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

CHARLESTON DIVISION

CAROL JEAN DIMOCK,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-401

ETHICON, INC., et al.,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motions in Limine)

Pending before the court are the plaintiff's Omnibus Motion in Limine [ECF No. 131] and the defendants' Omnibus Motion in Limine [ECF No. 129].

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)

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 Omnibus Mot. Lim. 2–5.

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 **GRANTS** the plaintiff's Motion in Limine No. 1. 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).

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

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 under Federal Rules of Evidence 403 and would require presentation of evidence on a collateral issue. Def.'s Mem. Supp. Omnibus Mot. Lim. 3–6 [ECF No. 130]. The plaintiff does not contest this Motion. Pl.'s Br. Opp'n Def.'s Mot. Lim. 3–4 [ECF No. 134]. 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** the defendants' Motion on this point.

c. Conclusion

The remaining Motions do 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. Accordingly, the plaintiff's

Omnibus Motion in Limine [ECF No. 131] and the defendants' Omnibus Motion in Limine [ECF No. 129] are **GRANTED in part** and **DENIED without prejudice in part**. The plaintiff's Motion in Limine No. 1 and the defendants' Motion in Limine No. 2 are **GRANTED**. All other Motions in Limine are **DENIED without prejudice**.

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

ENTER: November 29, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE