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. 12 To Exclude Evidence Of FDA Regulatory Actions And Other Regulatory Issues (Exhibit L, Attachment 12 to Defendants' Omnibus Motions In Limine (Doc. #206)) filed March 8, 2021.[1]

The U.S. Food & Drug Administration cleared Prolift for sale in the United States as a Class II medical device under the Section 510(k) Premarket Notification Process. Defendants state that plaintiff wants to exclude evidence of the FDA clearance but offer evidence of other regulatory actions which the FDA took with respect to certain types of pelvic mesh devices. Defendants specifically ask the Court to exclude the following FDA regulatory evidence: (1) third-party submissions to the 2011 FDA Advisory Committee meeting on transvaginal mesh; (2) the FDA issuance of "522 Orders" for Prolift and other Ethicon pelvic mesh products; and (3) FDA

[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.

regulatory actions in 2014, 2016 and 2019 addressing the classification of transvaginal prolapse mesh.

I. Evidence Which Third Parties Submitted To The FDA For The 2011 FDA Advisory Committee Meeting

In September of 2011, over four years after plaintiff's implant in 2007, the FDA held an Advisory Committee Meeting to discuss the safety and efficacy of transvaginal prolapse mesh. Defendants ask the Court to exclude evidence which third parties submitted to the FDA, the transcript of the meeting and the FDA's conclusions at the meeting. The meeting was allegedly a forum for third parties to air informal and unverified views. Defendants argue that the comments are hearsay and that exclusion is necessary to prevent the jury from receiving the false impression that the FDA accepted or endorsed the views expressed.

II. 2012 FDA 522 Orders

Defendants ask the Court to exclude the "522 Orders" which the FDA issued to Ethicon in 2012, five years after plaintiff's implant, instructing Ethicon to collect and provide post-market surveillance data for Prolift and certain other devices not at issue here.

III. FDA's 2014, 2016 And 2019 Actions Concerning The Classification Of Transvaginal Prolapse Mesh

On May 1, 2014, seven years after plaintiff's implant with Prolift and two years after Ethicon "decommercialized" Prolift, the FDA published two proposed orders recommending that transvaginal prolapse mesh devices be reclassified as Class III medical devices, which would require a more strict premarket approval. In January of 2016, the FDA completed this process by issuing a final order reclassifying transvaginal prolapse mesh devices as Class III devices.

In response to defendants' motion, plaintiff agrees not to reference FDA regulatory actions or other FDA regulatory issues if the Court grants her pending motion in limine on FDA evidence,

and if defendants do not open the door by successfully admitting FDA evidence at trial. The Court has sustained plaintiff's motion to exclude FDA evidence, so defendants' motion is moot.

IT IS THEREFORE ORDERED that Defendants' Motion In Limine No. 12 To Exclude Evidence Of FDA Regulatory Actions And Other Regulatory Issues (Exhibit L, Attachment 12 to Defendants' Omnibus Motions in Limine (Doc. #206)) filed March 8, 2021, be and hereby is **OVERRULED AS MOOT.**

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

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