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 in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 139]. For the reasons stated below, the motion is **GRANTED**.

I. Background

This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process. *See, e.g.*, *Lewis v. Johnson & Johnson*, --- F. Supp. 2d. ---, No. 2:12-cv-04301, 2014 WL 152374, at *4-6 (S.D. W. Va. Jan. 15, 2014); *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). In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to safety or efficacy of medical devices and because of the potential to mislead and confuse the jury.

In this case, the plaintiffs previously moved that I automatically extend my earlier 510(k) rulings to this case. I denied that motion and wrote that "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*." *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 1347372, at *1 (S.D. W. Va. Apr. 3, 2014). As the plaintiffs correctly point out, I sought briefing from the parties regarding how, if at all, Illinois law differed from that of Georgia and Texas, and how those differences affected the admissibility of the FDA's 510(k) process. Even so, Ethicon focused the majority of its briefing on extraneous issues, ultimately urging me to reconsider the bases for my earlier rulings. I do not address those issues here, and I decline to reconsider the bases for any of my prior rulings on admissibility of 510(k) evidence. I now hold that the evidence of the FDA's 510(k) process is **INADMISSIBLE** in this case.

II. Analysis

My reasoning for excluding evidence of the 510(k) process in general is fully set out in *Lewis*, 2014 WL 152374, at *2, 4-6. I will not rehash it here. I will simply describe relevant Illinois law and explain why evidence of the 510(k) process should be excluded in this case.

A. Relevance under Illinois's Consumer-Expectation and Risk-Utility Tests

In order to recover on a product liability claim under Illinois law, a plaintiff must prove that the injury resulted from a condition of the product that was "unreasonably dangerous." *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 335 (Ill. 2008). A product may be unreasonably dangerous based on a defect in its design, manufacturing, or warnings. *Id.*; *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002). A plaintiff may establish that a product is unreasonably dangerous using either the consumer-expectation test or the risk-utility test, or both. *Mikolajczyk*, 901 N.E.2d at 336.

Under the consumer-expectation test, "the plaintiff may introduce 'evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an

intended or reasonably foreseeable manner.'" *Mikolajczyk*, 901 N.E.2d at 336 (quoting *Lamkin v. Towner*, 563 N.E.2d 449, 457 (Ill. 1990)). The plaintiffs argue that because this test focuses on how "safely" an ordinary consumer expects a product to perform, evidence of 510(k) clearance is per se inadmissible. (*See* Pls.' Mot. in Limine [Docket 140], at 8). Ethicon does not respond to this argument, and I agree with the plaintiffs. Clearance to market under the 510(k) process does not relate to the safety of a product. Therefore, the 510(k) process is irrelevant and inadmissible under Federal Rule of Evidence 402 with respect to the consumer-expectation test.

In contrast to the consumer-expectation test, "[t]he risk-utility test . . . is a multifactor analysis and [is] therefore[] much broader in scope[.]" *Mikolajczyk*, 901 N.E.2d at 352. Under this test, a plaintiff "may introduce evidence that the product's design proximately caused his injury. If the defendant thereafter fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs, the plaintiff will prevail." *Mikolajczyk*, 901 N.E.2d at 336. (internal quotations omitted). Illinois courts consider a wide range of factors under the risk-utility test, including

> "the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing," as well as "the likely effects of the alternative design on production costs; the effects of the alternative design on product longevity, maintenance, repair, and esthetics; and the range of consumer choice among products."

Id. at 352 (quoting Restatement (Third) of Torts: Product Liability § 2, cmt. f, at 23 (1998)).

The point of all these factors, however, is to assist the jury in determining whether the benefits of a product outweigh the product's "risk of danger." *Mikolajczyk*, 901 N.E.2d at 336. A plaintiff must prove that "the magnitude of the danger outweighs the utility of the product, as designed." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 257 (Ill. 2007). A product's utility must

be weighed against its "risk of harm" or "gravity of harm." *Id.* (quoting 63A Am. Jur. 2d *Products Liability* § 978, at 146-47 (1997)).

The plaintiffs argue that because the 510(k) process is not a safety standard, it does not factor into the jury's consideration of either the risk or utility of the product, and it is therefore irrelevant under the risk-utility test. (*See* Pls.' Mot. [Docket 140], at 9). Ethicon does not respond to this argument. The focus of the risk-utility test is on a product's risk of harm compared with the product's utility. The 510(k) process is irrelevant to this analysis because it does not relate to safety or efficacy of a product.

B. Regulatory Compliance

While ignoring the plaintiffs' arguments that the 510(k) process is irrelevant under the consumer-expectation and risk-utility tests, Ethicon contends that regulatory compliance is relevant to the plaintiff's claims. In support, Ethicon cites *Rucker v. Norfolk & W. Ry. Co.*, 396 N.E.2d 534 (1979), where the court held that evidence of compliance with then-existing federal standards was admissible in determining whether a railroad tank car was unreasonably dangerous. The tank car in question collided with a boxcar and exploded, killing a railroad employee. The tank car was manufactured before federal regulations required a "'headshield,' a protective device that would shield the car from damaging contact with other cars and objects." *Rucker*, 396 N.E.2d at 536. The court stated that:

> [E]vidence of compliance with Federal standards is relevant to the issue of whether a product is defective, as well as the issue of whether a defective condition is unreasonably dangerous, as GATX contends. If the product is in compliance with Federal standards, the finder of fact may well conclude that the product is not defective, thus ending the inquiry into strict liability. If a finding is entered that the product is defective, evidence of compliance becomes additionally relevant to the issue of whether the defective condition is unreasonably dangerous. The fact of compliance may indicate to the finder of fact that the defect is not unreasonably dangerous.

Id. at 536-37 (citation omitted).

Contrary to Ethicon's contentions, *Rucker* does not mean that compliance with *any* federal regulation is admissible. Rather, the regulation must relate to the safety or efficacy of a product. In fact, the court stated that "it would be reasonable to conclude that the purpose of the [headshield] regulations is to insure greater safety . . . ." *Id.* at 537. And just three years after *Rucker*, the Illinois Supreme Court explicitly stated that *Rucker* concerned the admissibility of *safety* regulations: "In *Rucker* . . . this court held that evidence of a product's compliance with governmental *safety* standards is relevant and admissible in a product liability case on the issues of whether the product is defective and whether a defect in the product is unreasonably dangerous." *Moehle v. Chrysler Motors Corp.*, 443 N.E.2d 575, 577 (Ill. 1982) (emphasis added).

Ethicon also cites *Sosnowski v. Wright Med. Tech., Inc.*, 2012 WL 1030485 (N.D. Ill. Mar. 27, 2012). There, the court granted summary judgment to a medical device manufacturer after considering, among other things, evidence that the medical device received 510(k) clearance. *Sosnowski*, 2012 WL 1030485, at *3-4. In considering the "industry standards factor" under the risk-utility test, the court noted that the plaintiff did "not dispute that the defendant received clearance from the FDA to sell the [device]." *Id.* at 4. The court did not consider whether the 510(k) process relates to the safety of a product. The court merely noted that the plaintiff argued 510(k) clearance "does not involve rigorous review." *Id.* Further, the court did not consider whether the 510(k) process is admissible in spite of Federal Rules of Evidence 402 and 403. *Sosnowski* is therefore not on point.

None of the other cases cited by Ethicon stands for the proposition that compliance with *non-safety* regulations is relevant to whether a product is unreasonably dangerous. *See, e.g.*,

Ruffiner v. Material Serv. Corp., 506 N.E.2d 581, 58-59 (Ill. 1987) (finding that standards for fixed ladders in factories and industrial plants were not relevant to plaintiff's claim that tugboat ladder was unreasonably dangerous, even though the standards were "animated by a concern for safety"); *Estate of Carey v. Hy-Temp Mfg. Inc.*, No. 82-c-7171, 1991 WL 161394, at *4 (N.D. Ill. Aug. 19, 1991) ("The jury shall be instructed as to the applicable law regarding compliance with safety regulations. Accordingly, plaintiffs' motion to prevent defendants from arguing that compliance with safety regulations bars liability is inappropriate."); *Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105, 1109 (Ill. Ct. App – 1st Dist. 1984) (discussing admissibility of FDA approval process for prescription drugs).

C. Punitive Damages

Finally, Ethicon argues that evidence of regulatory compliance is relevant to the plaintiffs' claim for punitive damages. However, Ethicon fails to explain this argument or cite any controlling law in support. Ethicon simply states that its "briefs in support of summary judgment on punitive damages under the law of New Jersey and Georgia explain this." (Resp. in Opp. to Pls.' Mot. in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 190], at 6). Ethicon's brief under New Jersey law, the law that the parties agree controls punitive damages in this case, does not argue that regulatory compliance with non-safety standards is relevant to the punitive damages claim. Instead, that brief focuses on whether the New Jersey Products Liability Act precludes recovery of punitive damages in this case. That is a separate issue, which I will address separately.

Whether or not compliance with *non-safety* regulations is relevant to punitive damages in this case, I hold that 510(k) evidence is inadmissible because of its potential to confuse the issues and mislead the jury.

III. Conclusion

In short, Ethicon has not identified any cases, statutes, or other authorities indicating that 510(k) clearance, which focuses on equivalence, not safety, is relevant in determining whether a product is unreasonably dangerous under the law applicable to this case. And, to the extent that authorities identified by Ethicon *do* indicate relevance, I again **FIND** that evidence of the 510(k) process is inadmissible under Federal Rule of Evidence 403 because of its potential to confuse the issues and mislead the jury. For these reasons, the Plaintiffs' Motion in Limine No. 1: To Exclude FDA 510(k) Evidence [Docket 139] is **GRANTED**.

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

ENTER: May 12, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE