

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

CHARLESTON DIVISION

TERRESKI MULLINS, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:12-cv-02952

ETHICON, INC., et al.,

Defendants.

**MEMORANDUM OPINION & ORDER**  
**(Order re: 510(k) Clearance Motion in Limine)**

On June 10, 2016, the court denied without prejudice the plaintiffs' Omnibus Motion *in Limine* No. 1: Regarding FDA Related Evidence and that Ethicon Cannot Defend Based on 510(k) Clearance or Compliance with Any Regulations [ECF No. 142]. *See* Order, Jun. 10, 2016 [ECF No. 660]. For reasons appearing to the court, it is **ORDERED** that the court's June 10, 2016, Order [ECF No. 660] be **VACATED in part** only as to the plaintiffs' Motion [ECF No. 142]. For the following reasons, the Motion is **GRANTED in part** and otherwise **DENIED without prejudice**.

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 Omnibus Motion in Limine No. 1: Regarding FDA Related Evidence and That Ethicon Cannot Defend Based on 510(k) Clearance or Compliance with Any Regulations [ECF No. 142]**

The plaintiffs ask 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.

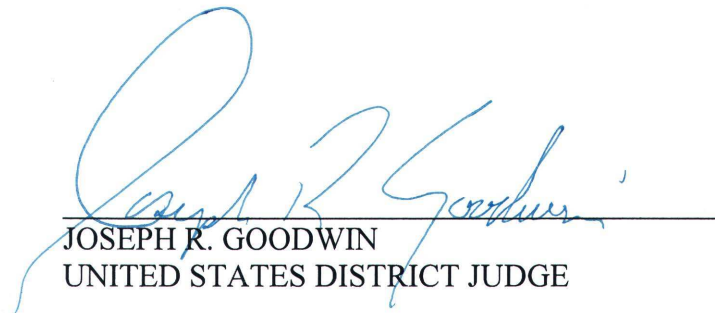
In short, the 510(k) process “does not in any way denote official approval of [a] device.” 21 C.F.R. § 807.97. The process is not focused on whether a device is safe; it

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 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 plaintiffs' Motion [ECF No. 142] as to FDA evidence and 510(k) clearance process. To the extent the plaintiffs attempt to exclude evidence not related to the FDA, it is **DENIED without prejudice**.

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

ENTER: February 23, 2017

  
JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE