **DENIED.**

As to the third statement—that Ms. Lewis's attorney gave her the name of the surgeon who performed her revision surgery—Ethicon argues that this statement is probative of Dr. Zimmern's bias, implying that Dr. Zimmern relied on the plaintiffs' attorneys for referrals. But Ethicon does not proffer any evidence that Dr. Zimmern acted outside of the accepted standard of care. Therefore, any statements implying that Dr. Zimmern was biased are not probative of a fact of consequence and serve only to unfairly prejudice the plaintiffs. Accordingly, the plaintiffs' motion on this issue is **GRANTED.**

—Motion in Limine No. 6: Motion to Exclude References to TVT Being the "Gold Standard" or the "Standard of Care"

The plaintiffs argue that Ethicon should be prohibited from presenting evidence or argument that the TVT is the "gold standard" or "standard of care" for the treatment of SUI. The plaintiffs believe that these statements should be excluded under Rule 403 because they would confuse the jury, result in needless mini-trials, and would unduly prejudice the plaintiffs. I disagree. Whether the TVT is the "gold standard" or the "standard of care" is highly probative: it goes to the very essence of whether the TVT is unreasonably dangerous or whether there exists a safer alternative design. If the plaintiffs believe that terms like "gold standard" are imprecise and confusing, they may cross examine the witnesses. Similarly, if the plaintiffs believe Ethicon's experts have contradicted themselves on this issue, they are free to highlight those contradictions on cross examination. Accordingly, this motion in limine is **DENIED.**

—Motion in Limine No. 7: Motion to Exclude Evidence of an Extramarital Affair

The plaintiffs have dismissed their loss of consortium claim, and move to exclude evidence that Mr. Lewis had an extramarital affair approximately twelve years ago. Ethicon does not oppose this motion. Accordingly, this motion in limine is **GRANTED.**

III. Ethicon's Motions

—Motion in Limine No. 1: Motion to Exclude Evidence Relevant Only to Failure to Warn and Breach of Warranty

Ethicon seeks to preclude all evidence that is relevant only to the plaintiffs' dismissed claims—failure to warn and breach of warranty. Ethicon lists the following as representative of this type of evidence: "patient brochures and physician mailers, marketing plans, marketing research, and marketing overviews, professional education materials, sales training materials." (Defs.' Mem. in Supp. of Omnibus Mot. in Limine ("Defs.' Mem.") [Docket 208], at 5). Ethicon argues that I should exclude this evidence because it is irrelevant to the plaintiffs' remaining claims. The plaintiffs contend warning evidence, such as the TVT's instructions for use ("IFU"), is relevant to their strict liability-design defect claim, specifically, "whether 'suitable warnings or instructions' made the product safer." (Pls.' Resp. to Defs.' Mots. in Limine ("Pls.' Resp.") [Docket 221], at 3–4).

***4** In essence, this motion seeks to reaffirm Federal Rule of Evidence 402, which dictates that irrelevant evidence is inadmissible. Clearly, evidence only relevant to the plaintiffs' dismissed claims is irrelevant and must be excluded. I have already ruled that evidence related to the TVT's IFU and patient education brochures is not relevant to the plaintiffs' design defect claim. (*See* Mem. Op. & Order [Docket 246], at 11). The parties do not need this court to rule on or restate the obvious. Accordingly, this motion in limine is **DENIED without prejudice.**

—Motion in Limine No. 2: Motion to Exclude Evidence or Argument Concerning Unrelated Alleged "Bad Acts" and Investigations

Ethicon anticipates that the plaintiffs will introduce evidence of unrelated bad acts and investigations, such as

> (1) criminal guilty pleas and fines ... relating to the drug Topamax; (2) state attorney general actions ... relating to the over-the-counter drug Motrin and the multiple attorney general actions relating to the drug Risperdal; (3) consent decrees with the U.S. Department of Justice or FDA, such as that regarding various McNeil manufacturing plants; (4) settlements or fines with the U.S. Department of Justice or Securities and Exchange Commission, such as any settlement related to the drug Risperdal, the entity Omnicare, Inc., and overseas activities, including any reserves set aside for settlement payments; and (5) any investigations or proceedings by any political bodies or enforcement agencies, such as investigations related to the drug Doribax or the congressional

> investigation into the over-the-counter McNeil drugs.

(Defs.' Mem. [Docket 208], at 5 n. 2). I will not admit this evidence because it is clearly irrelevant. But some other "bad acts" evidence may be relevant to the punitive damages claim or the negligence claim. At this stage, without knowing the precise evidence at issue and how the parties intend to use it, I cannot rule on the admissibility of all "bad acts" evidence. However, the plaintiffs are cautioned to tread carefully when introducing this kind of evidence. Accordingly, Ethicon's motion on this issue is **DENIED without prejudice.**

—Motion in Limine No. 3: Motion to Exclude Evidence or Argument Regarding Duty to Test and Duty to Train Physicians

Ethicon anticipates that the plaintiffs will argue that Ethicon assumed and failed to discharge two duties: (1) the duty to further test the TVT and (2) the duty to train physicians. (Defs.' Mem. [Docket 208], at 7). Ethicon argues that such evidence and argument is irrelevant and unduly prejudicial.

Although there is no failure to test claim, evidence that Ethicon failed to conduct particular tests may be relevant to the negligence claim. Under the negligence claim, whether Ethicon breached a duty to manufacture a safe product depends upon whether Ethicon "failed to do that which an ordinarily prudent [manufacturer] would have done in the exercise of ordinary care." *Dewayne Rogers Logging, Inc. v. Propac Indus.,* 299 S.W.3d 374, 385 (Tex.App.2009) (analyzing claims for negligent design, manufacture, and marketing). Accordingly, the plaintiffs may argue that Ethicon failed to act as an ordinarily prudent manufacture by failing to sufficiently test the TVT. Ethicon's motion with respect to argument or evidence of testing is **DENIED.**

***5** The analysis is different with respect to evidence or argument that Ethicon negligently trained physicians. Texas cases recognize the duty of drug and medical device manufacturers to warn physicians, not to provide training to them. *See Centocor, Inc. v. Hamilton,* 372 S.W.3d 140, 154 (Tex.2012); *Wyeth–Ayerst Labs. Co. v. Medrano,* 28 S.W.3d 87, 91 (Tex.App.2000). Further, there is no claim for negligent training in this case. However, whether evidence or argument relating to physician training is relevant for some other purpose depends on the context and method by which it is introduced. Accordingly, Ethicon's motion with respect to argument and evidence of negligent training is **DENIED without prejudice.**

—Motion in Limine No. 4: Motion to Exclude Medical Device Reports ("MDRs")

Ethicon seeks to preclude "all evidence relating to MDRs for TVT or any other product because the reports are hearsay, irrelevant, and the introduction of the reports would result in juror confusion, undue delay, and unfair prejudice." (Defs.' Mem. [Docket 208], at 10). MDRs are inadmissible to the extent that they are covered under 21 U.S.C. § 360i(b)(3). [2] However, there are MDRs that do not fall within the scope of § 360i and are therefore admissible. *See Chism v. Ethicon Endo–Surgery, Inc.,* No. 4:08CV00341–WRW, 2009 WL 3066679, at *1 (E.D.Ark. Sept.23, 2009) (finding that "no report made by a device user facility" may be admissible, but that " § 360i does not prohibit the admissibility of manufacturer reports into evidence"). As I have written, "there are simply too many factors that might determine whether product complaints ... and MDRs might be admissible." *In re C.R. Bard, Inc.,* MDL 2187, 2013 WL 3282926, at *6 (S.D.W.Va. June 27, 2013). Without knowing the contents of the specific MDRs at issue or how the parties intend to use them, I cannot make a ruling on their admissibility at this time. Accordingly, Ethicon's motion on this issue is **DENIED without prejudice.**

2 This section states:

> (3) No report made under paragraph (1) by—
> (A) a device user facility,
> (B) an individual who is employed by or otherwise formally affiliated with such a facility, or
> (C) a physician who is not required to make such a report, shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.
> 21 U.S.C. § 360i(b)(3).

—Motion in Limine No. 5: Motion to Exclude Evidence of Other Lawsuits Concerning Ethicon's Other Products, Including Lawsuits Over TVT, and Particularly Over Different Mesh Products Such as Prolift or TVT–Secur.
Ethicon seeks to bar evidence of other lawsuits concerning its mesh products. The plaintiffs contend that these lawsuits are evidence of Ethicon's knowledge of the defectiveness of the TVT and similar products. "When evidence of other accidents or occurrences is offered for any purpose other than to show notice, the proponent of that evidence must show that the facts and circumstances of the other accidents or occurrences are 'closely similar' to the facts and circumstances at issue." *Johnson v. Ford Motor Co.,* 988 F.2d 573, 579 (5th Cir.1993); *see also Jackson v. Firestone Tire & Rubber Co.,* 788 F.2d 1070, 1082 (5th Cir.1986) ("Evidence of similar accidents occurring under substantially similar circumstances and involving substantially similar components may be probative of defective design.").

***6** But even though evidence of similar accidents may be admissible, evidence of lawsuits is generally considered inadmissible hearsay. *See Johnson,* 988 F.2d at 579 ("a brief summary of claims, lawsuits, and complaints ... amounts to nothing more than a summary of allegations by others which constitute hearsay"); *Roberts v. Harnischfeger Corp.,* 901 F.2d 42, 44–45 (5th Cir.1989) (affidavit summarizing copies of notices of pending litigation against the defendant properly excluded as hearsay); *Abu Dhabi Commercial Bank v. Morgan Stanley & Co. Inc.,* No. 08 CIV. 7508 SAS, 2013 WL 1155420, at *7 (S.D.N.Y. Mar.20, 2013) (excluding "[r]eferences to other lawsuits including their factual allegations and evidence").

Further, evidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. Although other lawsuits may ultimately show that the TVT is defective, the jury must still find that the TVT caused Ms. Lewis's injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to Ethicon. Accordingly, Ethicon's motion on this issue is **GRANTED.**

—Motion in Limine No. 6: Motion to Bar Plaintiffs from Implying that Ethicon Was Bound by Disclosure Standards that Did Not Exist
The plaintiffs seek to introduce "evidence of [Ethicon's] financial support for articles on which it, or its experts, rely" (Pls.' Resp. [Docket 221], at 13), and suggestions that "Ethicon itself had an obligation to disclose to the FDA, in the 510(k) premarket notification for TVT, a supposed conflict of interest in the research supporting it" (Defs.' Mem. [Docket 208], at 16). Ethicon contends that this evidence is irrelevant because no legal or journalistic standards required the disclosure of these particular financial conflicts of interest. I disagree. Regardless whether legal or ethical standards required the disclosure of these financial conflicts, the issue is whether an ordinarily prudent manufacturer would have relied on those allegedly financially conflicted studies or articles. That evidence is relevant to the negligence claim and punitive damages claim.

However, the plaintiffs may not suggest or assert that Ethicon's 510(k) applications were somehow incomplete or inadequate. Doing so would unfairly prejudice Ethicon because, in accordance with my prior rulings, Ethicon will not be able to respond that it complied with the FDA's 510(k) process. Accordingly, Ethicon's motion is **GRANTED** with respect to evidence, arguments, or suggestions that its 510(k) applications were inadequate, and is otherwise **DENIED.**

—Motion in Limine No. 7: Motion to Bar Plaintiffs from Making Speculative Allegations that Professor Ulmsten Was Paid for a Favorable Result
Ethicon seeks to bar evidence that Professor Ulf Ivar Ulmsten, the inventor of the TVT, received "milestone payments" during the development of the TVT. Ethicon argues that the milestone payments merely enabled both Professor Ulmsten and Johnson & Johnson to share in the risks and rewards of developing and marketing the TVT. (*See* Defs.' Mem. [Docket 208], at 18). Ethicon accordingly seeks, under Rule 403, to "bar any testimony that the contract means Ulmsten was paid for a favorable result" when he provided data on the TVT to Johnson & Johnson. (*See id.*).

***7** The plaintiffs argue that "[t]he Ulmsten study was one of only three studies submitted with the TVT's application for 510(k) clearance, and Rick Isenberg, Ethicon's former medical director, described the Ulmsten studies as the 'cornerstone' of Ethicon's marketing program regarding the safety and efficacy of the TVT." (Pls.' Resp. [Docket 221], at 15). Therefore, evidence about Professor Ulmsten's financial interest is probative of the negligence and punitive damages claim and is not unduly prejudicial. Accordingly, Ethicon's motion on this issue is **DENIED.**

—Motion in Limine No. 8: Motion to Bar Plaintiffs from Submitting Evidence of the FDA's 483 Actions that Preceded the Hiring of Meng Chen as the Medical Director for Postmarket Surveillance

Ethicon anticipates that the plaintiffs will introduce an FDA "Form 483" letter that advised Ethicon that "there is no documentation to show that a determination of whether the device failed to meet specifications was conducted for MDR reportable complaints, including death and serious injury events." (FDA Letter [Docket 207–1], at 118). Ethicon believes that plaintiffs will use this letter to show that Ethicon did not have a physician on staff to handle postmarket surveillance. Ethicon argues that this evidence is irrelevant because Ethicon subsequently hired Dr. Meng Chen in 2006 to oversee postmarket surveillance, three years before Ms. Lewis's implantation. I disagree. Whether Ethicon monitored the TVT's safety and effectiveness while it was on the market, before Ms. Lewis received her implant, may be relevant to the negligence and punitive damages claims. However, although the plaintiffs may offer evidence that Ethicon failed to conduct postmarket surveillance, they may not mention the FDA or FDA enforcement actions in any way, as that would unfairly prejudice Ethicon. Accordingly, Ethicon's motion on this issue is **GRANTED.**

—Motion in Limine No. 9: Motion to Preclude Plaintiffs from Questioning Witnesses About Documents for Which No Foundation Has Been Laid With That Witness

Ethicon claims that during discovery, the plaintiffs continually asked witnesses questions about documents they had never seen and/or for which no foundation was laid. Because this line of questioning was so pervasive, Ethicon seeks a preemptive ruling preventing the plaintiff from continuing this practice during trial.

As Ethicon acknowledges, individual objections at trial are preferred over blanket exclusions of evidence before trial. I presume that Ethicon's counsel is familiar with the Federal Rules of Evidence. If Ethicon believes that the plaintiffs' counsel is improperly questioning witnesses about documents, it may object at trial. Accordingly, this motion in limine is **DENIED without prejudice.**

—Motion in Limine No. 10: Motion to Preclude Plaintiffs from Referring to the Designation of Documents as Confidential for Purposes of Discovery

During discovery, the parties entered into a protective order which permitted the parties to designate documents as confidential. Ethicon moves to preclude the plaintiffs from referring to a document's confidential status. Ethicon argues that whether it designated a document as confidential is irrelevant to the issues in this case. In addition, Ethicon contends the probative value of suggesting it had an illicit purpose for keeping documents confidential is outweighed by the danger of unfair prejudice and confusing the issues. I agree with Ethicon. Whether a party designates a document as confidential during the litigation process is absolutely irrelevant. Accordingly, Ethicon's motion in limine on this matter is **GRANTED** with respect to documents that were designated as confidential during discovery.

—Motion in Limine No. 11: Motion to Preclude Plaintiffs from Referring to Irrelevant and Off–Color Emails

***8** Ethicon seeks to exclude emails that contain "rude jokes and off-color humor as well as sexual innuendo and content." (Defs.' Mem. [Docket 208], at 25). The parties each provide an email chain they believe is representative of these "off-color" emails. Ethicon attaches an email where Ethicon physicians discussed whether Ethicon should maintain a Prolift registry or provide the information to physicians in a CD–Rom. (*See generally* Defs.' Mot. Ex. J, Email Chain Between Piet Hinoul and Aaron Kirkemo [Docket 207–2], at 67–69; Ex. K, Kirkemo Dep. [Docket 207–2]; Ex. L., Hinoul Dep. [Docket 207–2]). In the email chain, a physician commented that if physicians were not provided a CD–

Rom, "then they [could] not use it as a pessary when the mesh fails." (Ex. J, Email Chain Between Piet Hinoul and Aaron Kirkemo [Docket 207–2], at 67).

The plaintiffs direct the court to an email chain discussing a complaint Ethicon received wherein a woman reported that the TVT product had eroded into her vaginal wall, prompting her husband to state that "sex felt like screwing a wire brush[.]" (Pls.' Resp. Ex. L, Email Chain Between Terry Courtney and Martin Weisberg [Docket 221–12], at 4). Dr. Weisberg, Ethicon's Director of Medical Affairs, responded that the situation "[s]ounds like a buttonhole. It can be locally excised. I've never tried the wire brush thing so I won't comment." (*Id.* at 1).

Ethicon claims these emails are excludable as irrelevant, unfairly prejudicial, and inadmissible hearsay. The plaintiffs counter that these emails are relevant to their claim for punitive damages. In addition, the plaintiffs contend that the emails are not hearsay because they will be offering these statements not for their truth, but to establish that the defendants acted with a wanton and willful disregard to the consumers who could be foreseeably injured by their products.

Under New Jersey law, a plaintiff is entitled to punitive damages if she can prove "by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J. Stat. Ann. § 2A:15–5.12(a). While the statements in these emails show that Ethicon may have acted in bad taste, they do not tend to show that the defendants were aware of an unnecessary risk and acted with actual malice or wanton wilful disregard of that risk. Accordingly, Ethicon's motion in limine on this matter is **GRANTED** with respect to these two emails, but is **DENIED without prejudice** otherwise.

—Motion in Limine No. 12: Motion to Prohibit the Parties from Using Deposition Videos or Testimony in Opening Statements

Ethicon moves to preclude the playing or reading of recorded deposition testimony during opening statements. I ruled on this issue in the C.R. Bard litigation: "the use of video clips during opening statements is precluded as to all parties, but I will not preclude the parties from summarizing or quoting deposition testimony in their opening statements." *In re C.R. Bard, Inc.,* 2013 WL 3282926, at *8 (S.D.W.Va. June 27, 2013). I **ADOPT** that ruling here. Accordingly, Ethicon's motion is **GRANTED** with respect to the use of video clips during opening statements, and **DENIED** otherwise.

—Motion in Limine No. 13: Motion to Exclude Heniford DVD Concerning Kugel Composix Hernia Mesh

***9** Ethicon seeks to exclude a video featuring Dr. Todd Heniford entitled "The Benefits of Lightweight Meshes in Ventral Hernia Repair." According to Ethicon, "[t]his video features the Kugel Composix hernia mesh, manufactured by C.R. Bard, Inc." (Defs.' Mem. [Docket 208], at 28). Dr. Heniford "discusses certain attributes of 'heavyweight' hernia meshes, along with the historical use of polypropylene mesh in hernia repair and the development of lighter-weight meshes for use in the abdomen." *Id.*

A review of the video reveals that, in addition to discussing mesh in a hernia application, Dr. Heniford also discusses the general benefits of using lightweight versus heavyweight mesh. (Exhibit FF [Docket 34], at 2:23–5:07, 6:16–6:26, 6:43–7:12, 7:40–8:27). During this general discussion, Dr. Heniford notes that lightweight polypropylene mesh, which has a larger pore size than heavyweight mesh, "allows for better tissue ingrowth" and "improved vascularization of the mesh." (*Id.* 6:43–7:12). While the plaintiffs might use these statements to impeach Dr. Heniford's current views regarding Ethicon's product, Ethicon states in its memorandum "that Dr. Heniford was withdrawn as a testifying expert in this matter on December 11, 2013." (Defs.' Mem. [Docket 208], at 29 n. 10). Accordingly, Ethicon's motion on this issue is **GRANTED.** If Dr. Heniford does testify at trial, I will revisit this issue at that time.

—Motion in Limine No. 14: Motion to Exclude Evidence of Recall of the ProteGen Sling

Ethicon argues that the plaintiffs should not be permitted to introduce evidence or argument of the Boston Scientific

recall of their ProteGen device, which served as a substantially equivalent device for the TVT in its 510(k) application. In their response, the plaintiffs state that they do not intend to present this evidence in their case-in-chief but will present it "[i]f Ethicon were to inject evidence relating to its Prolene suture or hernia mesh material." (Pls.' Resp. [Docket 221], at 27).

As I have previously found, "[t]he 510(k) process is not a safety statute or administrative regulation." (Mem. Order & Op. (Mot. in Limine No. 1, Summ. J. Mot. on 510(k) Issue) [Docket 196], at 9). The 510(k) process is about equivalence, not safety. While 510(k) approval may mean the ProteGen was "substantially similar" to the TVT, it did not mean the products were identical. A new device may be "substantially equivalent" even though its technology is very different from the predicate device. *See* 21 U.S.C. § 360c(1)(A).

Therefore, a recall of the ProteGen does not necessarily speak to the safety or efficacy the technology used in the TVT. As Ethicon points outs, it is possible Boston Scientific recalled the ProteGen due to key differences between the ProteGen and TVT. Therefore, Ethicon concludes that the recall of ProteGen is irrelevant in this case. Ultimately, admitting evidence of the ProteGen recall would necessitate discussing why the ProteGen and TVT are "substantially similar" under the 510(k) premarketing process. A discussion of the 510(k) process, whether in the context of the clearance of a new device or the recall of a predicate product, presents the danger of unfair prejudice and confusing the jury. Accordingly, Ethicon's motion in limine on this matter is **GRANTED.**

—Motion in Limine No. 15: Motion to Exclude Plaintiffs from Offering Certain MSDS Sheets, Including Any Suggestion That Polypropylene Causes or May Cause Cancer

***10** Ethicon requests that the court exclude all MSDSs from the trial and points to three particular material safety data sheets ("MSDS") that it contends should be excluded: (1) the Chevron Phillips MSDS for Marlex polypropylene mesh manufactured by C.R. Bard, Inc., (2) the Sunoco MSDS for C4001 polypropylene homopolymer, and (3) the Braskem MSDS. Each MSDS here applies to products other than the TVT or injuries other than the injuries Ms. Lewis has suffered. The Chevron Phillips MSDS was produced by C.R. Bard, Inc.'s polypropylene supplier, not Ethicon's supplier. The plaintiffs do not dispute that this language was not included on the MSDS produced by Ethicon's supplier. The Sunoco MSDS and Braskem MSDS relate to carcinogenicity, or whether polypropylene causes cancer. Ms. Lewis does not have cancer or allege any injuries related to an increased risk of cancer.

MSDSs from other companies' materials suppliers—such as the Chevron Phillips MSDS—are irrelevant to this case. Additionally, the risks discussed in the Sunoco and Braskem MSDSs are irrelevant to the plaintiffs' causes of action, as they relate to injuries that Ms. Lewis did not suffer. Therefore, this evidence should be excluded under Rule 403. However, Ethicon also asks this court to declare that all MSDSs should be excluded from this litigation. While the three MSDSs currently before the court should not be part of this litigation, it is possible that MSDSs from Ethicon's suppliers could be relevant. Ethicon's motion is therefore **GRANTED** as to the Chevron Phillips, Sunoco, and Braskem MSDSs and any MSDS not from an Ethicon supplier, but **DENIED** to the extent that Ethicon requests a ruling as to all MSDSs.

—Motion in Limine No. 16: Motion to Exclude Evidence of Payments to Consulting Physicians Who Are Not Witnesses In This Case

Ethicon argues that the plaintiffs should not be permitted to introduce evidence of payments to third party consultants because it is irrelevant and highly prejudicial. Ethicon does not go into detail regarding these payments or who they were made to, and describes the recipients as " 'key opinion leaders' who worked as consultants for Ethicon." (Defs.' Mem. [Docket 208], at 35–36). The plaintiffs argue that they anticipate Ethicon will introduce medical literature and statements made by physician trade associations or organizations, and that evidence of payments to the authors of those studies is relevant to show bias.

I agree with the plaintiffs. They have demonstrated that several authors of studies favorable to Ethicon were paid by Ethicon for their work. In one instance, the plaintiffs contend that Dr. Ulmsten and Ethicon agreed that Dr.

Ulmsten would receive $400,000 from Ethicon for every study of the TVT that did not report a significant number of complications. (*See* Pls.' Resp. [Docket 221], at 31; Pls.' Resp. Ex. J [Docket 221–10]). Evidence of Ethicon's payments to authors of favorable studies is relevant to the authors' potential bias. Therefore, Ethicon's motion to exclude this evidence is **DENIED.**

—Motion in Limine No. 17: Motion to Exclude Evidence of Successor SUI Mesh Products or Products Designed to Treat Pelvic Organ Prolapse

***11** Ethicon seeks to bar the plaintiffs from introducing evidence of successor products to the TVT because they were developed after the TVT or were designed to treat a different condition. The plaintiffs contend that evidence relating to these devices is relevant because they are substantially similar to the TVT and are linked to the same complications. The plaintiffs' primary argument is that the devices are all made of the same material, polypropylene, and the IFUs contain the same warnings. The bulk of the plaintiffs' arguments are related to the IFUs in the various products; however, the full scope of how the plaintiffs wish to use this evidence is unclear from the parties' briefing. It appears that Ethicon's motion has merit, as evidence relating to other devices is outside of the scope of the plaintiffs' design defect claim. However, this issue is better suited to be handled at trial, as evidence is presented. Therefore, Ethicon's motion to exclude evidence related to successor products is **DENIED without prejudice.**

—Motion in Limine No. 18: Motion to Exclude Evidence of the PA Consulting Group Report, "Investigating Mesh Erosion in Pelvic Floor Repair"

Ethicon argues that the PA Consulting Group report "Investigating Mesh Erosion in Pelvic Floor Repair" should be excluded as irrelevant. It argues that the report was created to aid in producing a new mesh product for the treatment of pelvic organ prolapse, not stress urinary incontinence. It also argues that the erosion rates used in the report are irrelevant because they are not related specifically to the TVT. The plaintiffs respond that the report is relevant because it "pertains to polypropylene mesh, generally, and its propensity to erode." (Pls.' Resp. [Docket 221], at 34).

Ethicon's arguments are misleading. While Ethicon argues that the report was written only to address issues related to pelvic organ prolapse, the report itself states that Ethicon asked PA Consulting Group "to conduct a broad analysis of the problem of mesh erosion[.]" (Pls.' Resp. Ex. GG [Docket 221–35], at 4). The report does not state anywhere that it was examining erosion only as it relates to pelvic organ prolapse; rather, it discusses mesh erosion generally, in line with the broad analysis requested by Ethicon. Although the overall purpose of the report may have been to aid Ethicon in developing a next-generation device for pelvic organ prolapse, its discussion of general mesh erosion is relevant to the plaintiffs' claims. It also contains erosion rates of mesh, which have probative value. Therefore, Ethicon's motion to exclude the report is **DENIED.**

—Motion in Limine No. 19: Motion to Exclude Evidence of Any Alleged Complications Associated with the Device Other Than Those Alleged by Ms. Lewis, Such as Cancer, Death, and Urinary Retention

Ethicon seeks to preclude the plaintiffs from presenting "evidence or argument that the TVT can cause adverse reactions or events other than those alleged by Ms. Lewis because evidence of potential adverse reactions other than those alleged here is irrelevant to the case and would serve only to confuse and inflame the jury." (Defs.' Mem. [Docket 208], at 40). In Texas, a plaintiff in a design defect case must prove, among other things, that the defect was the "producing cause" of the plaintiff's injury. *See Timpte Indus., Inc. v. Gish,* 286 S.W.3d 306, 311 (Tex.2009). Therefore, evidence that the TVT causes injuries not experienced by Ms. Lewis is not probative of the design defect claim. Ethicon's motion on this issue is **GRANTED.**

—Motion in Limine No. 20: Motion to Exclude Evidence of Medical Expenses Other than Those Paid by Plaintiffs

***12** Ethicon argues that the plaintiffs should be barred from introducing evidence of medical bills other than those paid by the plaintiffs. To the extent that Ethicon seeks to prevent the plaintiffs from introducing evidence of the full list price of medical services, rather than the adjusted charges actually billed to Ms. Lewis, the plaintiffs do not oppose this motion. The plaintiffs only oppose the motion to the extent that it seeks to prevent the plaintiffs

from presenting evidence of the adjusted charges Ms. Lewis was actually billed. The extent to which Ethicon seeks to exclude evidence of medical expenses is unclear from its motion.

Texas Civil Practices and Remedies Code Section 41.0105 provides that "recovery of medical or health care expenses incurred is limited to the amount actually paid or incurred by or on behalf of the claimant." The Supreme Court of Texas has stated that this provision "limits recovery, and consequently the evidence at trial, to expenses that the provider has a legal right to be paid." *Haygood v. De Escabedo,* 356 S.W.3d 390, 391 (Tex.2011). " '[A]ctually paid and incurred' means expenses that have been or will be paid, and excludes the difference between such amount and charges the service provider bills but has no right to be paid." *Id.* at 397. Thus, "section 41.0105 limits a claimant's recovery of medical expenses to those which have been or must be paid by or for the claimant." *Id.* at 398. The plaintiffs therefore must present evidence of the adjusted price of medical expenses negotiated by insurance companies or Medicare, not the full list price of the procedures. *See id.; Prabhakar v. Fritzgerald,* No. 05–10–00126–CV, 2012 Tex.App. LEXIS 7154, at *38, 2012 WL 3667400 (Tex.App. Aug. 24, 2012). Ethicon's motion is therefore **GRANTED** to the extent that it seeks to bar admission of evidence related to expenses not incurred by the plaintiffs and **DENIED** to the extent that it seeks to bar admission of evidence related to the costs billed to the plaintiffs.

—Motion in Limine No. 21: Motion to Exclude Any Reference to the Recent Chemical Spill or Water Contamination in West Virginia, Or Any Other Improper Appeal to the Jurors' Personal Interests

Ethicon asks that I prohibit the parties from referencing the recent West Virginia chemical spill that fouled this region's water supply. The plaintiffs do not oppose this motion. Therefore, Ethicon's motion in limine on this issue is **GRANTED.**

—Motion in Limine No. 22: Motion to Exclude as Hearsay the Plaintiffs' Testimony that Dr. Zimmern Called the Mesh a "Ticking Time Bomb"

Ethicon seeks to exclude a statement made by Dr. Zimmern, the physician who performed Ms. Lewis's mesh removal surgery. In their depositions, Mr. and Mrs. Lewis testified that Dr. Zimmern referred to the mesh as a "ticking time bomb." The defendants argue that this is classic hearsay under Federal Rule of Evidence 801 because it is an out-of-court statement offered for the truth of the matter asserted—that the mesh is dangerous. The plaintiffs contend that the statement falls under the present sense impression exception to hearsay under Rule 803(1).

***13** Rule 803(1) provides that "[a] statement describing or explaining an event or condition, made while or immediately after the declarant perceived it" is an exception to the hearsay rule. The attached excerpts of Mr. and Ms. Lewis's depositions do not make it clear whether Dr. Zimmern was speaking about Ms. Lewis's mesh specifically, or all mesh generally. If Dr. Zimmern was speaking specifically about the mesh he had just removed from Ms. Lewis, the statement may be admissible as a present sense impression. However, if Dr. Zimmern was speaking generally about all mesh, the statement is hearsay. Because the record does not make clear what Dr. Zimmern was referring to, Ethicon's motion is **DENIED without prejudice.**

IV. Conclusion

For the reasons discussed above, the Plaintiffs' Motions in Limine [Docket 206] are **GRANTED in part** and **DENIED in part,** and the Defendants' Omnibus Motion in Limine [Docket 207] is **GRANTED in part** and **DENIED in part.**

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

All Citations

Slip Copy, 2014 WL 505234

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