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. 4 To Exclude Post-Implant Revisions To The Prolift Insturctions [sic] For Use (Exhibit D, Attachment 4 to Defendants' Omnibus Motions In Limine (Doc. #206)) filed March 8, 2021.[1]

The Instructions for Use ("IFU") for Prolift underwent two separate revisions following plaintiff's surgical implant in 2007. Defendants argue that evidence and argument related to the subsequent changes should be excluded for two reasons: first, they constitute inadmissible subsequent remedial measures and cannot be used as substantive evidence of a product defect or defendants' negligence; and second, the post-implant labeling revisions are irrelevant, and their admission would only confuse and mislead the jury and unfairly prejudice defendants.

[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.

I. Subsequent Remedial Measures

Plaintiff asks the Court to deny this motion, first arguing that subsequent remedial measures are admissible for impeachment or (if disputed) to show ownership, control or the feasibility of precautionary measures. The Court agrees that evidence of post-implant IFU revisions might be relevant for impeachment purposes, but the parties have not spelled out specific items of testimony which would warrant such impeachment. Furthermore, impeachment evidence is not easily addressed in advance of trial, except by saying that if plaintiff seeks to use such evidence for purposes of impeachment, she must first seek approval from the Court. This case does not appear to involve disputed issues of ownership, control or feasibility of precautionary measures and to that extent, defendants' motion is well taken. In these respects, defendants' motion is sustained.

Plaintiff next argues that evidence of subsequent remedial measures is admissible when those measures were not voluntary, and were required by law, in the visage of the FDA. Here, according to plaintiff, "defendants did not seek to eliminate a harmful situation of their own accord in order to prevent further harm," but changed the Prolift IFUs "in direct response to FDA communications and directives pressuring it to correct its inaccurate warning." Plaintiff argues that the policy of Rule 407, Fed. R. Evid., is best served by "providing an incentive for device manufacturers to make voluntary changes to the device or label, rather than rewarding their inaction until their hand is forced." Defendants do not address the issue of voluntariness, except to say that allowing admission of post-implant changes to the IFU would "discourage medical device manufacturers from cooperating with the FDA in providing updates to their product warnings." On this record, defendants have not shown that post-implant revisions to the Prolift IFUs were sufficiently voluntary that under the letter or the spirit of Rule 407, they must be

excluded. The Court therefore rejects the argument that as subsequent remedial measures, evidence of post-implant revisions to the IFUs must be excluded and cannot be used as substantive evidence of a product defect or defendants' negligence.

II. Relevance And Rule 403

Defendants argue that the Court should also preclude plaintiff from introducing evidence of post-implant revisions to the Prolift IFU because it is irrelevant, confusing and unfairly prejudicial, given that Minnesota has adopted the learned-intermediary doctrine and IFU changes which occurred after plaintiff's implant are irrelevant to the decisions which she and her surgeon made in 2007. Plaintiff responds that such evidence is relevant under certain "what if" scenarios: What would plaintiffs' surgeon have done if the IFU had been different? What information would the surgeon have provided to plaintiff if the IFU had been different? According to plaintiff, post-implant revisions to the IFU are relevant to show that the injuries which plaintiff suffered are not within the common knowledge of implanting physicians, attacking the credibility of defendants and proving that the Prolift product was defective.

Such relevance, if any, is minimal. All of these subjects can be examined without reference to post-implant changes to the IFUs. The relevance of the changes is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, undue delay and wasting of time. See Rule 403, Fed. R. Evid. Defendants' motion on this issue is therefore sustained.

IT IS THEREFORE ORDERED that Defendants' Motion In Limine No. 4 To Exclude Post-Implant Revisions To The Prolift Insturctions [sic] For Use (Exhibit D, Attachment 4 to Defendants' Omnibus Motions In Limine (Doc. #206)) filed March 8, 2021, be and hereby is **SUSTAINED IN PART AND OVERRULED IN PART**, as outlined above.

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

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