IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

CAROLYN M. KIEFFABER,	)	
	)	
	)	
Plaintiff,	)	**CIVIL ACTION**
	)	
v.	)	**No. 20-1177-KHV**
	)	
ETHICON, INC. and	)	
JOHNSON & JOHNSON,	)	
	)	
	)	
Defendants.	)	
	)	

MEMORANDUM AND ORDER

This matter comes before the Court on Defendants' Motion In Limine No. 2 To Exclude Certain Irrelevant And Unfairly Prejudicial Company Documents (Exhibit B, Attachment 2 to Defendants' Omnibus Motions In Limine (Doc. #206)) filed March 8, 2021.[1]

Defendants seek to exclude "three irrelevant company emails" because they are irrelevant and inadmissible hearsay, and their admission would result in unfair prejudice, juror confusion and undue delay. Plaintiff has no objection as it relates to two of those documents. Plaintiff will not seek to introduce into evidence (1) Exhibit 1, an email string between Terry Courtney and Martin Weisberg where, in the course of a discussion regarding a woman's complaint about the erosion of a TVT product and her husband's remark that "sex felt like screwing a wire brush," Dr. Weisberg made the comment that the situation "[s]ounds like a buttonhole. It can be locally

[1] To expedite a ruling on this motion, the Court is communicating the reasons for its decision without attempting to draft a legal treatise or cite relevant case law. The law in this area is clear and the Court has taken into account the authorities which are cited in the parties' briefs, along with other authorities. If necessary for future proceedings, the Court may supplement this order with additional findings of fact or legal citations.

excised. I've never tried the wire brush thing so I won't comment;" or (2) Exhibit 6, a 2009 email string between Dr. Piet Hinoul and Dr. Aaron Kirkemo where, in the course of a discussion about a CD-ROM and the creation of a Prolift registry, Dr. Hinoul makes a comment that if the CD-ROM is not provided to doctors, "then they cannot use the CD-ROM as a pessary when the mesh fails." As to these documents, defendants' motion is overruled as moot.

Defendants seek to exclude six other exhibits, which the Court addresses in turn.

I. Exhibit 2

Exhibit 2 is an internal email dated February 27, 2004, from Dan Smith to Janice Burns and other Ethicon employees. There, in response to a physician's report that he had noticed that "small blue particles kept falling off the mesh," Smith said that sales representatives and surgeons should be told "UPFRONT that they will see BLUE sh*t and it is OK." At the time, Smith was Ethicon's lead TVT engineer and project manager.

Defendants argue that Exhibit 2 is irrelevant and inadmissible hearsay, and would result in unfair prejudice, juror confusion and undue delay. The email is not hearsay, however, because it is a statement by an opposing party under Rule 801(d)(2)(D), Fed. R. Evid. It is highly relevant to the issue of mesh degradation and what Ethicon knew about mesh degradation at the time of plaintiff's implant surgery in 2007. The exhibit is not "unduly" prejudicial under Rule 403, Fed. R. Evid., and defendants' motion to exclude it is overruled.

II. Exhibit 3

Exhibit 3 an email string in September and October of 2005 among European surgeons who were discussing potential follow-up questions to Prolift surgical patients. The email chain included commentary from Claude Rosenthal about questions directed towards "fellatio, sodomy, [etc.]" and another surgeon—Jacquetin Bernard, one of the inventors of Prolift—commenting on

the complexity of human sexuality, and stating "[i]sn't it this concern that has lead me to say (and I don't think I'll be the only for a while …) that I would not like for my wife to undergo this procedure."

Defendants argue that Exhibit 3 is irrelevant and inadmissible hearsay, and would result in unfair prejudice, juror confusion and undue delay. Plaintiff responds that (1) the hearsay argument is without merit because defendants stipulated "to the authenticity of, and satisfaction of the hearsay exceptions in the Federal Rules of Evidence 803(4) and 803(6)" of documents which defendants produced in this litigation "bearing an applicable Bates number;" and that, in any event, (2) Exhibit 3 is highly relevant to show that defendants were well aware of serious risks of the product prior to plaintiff's implant.

From the text, it is not clear how or when Ethicon received this email chain, or whether agents or employees of Ethicon are on the chain, but its argument with regard to notice is only this: "learning of an isolated incident does not provide notice that a problem is widespread or that a particular warning is needed, especially where the incident did not involve the product at issue." Ethicon concedes that Exhibit 3 involves the product at issue here, however, and does not dispute that it had notice of Exhibit 3 before the time of plaintiff's implant. Accordingly, it is relevant on the issue of notice and Rule 403 considerations do not require that it be excluded. Defendants' motion to exclude Exhibit 3 is therefore overruled.

III. Exhibit 10

Exhibit 10 is a 2009 email from Dr. Fah Che Leong to Ethicon employee Scott Jones reporting on a patient who allegedly had severe consequences as a result of an anterior and posterior Prolift implant, stating that there was "mesh extruding literally everywhere" and "[t]his patient will have a permanently [sic] destroyed vagina."

Defendants argue that the email is "rank hearsay" and does not fit within the business records exception in Fed. R. Evid. 803(6)(B); that it is not admissible for a non-hearsay purpose, such as to show notice, because Ethicon received it after plaintiff's implant surgery; and an uncorroborated report from a single doctor who did not perform the Prolift implant in question cannot constitute sufficient notice of a widespread issue, so the email has minimal probative value which is greatly outweighed by the risk of unfair prejudice and juror confusion stemming from the inflammatory language used in the email. See Fed. R. Evid. 403. Plaintiff responds that (1) the hearsay argument is without merit because defendants stipulated "to the authenticity of, and satisfaction of the hearsay exceptions in the Federal Rules of Evidence 803(4) and 803(6)" of documents which defendants produced in this litigation, "bearing an applicable Bates number;" (2) Exhibit 10 shows that defendants were on notice of the dangerous nature of the Prolene product; and (3) Exhibit 10 is relevant because plaintiff "has suffered substantially similar injuries as those described in the email."

Plaintiff's argument about notice is without merit, as any notice engendered by Exhibit 10 occurred after plaintiff's implant in 2007. In addition, if Exhibit 10 is not hearsay and is offered for the truth of the matter asserted—i.e., to substantiate plaintiff's claim of similar injuries—it runs afoul of Rule 403. Defendants correctly note that a report from a single doctor who did not perform the Prolift implant in question cannot constitute sufficient notice of a widespread issue, and that the email has minimal probative value which is greatly outweighed by the risk of unfair prejudice and juror confusion. Defendants' motion to exclude Exhibit 10 is sustained.

IV. Exhibit 13

Exhibit 13 is a 2002 email string between Drs. Axel Arnaud and Martin Weisberg in which Dr. Arnaud reviewed Dr. Weisberg's draft report on Prolene Soft mesh (not the Prolift device at

issue here) and expressed his concern about a statement concerning "Fistula & Erosions" in the discussion about potential complications. He noted that "this is a problem which arises rather commonly in practice even with polypropylene and it might be wise to be more elusive on this."

Defendants argue that this email string is wholly irrelevant because (1) it involves a different product than the one at issue in this case; (2) nothing in the Prolift IFU is "elusive" because the Prolift IFU clearly lists fistula and erosion as potential adverse events; and (3) such evidence would only serve to confuse or mislead the jury. See Fed. R. Evid. 401–403. Plaintiff responds that (1) Prolene Soft mesh is the exact mesh used in the Prolift; (2) the IFU for Prolift does not disclose the severity, duration and likelihood of fistulas and erosion, or the likelihood that such injuries will be life-long and disabling; and (3) Exhibit 13 is directly relevant to the issue of adequate warnings, product defect and punitive damages.

Defendants' arguments go to the weight rather than the admissibility of Exhibit 10. Its probative value is not so minimal as to invoke exclusion under Rule 403. Accordingly, defendants' motion to exclude Exhibit 13 is overruled.

V. Exhibit 15

In 2008, after plaintiff's implant surgery, Ethicon initiated research to evaluate the Prolift design and develop agreement on the business case for opening a Discovery Project to improve Prolift. The findings from this research were compiled into Exhibit 15, a document titled the "Prolift Physicians IDIs," which Patricia Wojdyla Qualitative Research & Consulting created based on 20 telephone interviews with physicians who used Prolift (one gynecologist, 11 urologists/urologic surgeons, and eight urogynecologists). The document was intended to be a "user snapshot" about Prolift.

Defendants seek to exclude Exhibit 15, arguing that the statements, and the author's conclusions based on these statements, should be excluded for two reasons: (1) the IDIs contain multiple levels of hearsay and plaintiffs cannot show that the IDIs qualify as business records under Fed. R. Evid. 803(6); and (2) any probative value of the IDIs is substantially outweighed by the risk of unfair prejudice to Ethicon, juror confusion and waste of time, especially since the IDIs post-date plaintiff's implant surgery and the statements are from such a small sampling of doctors. Plaintiff respond that Ethicon commissioned and directed the survey; that the hearsay argument is without merit because defendants stipulated "to the authenticity of, and satisfaction of the hearsay exceptions in the Federal Rules of Evidence 803(4) and 803(6)" of documents which defendants produced in this litigation "bearing an applicable Bates number;" and that the report proves that Ethicon had notice of the complications associated with Prolift.

As proof of notice, defendants' argument has merit because Exhibit 15 was not created until 2008, after plaintiff's implant surgery. On the other hand, plaintiff seeks to use Exhibit 15 as substantive evidence that the Prolift device design was defective. As such, it is highly relevant and tends to disprove defendants' claim that Prolift was perfectly safe. Given defendants' stipulation with regard to the hearsay issue, and the fact that Exhibit 15 is highly relevant, the Court cannot find that it is unduly prejudicial under Rule 403. Defendants' motion to exclude Exhibit 15 is overruled.

VI. Exhibit 18

Exhibit 18 is a report which PA Consulting Group prepared in June of 2011 for the investigation of a new pelvic organ prolapse product titled "Investigating Mesh Erosion in Pelvic Floor Repair."

Defendants argue that the report is inadmissible because (1) it is hearsay (not the statement of an opposing party under Rule 801(d)(2) or otherwise subject to the business records exception because its authors and/or PA Consulting will not be testifying to lay a proper foundation); (2) the report was not authored until after plaintiff's implant surgery and is not admissible to show notice of any alleged defect; and (3) the report is likely to confuse the jury because it references multiple products that are not at issue here, various studies and literature, multiple surgical methods for mesh implantation, variables that may affect erosion (including patient characteristics and co-morbidities) and the skills of the surgeon implanting the mesh as factors affecting mesh erosion; and (4) the report discusses degradation in polypropylene generally—not the mesh used to make Prolift, which has additives to prevent degradation. Plaintiff responds that the hearsay argument is without merit because defendants stipulated "to the authenticity of, and satisfaction of the hearsay exceptions in the Federal Rules of Evidence 803(4) and 803(6)" of documents which defendants produced in this litigation "bearing an applicable Bates number;" that the probative value of the report strongly outweighs any considerations of exclusion under Rule 403; and that this Court should follow the lead of the MDL Court in denying defendants' attempt to exclude Exhibit 18.

The Court agrees that Exhibit 18 is not relevant as proof of notice, since it was developed long after plaintiff's implant surgery in 2007. On the other hand, plaintiff seeks to use Exhibit 18 as substantive evidence that the Prolift device design was defective. As such, it is highly relevant. Given defendants' stipulation with regard to the hearsay issue, and the fact that Exhibit 18 is highly relevant, the Court cannot find that it is unduly prejudicial under Rule 403. Defendants' motion to exclude Exhibit 18 is overruled.

IT IS THEREFORE ORDERED that Defendants' Motion In Limine No. 2 To Exclude Certain Irrelevant And Unfairly Prejudicial Company Documents (Exhibit B, Attachment 2 to Defendants' Omnibus Motions In Limine (Doc. #206)) filed March 8, 2021, be and hereby is **SUSTAINED IN PART AND OVERRULED IN PART**.

Dated this 26th day of March, 2021 at Kansas City, Kansas.

s/ Kathryn H. Vratil
KATHRYN H. VRATIL
United States District Judge