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

CHARLESTON DIVISION

JO HUSKEY, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-cv-05201

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Before the court is the plaintiffs' Motion for Clarification of the Application of the Court's Prior Orders Excluding FDA 510(k) Evidence to Plaintiffs' Trial, and to Strike FDA Regulatory Opinions of Dr. Schultz and Mr. Ulatowski [Docket 114].[1] For the reasons stated below, the motion is **DENIED** and expert discovery related to the FDA's 510(k) process is **STAYED**.

I. Motion for Clarification

The plaintiffs seek several forms of relief. First, the plaintiffs seek to exclude "any evidence or testimony relating to the FDA's 510(k) clearance of the TVT-O product, or the lack of FDA enforcement action relative to the TVT-O product." (Pls.' Mot. [Docket 114], at 2). In support, the plaintiffs point to my past rulings where I determined that the 510(k) process does not relate to the safety and efficacy of products. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2187, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013) and *Lewis v. Johnson & Johnson*, — F. Supp. 2d —, 2:12-cv-04301, 2014 WL 152374, at *4-6 (S.D. W. Va.

[1] Under Local Rule of Civil Procedure 7.1, motions for clarification must be accompanied by a separately filed supporting memorandum. The plaintiffs are reminded to follow this rule in the future.

Jan. 15, 2014). The plaintiffs ask for "clarification" that the court's orders in *In re C. R. Bard, Inc.* and *Lewis* will apply in this case, thus precluding Ethicon from making any reference at trial to the FDA's 510(k) process. (Pls.' Mot. [Docket 114], at 3). The plaintiffs want to avoid "having to take expert discovery on these FDA regulatory issues—and prevent unnecessary *Daubert* briefing from being submitted to the court." (*Id.*).

The plaintiffs essentially seek a protective order limiting the scope of discovery. The court may, for good cause, enter an order "forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matters." Fed. R. Civ. P. 26(c)(1)(D). Here, the plaintiffs argue that it would be unnecessary to engage in discovery on the 510(k) process because they believe that this issue will ultimately be excluded from trial.

I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. Nonetheless, I have not reviewed the admissibility of the 510(k) process in relation to Illinois law, and it has not been fully briefed here. It is conceivable—although difficult to imagine—that my ruling on this issue could differ *in this case*. Therefore, the parties are invited to move in limine for a determination of the admissibility of the 510(k) process as soon as possible. The court will rule on such motions expeditiously. Accordingly, the plaintiffs' motion for clarification is **DENIED**.

Regarding expert discovery related to the 510(k) process, such discovery is **STAYED** until the court has an opportunity to rule on the admissibility of the 510(k) process.

II. Motion to Strike

Second, the plaintiffs move to strike the expert reports of Daniel Schultz, M.D. and Timothy A. Ulatowski, M.S. Federal Rule of Civil Procedure 12(f) gives courts the power to strike items from the record. The rule provides that the "court may strike from a pleading an

insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). As the rule clearly states, the court's power is limited to striking *pleadings*. Pleadings are complaints; third-party complaints; answers to complaints, third-party complaints, crossclaims, and counterclaims; and replies to answers. *See* Fed. R. Civ. P. 7(a). Expert reports are not pleadings and therefore are not subject to motions to strike. *See Rindfleisch v. Gentiva Health Servs.*, 962 F. Supp. 2d 1310, 1316 (N.D. Ga. 2013) (refusing to strike expert report because it was not a pleading and therefore not "subject to a motion to strike"); *MJ Harbor Hotel, LLC v. McCormick & Schmick Rest.*, 599 F. Supp. 2d 612, 623 (D. Md. 2009) ("Because [the expert's] report and testimony are not pleadings, they are not subject to [Rule 12(f)]."); *cf. Hrivnak v. NCO Portfolio Mgmt., Inc.*, 723 F. Supp. 2d 1020, 1029 (N.D. Ohio 2010) (refusing to strike an "offer of judgment" because it was not a pleading), *aff'd*, 719 F.3d 564 (6th Cir. 2013). Therefore, the plaintiffs' motion to strike is **DENIED**.

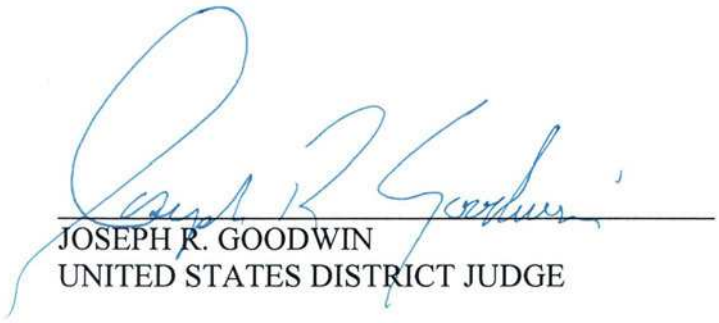
III. Motion for a Jury Instruction

Finally, the plaintiffs request an "instruction at the outset of trial that the manufacturer is responsible for safety and efficacy." (Pls.' Mot. [Docket 114], at 3). I will not entertain requests for jury instructions this far in advance of trial. The plaintiffs should submit their proposed jury instructions on all relevant issues on June 6, 2014, as directed by Pretrial Order #109 [Docket 88]. Accordingly, the plaintiffs' motion for a jury instruction is **DENIED**.

IV. Conclusion

For the reasons stated above, the plaintiffs' motion [Docket 114] is **DENIED** and expert discovery related to the 510(k) process is **STAYED**. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 3, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE