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 Plaintiff's Omnibus Motions In Limine Nos. 1–12 (Doc. #207) filed March 8, 2021.[1] Plaintiff's motion is sustained in part, and overruled in part, as follows:

I. MIL No. 1: To Exclude Statements Regarding The Number Of Randomized Controlled Trials That Allegedly Support The Safety Of Prolift And Similar Products

Plaintiff seeks to exclude evidence about the "number" of "randomized controlled trials" that purportedly support Prolift's safety and efficacy for the treatment of pelvic organ prolapse, because statements regarding the subject and/or conclusions of randomized control trials would constitute hearsay and the number of trials has "little if any probative value," so the danger of unfair prejudice requires that such evidence be excluded under Rule 403, Fed. R. Evid. Defendants correctly note (and plaintiff does not disagree) that to the extent defendants' experts relied on

[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.

randomized controlled trials in forming their opinions in this case, evidence about the trials is not hearsay. Nothing about the "number" of such trials is inherently prejudicial or subject to exclusion under Rule 403. Obviously, plaintiff can cross-examine to find out whether each randomized controlled trial in the count concerns Prolift and whether the study actually supports a finding that Prolift is safe and efficacious. To facilitate that cross-examination and avoid wasting the time of jurors and witnesses, the Court orders that not later than 5:00 p.m. on March 29, 2021, defendants identify for plaintiff each randomized controlled trial on which their experts intend to rely in counting them up at trial. Subject to these requirements, plaintiff's MIL No. 1 is overruled.

II. MIL No. 2: Defendants' Duty To Warn Cannot Be Abrogated By Its Unsupported Assumption That Users Would Have Knowledge Of The Undisclosed Prolift Risks

Plaintiff states that several defense witnesses have testified that Ethicon did not have to warn of certain risks because surgeons who used Prolift already knew those the risks. Plaintiff argues that "[i]t is . . . disingenuous to represent that the risks were well-known by all doctors" and that this defense is, "at its essence, a mechanism for the wholesale introduction of a mass of unverifiable hearsay and uncorroborated speculation as to the supposed knowledge held by thousands of physicians." Defendants respond, and the Court agrees, that plaintiff's motion seeks to exclude evidence that is both admissible and essential to the defense of plaintiffs' failure to warn claim. Accordingly, the Court cannot oblige plaintiff's request to bar defendants from "advanc[ing] the position" that surgeons who would use Prolift are knowledgeable about the associated risks—a request that is tantamount to an unsubstantiated request for judgment as a matter of law on plaintiff's claim of failure to warn.

Plaintiff can make contemporaneous objections to the issues of concern: "general, unverifiable hearsay statements and incompetent expert opinions, unsupported by any reliable foundation." To broadly preclude defendants from asserting the "common knowledge" doctrine

is inappropriate and inconsistent with Minnesota law. Plaintiff's motion MIL No. 2 is therefore overruled.

III. MIL No. 3: Defendants Cannot Generally Refer To What Was Taught To Physicians In Professional Education As A Defense

Plaintiff anticipates that when deficiencies in the IFU and other labels and related documents are pointed out to Ethicon's fact and expert witnesses, they will vaguely respond that additional information was provided to physicians through "professional education." Absent proof that a document was actually used to educate plaintiff's own surgeon (with details when, how and by whom it was used), plaintiff argues that such blanket hearsay references should be precluded. Specifically, plaintiff argues that without specific information or documents about "professional education" provided to Dr. Beer, general information or documentation that may have been taught as part of professional education to other physicians is "just 'noise' and is of no probative value to Ms. Kieffaber's case."

Plaintiff correctly notes that in terms of warnings, the critical issue in this case is what Dr. Beer knew. Therefore, unless defendants can tie the "professional education" to him in some way, the Court sustains plaintiff's motion to exclude general evidence about professional education of other surgeons. Minnesota applies the learned-intermediary doctrine in failure-to-warn cases, which imposes a duty on the manufacturer to adequately warn and instruct physicians about the dangers associated with a medical device. Because evidence about other surgeons is "just noise," the only relevant issue is whether defendants gave "professional education" to Dr. Beer. The Court sustains MIL No. 3.

IV. MIL No. 4: To Bar References To The Surgeon's Monograph

Plaintiff argues that the Gynecare Prolift Surgeon's Monograph is irrelevant since Dr. Beer did not specifically remember whether he saw or received a copy of it. This argument is easily

rejected. The Court assumes that defendants can handily offer a sufficient evidentiary foundation for this document and it is directly relevant to plaintiff's claim of failure to warn. Dr. Beer's current recollection of the monograph is irrelevant. Plaintiff's MIL No. 4 is overruled.

V. MIL No. 5: To Bar Defendants From Introducing Testimony That Severe Prolift Complications Are Rare

Plaintiff asks the Court to order that in discussing the occurrence rate of "severe" Prolift complications, defense witnesses and attorneys be limited to "specific rates or frequencies of complications as documented in specific studies," and not be allowed to testify that such complications occur "rarely" or "very rarely."

If plaintiff disagrees with the witnesses' choice of words, the appropriate recourse is vigorous cross-examination, not exclusion based on their choice of words. The Court assumes that plaintiff is well familiar with the studies on which defendants' experts have relied, and that she is at no disadvantage developing effective cross-examination on this point. Moreover, it is not clear what plaintiff identifies as "severe" complications, so the Court could not realistically enter an order in limine on this subject. Plaintiff's MIL No. 5 is overruled.

VI. MIL No. 6: To Preclude Defendants From Defending Based On A Long History Of Use Of Polypropylene In The Human Body

Plaintiff asks the Court to prevent defendants from arguing that polypropylene has been "safely" used in the human body in sutures and in hernia mesh for many years. Plaintiff argues that because such use does not equate to safety for use in the pelvic floor and such argument "would implicate massive, imprecise hearsay, which would require extensive cross-examination and rebuttal evidence to explain the irrelevance and misleading nature of that vague but powerful assertion to the jury." Defendants respond—and the Court agrees—that defendants should be allowed to offer evidence that both polypropylene and Prolene have a long history of safe and

effective use in the human body, and that polypropylene is used in many other permanent medical implants. This evidence is relevant not only to rebut plaintiff's attack on polypropylene mesh material and to show that Prolift is not defective, but also to establish Ethicon's lack of negligence in selecting polypropylene as the base material for Prolift. Such evidence does not necessarily open the door to evidence of polypropylene mesh devices that have been withdrawn from the market for safety reasons, warnings that the polypropylene base material in very similar devices should not be used to form medical devices for permanent implantation, or the massive number of lawsuits that have been filed both for pelvic mesh and hernia mesh. Plaintiff shall refrain from mentioning any such matters without prior approval from the Court, following a conference outside the hearing of the jury. Plaintiff's MIL No. 6 is overruled.

VII. MIL No. 7: To Bar Any Testimony Or Evidence Criticizing The Care And Treatment By Or The Surgical Approach Of Mrs. Kieffaber's Treating Physicians

Plaintiff asks the Court to exclude any evidence (1) that Dr. Beer's surgical implant of Prolift was not consistent with the recommendations of Ethicon and/or that his surgical technique caused or contributed to cause plaintiff's injuries; and (2) that Dr. Goldman could have used a less invasive approach, as opposed to removing as much Prolift mesh as possible. Plaintiff argues that defendants have no expert testimony that either of these physicians fell below the standard of care, and any testimony relating to or criticizing their techniques is therefore irrelevant under Minnesota law.

Defendants have not brought third-party negligence claims against Drs. Beer or Goldman and do not intend to argue that these doctors were negligent in their treatment of plaintiff or that they breached the standard of care. Accordingly, plaintiff's motion is moot to the extent it is limited to that specific argument. Dr. Rosenblatt, however, may not testify that Dr. Beer or Dr. Goldman caused or contributed to plaintiff's injuries unless he has previously been qualified

to testify, to a reasonable degree of medical certainty, that their conduct caused or contributed to plaintiff's injuries. Whether plaintiff's doctors caused or contributed to her injuries is a subject well beyond the grasp of a lay jury, and allowing defendants to discredit her claim of causation with medical proof which is couched in terms of mere "possibilities" would do nothing but invite speculation on this issue. Moreover, it would infect the trial with the danger of unfair prejudice, confusing the issues, misleading the jury, undue delay and waste of time. In this regard, plaintiff's MIL No. 7 is sustained.

VIII. MIL No. 8: Defendants Cannot Defend The Case In Reliance On The TVT And SUI Devices

Plaintiff asks the Court to prevent defendants from submitting evidence about the safety and efficacy of other mesh devices, including the TVT and SUI mid-urethral slings, because if admitted, plaintiff will need to submit substantial evidence as to the defects and the dangers of the TVT devices and this will result in wasteful minitrials on devices that are not at issue in this case. Defendants respond that to the extent that TVT and SUI products played a role in the history and development of Prolift, this evidence is relevant and admissible. The Court agrees, and it appears that plaintiff also agrees.

The Court is therefore confused by plaintiff's request that "defendants should not be permitted to rely at all on the TVT or similar SUI devices, or their clinical data, literature, professional society position statements, or other such evidence in defense of this case; nor should Defendants be permitted to elicit testimony from Plaintiff's treating physicians about their use of, experience with, or opinions of the TVT or similar SUI devices." Because the Court cannot exclude evidence about TVT and SUI products, and the role which they played in the history and development of Prolift, and it does not understand what other evidence plaintiff is concerned about, plaintiff's MIL No. 8 is overruled.

IX. MIL No. 9: To Bar Defendants From Referencing The Consent Form Signed By Plaintiff

Plaintiff seeks a pretrial ruling to preclude at trial evidence and argument relating to the "Informed Consent for Procedure(s)" form which plaintiff signed before her Prolift implant procedure, because the document may improperly imply that plaintiff consented with knowledge of the potential long-term complications of the device. Plaintiff's informed consent form is highly relevant to the defense, however, and should not be excluded. The import of the informed consent form is a classic evidentiary issue for the jury to resolve. Plaintiff's MIL No. 9 is overruled.

X. MIL No. 10: To Exclude Evidence Of Defendants' General Contributions To Society, Including Without Limitation The Johnson & Johnson COVID-19 Vaccine

Plaintiff seeks an order precluding evidence and argument regarding defendants' general contributions to society and, in particular, Johnson & Johnson's COVID-19 vaccine or other products and treatments associated with defendants which are currently used in the ongoing pandemic, because such evidence would only serve to confuse and mislead the jury and be unfairly prejudicial. Defendants respond that they have no intention of offering unrelated evidence concerning their general "good character" or "good reputation," or to make any references to the development and use of the Johnson & Johnson COVID-19 vaccine. To this extent, plaintiff's motion is moot.

Defendants make the mysterious argument that "Ethicon should be allowed to introduce evidence concerning its development of other products in order to give the jury a better understanding of its business." Defendants do not identify those products or why the jury needs to better understand their business by learning about them. Accordingly, on this point, plaintiff's motion is sustained.

XI. MIL No. 11: To Exclude The "Time To Rethink" Article

In 2011, Ethicon consultants (Miles Murphy, Vincent Lucente and Heather Van Realte) and a Boston Scientific consultant (Adam Holzberg) wrote an article which was published in the International Urogynecology Journal. (Murphy M et al. Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Int Urogynecol J 2012; 23: 5-9. Epub 11-16-2011.) The purpose of the article was to address "The Recent FDA Update" (July 2011) and show that some doctors felt that not all mesh repairs should be banned, without reference to or analysis of a specific device or system. The authors circulated a petition which 600 doctors signed to confirm that they agreed.

Plaintiff argues that the article is an unscientific non-peer-reviewed propaganda opinion piece and should not be referenced at trial. Defendants respond that the "Time to Rethink" article addresses the specific condition for which plaintiff was implanted with Prolift and examines the safety and efficacy of the class of devices to which Prolift belongs, so the article is relevant to plaintiffs' claims and should not be excluded.

On this record, the Court sustains plaintiff's motion. The article was published in 2011, well after plaintiff's implant. It is replete with hearsay. Most importantly, it is a response to an FDA Safety Communication UPDATE about transvaginal placement of surgical mesh (TVM) for pelvic organ prolapse (POP). The FDA issued the update to inform the healthcare community that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

The Court has elsewhere determined to exclude evidence about the FDA approval and regulatory process, on grounds that it is only minimally relevant (if at all) and that considerations under Rule 403 dictate against receiving such evidence. It appears that the "Time to Rethink"

article falls in the same category of evidence because to put the article in context, one needs to understand the FDA regulatory process. Accordingly, plaintiff's MIL No. 11 is sustained.

XII. MIL No. 12: To Bar Any References To Amounts Paid To Experts Beyond The Amounts Paid In This Case

Plaintiff requests that this Court bar any reference to the amounts paid to expert witnesses in cases other than this one because such testimony is irrelevant and could be used to imply "improper influence." Plaintiff's motion is overruled. Overall compensation, including financial interests or investments in the litigation of pelvic mesh cases, is highly relevant and probative on the issue of bias, and its relevance is the reason to admit it—not to exclude it. The same is true, obviously, for defendants' experts. Accordingly, plaintiff's MIL No. 12 is overruled.

IT IS THEREFORE ORDERED that Plaintiff's Omnibus Motions In Limine Nos. 1–12 (Doc. #207) filed March 8, 2021, be and hereby is **SUSTAINED IN PART AND OVERRULED IN PART**, as set forth above.

IT IS FURTHER ORDERED that not later than 5:00 p.m. on March 29, 2021, defendants identify for plaintiff each randomized controlled trial on which their experts intend to rely in counting them up at trial.

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

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