

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

FRAN DENISE COLLINS,

Plaintiff,

v.

CIVIL ACTION NO. 2:12-cv-00931

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION AND ORDER  
(Motions in Limine)**

Pending before the court are the plaintiff's Motion in Limine [ECF No. 106], the defendants' Motions in Limine [ECF Nos. 102, 104], and the defendants' Motion for Leave to File a Reply [ECF No. 110].

This case resides in one of seven MDLs assigned to the Honorable Judge Joseph R. Goodwin 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"). This individual case is one of a group of cases reassigned to me on November 22, 2016. *See Order, Nov. 22, 2016* [ECF No. 123]. In the seven MDLs, there are approximately 29,000 cases currently pending, approximately 17,000 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, Judge Goodwin previously indicated that he 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”). Judge Goodwin further cautioned that he 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. 106]**

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.

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 irrelevant and, in any event, does not survive a Rule 403 analysis. The court will not belabor the point here as Judge Goodwin has already discussed it on several occasions. *See, e.g., Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754–56 (S.D. W. Va. 2014). Accordingly, the court **GRANTS in part** the plaintiff’s Motion in Limine [ECF No. 106] as to Motion in Limine No. 1 and in any other instance where the defendants conceded the plaintiff’s Motion. The remainder of the plaintiff’s Motion in Limine [ECF No. 106] 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. 102]**

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 Rule of Evidence 403 and would require presentation of evidence on a collateral issue. Mem. Supp. Mot. Lim. 2–5 [ECF No. 103]. The plaintiff does not contest this Motion. Resp. 4 [ECF No. 108]. 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). Accordingly, the court **GRANTS in part** the defendants’ Motion in

Limine [ECF No. 102] on this point and in any instance where the plaintiff concedes the defendants' Motion; the remainder of the Motion is **DENIED without prejudice**.

**c. The Defendants' Motion to Exclude Evidence of Plaintiff's Allegations of Spoliation [ECF No. 104]**

The defendants have separately filed a motion in limine to exclude evidence related to spoliation. [ECF No. 104]. The plaintiffs have repeatedly alleged that the defendants lost or destroyed documents relevant to this multidistrict litigation. On February 4, 2014, Magistrate Judge Eifert held that the defendants' actions were negligent, not willful or deliberate, and denied the plaintiffs' motions for severe sanctions, such as default judgment, striking of defenses, or offering an adverse instruction in every case. Pretrial Order No. 100, Feb. 4, 2014 [ECF No. 1069]. However, Judge Eifert recommended that I allow the plaintiffs be allowed "the opportunity to introduce evidence regarding [the defendants'] loss of relevant documents on a case-by-case basis, and, when appropriate, to tender an adverse inference instruction." *Id.* at 42–43. The plaintiffs have since asked Judge Eifert to reconsider Pretrial Order # 100, claiming that they have discovered new evidence that establishes that the defendants' duty to preserve evidence began earlier than previously thought. *See* Pls.' Request for Clarification and Reconsideration [2:12-md-2327 ECF No. 1099].

While a motion for reconsideration is pending before Judge Eifert, the parties have indicated that they do not desire a ruling on the motion at this time. If and until Judge Eifert rules on the motion to reconsider, her original ruling remains in force

and effect. Moreover, the plaintiff has offered no evidence or argument that evidence of spoliation will be relevant *in this case*. Therefore, the defendants' Motion in Limine [ECF No. 104] on the issue of spoliation is **GRANTED**.

Accordingly, the defendants' Motion for Leave to File a Reply [ECF No. 110] is **DENIED as moot**.

**d. Conclusion**

The plaintiff's Motion in Limine [ECF No. 106] is **GRANTED in part** as to Motion in Limine No. 1 and any other conceded motion therein; the remainder of the Motion is **DENIED without prejudice**. The defendants' Motion in Limine [ECF No. 102] is **GRANTED in part** as to Motion in Limine No. 2 and any other conceded motion therein; the remainder of the Motion is **DENIED without prejudice**. The defendants' Motion to Exclude Evidence of Plaintiff's Allegations of Spoliation [ECF No. 104] is **GRANTED**. The defendants' Motion for Leave to File a Reply [ECF No. 110] is **DENIED as moot**.

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

ENTER: December 13, 2017



ROBERT C. CHAMBERS  
UNITED STATES DISTRICT JUDGE