IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

BETH HARTER,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-737

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(Motions in Limine)

Pending before the court are the plaintiff's Motions in Limine [ECF No. 96, 101] and the defendants' Motion in Limine [ECF No. 97].

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 28,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). The court seeks the assistance of the

parties in completing these tasks by asking the parties to focus on discrete, important, or more relevant matters. Here, the court expected the parties to focus their motions in limine on "highly prejudicial statements in opening or closing statements or questions at trial that, once heard by the jury, cannot be easily cured by an instruction to disregard." Pretrial Order No. 234, at 5 [2:12-md-2327 ECF No. 2314] ("PTO 234"). The court further cautioned that it would "not provide advisory opinions on the admissibility of evidence a party may offer at trial and [would] summarily deny those motions as premature." *Id.*

a. The Plaintiff's Motion to Preclude Evidence Relating to the FDA (Motion in Limine No. 1) [ECF No. 96]

The plaintiff asks the court to exclude evidence related to the FDA, including the FDA's 510(k) process, arguing it is impermissibly irrelevant and prejudicial under Federal Rules of Evidence 402 and 403. Pl.'s Mot. Lim. 1–4 [ECF No. 96].

In short, the 510(k) process "does not in any way denote official approval of [a] device." 21 C.F.R. § 807.97. The process is not focused on whether a device is safe; it is concerned with the device's equivalence to another device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Because the process does not speak to the safety or efficacy of any product, whether Ethicon products were approved through this process is irrelevant. Even if the 510(k) process were relevant, the court would exclude this evidence under Rule 403. Any kernel of relevance is outweighed by "the very substantial dangers of misleading the jury and confusing the issues." *In re C. R. Bard*, 810 F.3d 913, 922 (4th Cir. 2016) (affirming the court's exclusion of 510(k) evidence).

Put simply, evidence of this sort is inadmissible and, in any event, does not survive a Rule 403 analysis. The court will not belabor the point here as it has already done so on several occasions. *E.g., Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014). The court **GRANTS in part** the plaintiff's Motion in Limine [ECF No. 96] as to Motion in Limine No. 1 and in any instance where the defendants conceded to the plaintiff's Motion. The remainder of the plaintiff's Motion in Limine [ECF No. 96] is **DENIED without prejudice**.

b. The Defendants' Motion to Exclude the January 2012 "522" Letters and Subsequent FDA Actions (Motion in Limine No. 2) [ECF No. 97]

The defendants ask the court to exclude evidence of the January 2012 "522" letters and subsequent FDA actions that would have applied to Ethicon devices if they had not been discontinued, arguing it is prejudicial and would require presentation of evidence on a collateral issue. Defs.' Mem. Supp. Mot. Lim. 3–5 [ECF No. 98]. The plaintiff does not contest this Motion. Pl.'s Mem. Opp'n Defs.' Mot. Lim. 4 [ECF No. 105]. Indeed, the court has excluded this same evidence on prior occasions. *See, e.g.*, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 6680356, at *1 (S.D. W. Va. Nov. 25, 2014). The court **GRANTS in part** the defendants' Motion in Limine [ECF No. 97] on this point and in any instance where the plaintiff conceded to the defendants' Motion; the remainder of the Motion is **DENIED without prejudice**.

c. Remaining Motions

The remaining Motion in Limine [ECF No. 101] does not comport with PTO 234's requirement to focus on "highly prejudicial statements in opening or closing

statements or questions at trial that, once heard by the jury, cannot be easily cured by an instruction to disregard" and are more appropriately handled by the trial court judge following remand or transfer at or before trial. PTO 234 at 5. The plaintiff's Motion in Limine [ECF No. 101] is **GRANTED** insofar as the defendants conceded to the plaintiff's Motion and is otherwise **DENIED without prejudice**.

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

ENTER: December 14, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE