IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION, Plaintiffs, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	Civil Action No. 1:17-MD-2782-RWS [Lead Case MDL 2782]

ORDER

This matter is before the Court on Plaintiffs' Motion *in Limine* to Exclude Evidence Relating to the United States Food and Drug Administration ("FDA") or its Processes ("Motion"). [Docs. 605, 634, 635].

BACKGROUND

PHYSIOMESH™ Flexible Composite Mesh ("Physiomesh"), a medical device, is a synthetic polypropylene-based mesh indicated for the repair of hernia defects. Physiomesh was structured with the polypropylene mesh between two layers of a Monocryl® anti-adhesive barrier. Physiomesh was conceived as an intraperitoneal onlay mesh ("IPOM") and designed to be implanted

laparoscopically and within the abdominal cavity. In 2010, the FDA cleared Physiomesh for market pursuant to its 510(k) process, which means that the FDA found that Physiomesh was "substantially equivalent" to another device already available on the market.

Defendant Ethicon, Inc., and its parent company, Defendant Johnson & Johnson (collectively, "Ethicon"), designed, manufactured, distributed, and sold Physiomesh worldwide between April 2010 and May 2016.[1]

Plaintiffs in these consolidated multidistrict proceedings consist of individuals who were implanted with Physiomesh to treat medical conditions, primarily for laparoscopic hernia repair. In some cases, Plaintiffs also include the spouses of individuals implanted with Physiomesh. Plaintiffs bring claims against Ethicon alleging strict product liability for defective design, failure to warn, and manufacturing defects, as well as liability for negligence, violation of state consumer protection laws, gross negligence, and loss of consortium. [Doc. 239 - Master Long Form Complaint ("Master Complaint"), *passim*]. Plaintiffs seek to recover compensatory damages, restitution and disgorgement of profits, reasonable

[1] Johnson & Johnson Medical GmbH, an entity owned or affiliated with Defendants, manufactures Physiomesh in Germany and does business as Ethicon, Inc., which is listed as the owner/operator of Johnson & Johnson Medical GmbH.

attorneys' fees, costs, economic damages, punitive damages, survival damages (if applicable), and wrongful death damages (if applicable). [Master Complaint, Prayer for Relief].

ISSUE

In anticipation of the first bellwether trial, Plaintiffs seek to preclude Ethicon from introducing any argument, evidence, or testimony related to the FDA or its processes, including the Physiomesh regulatory history (or "FDA evidence"), pursuant to Rules 402 and 403 of the Federal Rules of Evidence. According to Plaintiffs, evidence related to the FDA and its processes is inadmissible for two reasons: (1) FDA evidence is irrelevant to the product liability issues to be decided; and (2) the probative value of FDA evidence is substantially outweighed by the potential to confuse, mislead, and prejudice the jury.

Ethicon opposes Plaintiffs' Motion and suggests that FDA evidence, including the Physiomesh 510(k) clearance process, along with FDA communications with Ethicon in connection with Physiomesh, are highly relevant and necessary to rebut Plaintiffs' claims. Ethicon also contends that it should be able to rely upon other FDA evidence, including the FDA's statements regarding the risks of hernia mesh devices generally. Ethicon argues that the reasonableness

of its actions concerning the design, labeling, and marketing of Physiomesh, must be considered within this context.[2]

DISCUSSION

I. Choice of Law

Title 28, United States Code, Section 1407, grants an MDL transferee court the authority to rule on pretrial motions. In multidistrict litigation cases involving diversity jurisdiction, "choice-of-law for . . . pre-trial motions depends on whether they involve federal or state law." Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 752 (4th Cir. 2014). "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located." In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). However, when analyzing matters of state law, "the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." Id. (internal citations omitted).

"An order *in limine* allows the trial court to rule in advance of trial on the admissibility and relevance of certain forecasted evidence." Salinero v. Johnson &

[2] Ethicon goes so far as to contend that not to allow the jury to consider any of the evidence demonstrating its efforts to comply with federal regulatory standards would amount to a violation of due process.

Johnson, 2019 WL 7753438, at *1 (S.D. Fla. September 25, 2019) (citing Luce v. United States, 105 S. Ct. 460, 462-63 nn. 2, 4 (1984)). Plaintiffs' Motion *in Limine* implicates federal evidentiary rules, and Plaintiffs bear the burden to establish the inadmissibility of the evidence they seek to exclude. Id. (citations omitted).

Although Plaintiffs' Motion *in Limine* was filed in the Lead MDL Case, 1:17-md-2782-RWS, the Motion is in response to the First Trial Case, which is scheduled to commence January 25, 2021. [MDL 2782, Doc. 621 – PPO No. 22, ¶ 2(a) (Jim B. Crumbley and Diane Crumbley v. Ethicon, Inc., et al. ("Crumbley"), Civil Action No. 1:18-cv-748-RWS); MDL 2782, Doc. 677 – PPO No. 24].[3] The parties agree that Georgia state law governs the substantive claims asserted in Crumbley.

The Court's ruling is intended to apply beyond the Crumbley trial and may be construed broadly.[4]

[3] The instant ruling impacts the testimony of several proposed witnesses, including, *inter alia*, Defendants' proposed expert witness Timothy A. Ulatowski, Defendants' non-retained expert and Senior Director of Regulatory Affairs, Reynaldo Librojo, Defendants' Director of Global Strategic Marketing for Hernia, Martin Chomiak, and Defendants' former Medical Director, Jeffrey Hammond.

[4] Defendants posit that the Court cannot conduct a Rule 403 analysis "without knowing either the applicable law or the particular facts" in dispute. [Doc. 634 at 19].

The Court begins with a summary of the regulatory framework.

II. FDA Review and the 510(k) Process

Prior to 1976, medical devices did not require premarketing approval by the FDA. 21 U.S.C. § 360e(d)(2). Generally, the premarketing approval ("PMA") process requires the proponent of a new medical device "to demonstrate a 'reasonable assurance' that the device is both 'safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling'" before the device may be marketed and sold. Eghnayem v. Boston Sci. Corp., 873 F.3d 1304, 1317 (11th Cir. 2017) (citations omitted).

However, in 1976, Congress enacted the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic v. Lohr, 116 S. Ct. 2240, 2245 (1996) (internal citation and quotation marks omitted). Toward this end, the MDA "established various levels of oversight for medical devices, depending on the risks they present." Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1003 (2008). The MDA tasked the FDA with classifying all medical devices on the market in 1976. 21 U.S.C. § 360c(b)-(d).

Pursuant to the MDA's statutory classification, Class I devices are "subject to the lowest level of oversight: 'general controls,' such as labeling requirements."

Riegel, 128 S. Ct. at 1007 (internal citation omitted). In addition to meeting the Class I device "general controls," Class II devices may be subject to "special controls" such as performance standards and post-market surveillance measures[.]."[5] Id. Class III devices pose the most risk to the public and "receiv[e] the most federal oversight." Id. (citation omitted).[6]

As a result of the MDA, medical devices intended for human use are classified as Class III devices by default and must undergo the PMA process, unless exempted. Salinero, 2019 WL 7753438 at *2 (citations omitted). A device may be exempted in one of two ways. Lohr, 116 S. Ct. at 2247. First, devices already on the market prior to the MDA were allowed to stay on the market (through a grandfathering process) until the FDA completed its PMA process or determined that a lesser classification was in order. Id.; 21 U.S.C. § 360e(b)(1)(A).

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[5] The "special controls" for Class II devices were introduced via The Safe Medical Devices Act of 1990 ("SMDA"). [Doc. 634-13, Defs. Exhibit 12 – *FDA Draft Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications*] (Dec. 27, 2011) (citing Section 513(a)(1)(B) of the FD&C Act (21 U.S.C. § 360c(a)(1)(B)) (examples of special controls).

[6] "[A] device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" Riegel, 128 S. Ct. at 1003 (quoting § 360c(a)(1)(C)(ii)).

Second, upon notification to the FDA, devices found to be "substantially equivalent" to a device brought to market after 1976 and classified as a Class I or Class II device could also be exempt from PMA. Id.; 21 U.S.C. § 360e(b)(1)(B). "The [FDA]'s review of devices for substantial equivalence is known as the § 510(k) process. . . ." Riegel, 128 S. Ct. at 1004; 21 U.S.C. § 360(k); see also 21 C.F.R. § 807.92 (outlining content and format of 510(k) summary).[7]

Notably, the FDA 510(k) and PMA of a product are different processes, with "distinct requirements and different goals." Eghnayem, 873 F.3d at 1317. "PMA 'is federal safety review,' . . . whereas 'the 510(k) process is focused on equivalence, not safety[.]'" Id. (internal citations and quotation marks omitted). In Lohr, the Supreme Court explained:

> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."

116 S. Ct. at 2247-48 (internal citations omitted). Likewise, in Riegel, the Supreme Court reiterated that premarket approval is a "rigorous process" that requires a manufacturer to "submit what is typically a multivolume application" containing

[7] "510(k)" refers to its section number in the original act [21 U.S.C. § 360(k)].

safety information for the FDA's review, including reports on safety studies and investigations, a statement concerning how the device is made, a description of the methods and controls used in manufacturing, samples or device components, and proposed labeling. 128 S. Ct. at 1004. The FDA grants approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness," § 360e(d), after "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Id. (quoting § 360c(a)(2)(C)).

III. Physiomesh 510(k) Clearance, Effective April 9, 2010

On December 18, 2009, Defendants submitted the Physiomesh 510(k) application seeking to be exempt from the PMA. In the 510(k) application, Defendants identified three different predicate devices, all established as Class II devices, post-1976. The predicate devices identified in the application are: PROCEED Mesh (established as a Class II device in 2003), ULTRAPRO Hernia System (established as a Class II device in 2007), and ULTRAPRO Mesh (established as a Class II device in 2004). [Doc. 634, Defendants' ("Defs.")

Exhibit 1 – Traditional 510(k) Premarket Notification – ETHICON PHYSIOMESH].[8]

In order to be deemed "substantially equivalent" to one of these predicate devices for purposes of 510(k), Ethicon was required to show either that Physiomesh "has the same technological characteristics as [one or more of] the predicate device[s] *or* has different technological characteristics and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device." Salinero, 2019 WL 7753438 at *2 (citations omitted; emphasis added); 21 U.S.C. § 360c(i)(1)(A) (defining substantial equivalence). Under the first of these two options, no safety or efficacy showing is contemplated.

Here, Defendants presented Physiomesh to the FDA as a device for the same intended use and possessing "the same technological characteristics as the predicate[s.]" [Defs. Exhibit 1]. Defendants represented that, "[p]erformance testing, including bench and animal testing[,] demonstrate that the PHYSIOMESH is as safe and effective as the predicate devices." [Defs. Exhibit 1].

[8] Because all three predicate devices were Class II devices first marketed after enactment of the MDA, no PMA was required of any Physiomesh predicate.

Physiomesh was classified as a Class II device, and on April 9, 2010, Defendants obtained 510(k) clearance from the FDA to bring Physiomesh to market.[9] It is undisputed that the FDA has never adopted any special controls for surgical mesh generally or for Physiomesh. [Doc. 605-1, Plaintiffs' ("Pls.") Exhibit 1 -- Deposition of Timothy A. Ulatowski ("Ulatowski Dep.") 204, 206].

IV. Analysis

For the reasons set forth below, the Court, in its discretion, finds that Plaintiffs have met their burden to demonstrate that FDA evidence is properly excluded under both FED. R. EVID. 402 and 403.

A. FDA Evidence Has Minimal Probative Value, If Any

Plaintiffs argue that FDA evidence is irrelevant and does not make any of the issues to be decided at trial more or less probable. See FED. R. EVID. 402. Plaintiffs contend that evidence of the FDA process and the like has minimal probative value, at best.

Caselaw overwhelmingly supports Plaintiffs' position that 510(k) clearance is about something less than safety and "is of little or no evidentiary value." In re C.R. Bard, Inc. ("Cisson"), Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913, 920

[9] In 1988, the FDA determined that all "surgical mesh" would be characterized as Class II. 53 Fed. Reg. 23856 (June 24, 1988); see also 21 C.F.R. 878.3300 (defining surgical mesh).

(4th Cir. 2016) (citations omitted) (affirming MDL trial judge ruling excluding FDA 510(k) evidence for all purposes under Georgia product liability law). As discussed *infra*, even the courts that have admitted limited FDA evidence or allowed for that possibility acknowledge its limited probative value for this reason.[10]

With that said, Defendants are correct that Lohr and Eghnayem are not entirely on all fours with the facts here given that neither case involved the same regulatory pathway to market as Physiomesh.[11] [Doc. 634]. To a lesser degree, Defendants also argue that Lohr does not apply because it did not consider the

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[10] See, e.g., Keen v. C.R. Bard, Inc., 2020 WL 4818801, at **2-3 (E.D. Pa. August 19, 2020); accord In re Bard IVC Filters Prod. Liab. Litig., 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018); Winebarger v. Bos. Sci. Corp., 2015 WL 5567578, at *7 (W.D.N.C. September 22, 2015).

[11] Defendant describes the two different uses of 510(k) as follows:

> (1) The transitional use Congress allowed for devices that FDA had not yet convened a medical panel to classify, which allowed clearance based on equivalence to devices only on the market before 1976[; and]
> (2) The use Congress intended to be permanent, in which the device is cleared based on equivalence in safety and effectiveness to a device type which FDA has placed in Class II as not presenting an unreasonable risk.

[Doc. 634 at 10-11]. And see Salinero, 2019 WL 7753438 at *4 (citation omitted) (rejecting identical argument made by Ethicon and highlighting that "[the predicate chain of devices] show how clearance was based on 510(k)'s "equivalence" review – based on comparison to predicate devices – rather than an independent safety assessment").

SMDA, which added new requirements that "expressly included safety and effectiveness in the 510(k)-review process for Class II medical devices." [Doc 634 at 9-16].[12] Concerning the regulatory pathway, Defendants point out that the device in Lohr was found substantially equivalent to a Class III pre-1976 device, while Physiomesh entered the market after being found substantially equivalent to a post-1976 Class II device. According to Defendants, the Class II designation means that the FDA determined that no assurance of safety and effectiveness was necessary. [Doc. 634 at 12]. In other words, Ethicon's only avenue to bring Physiomesh to market was through 510(k) because PMA is not available for a Class II device. 21 U.S.C. § 360c(a)(1)(B). It is also true that the Eleventh Circuit did not address whether the analysis would change for a pre-1976 Class III device that obtained 510(k) clearance. Eghnayem, 873 F.3d at 1318 n.3; Salinero, 2019 WL 7753438, at *4 (alteration in original) (acknowledging that "Eghnayem did not address the post-1976 predicate rationale that Ethicon invokes here"). In the

[12] The Court need not address Defendants' arguments based upon the SMDA. Put simply, the SMDA had no significant impact on the level of review a new device is required to undergo. Contrary to Defendants' argument, another court observed that the SMDA "created a more tangential relationship between FDA clearance and the safety-focused PMA process" by eliminating the requirement that a post-1976 device rely upon at least one pre-MDA predicate device (that underwent a formal PMA safety review) in its chain/family tree. See Kaiser v. Johnson & Johnson, 2018 WL 1358407, at *2 (N.D. Ind. 2018), aff'd, 947 F.3d 996 (7th Cir. 2020).

Court's view, this is a distinction without a difference.[13] Even so, the distinction does not negate the teachings of the Supreme Court decisions on this subject matter. See Eghnayem, 873 F.3d at 1318 (signaling approval of lower courts taking into account and applying the rationale of Lohr and Riegel notwithstanding that they were preemption cases primarily).

As emphasized by Plaintiffs, the 510(k) clearance is "a qualification for an exemption" -- a way around – actual safety review. Riegel, 128 S. Ct. at 1007; accord Cisson, 810 F.3d at 920-21 (citations omitted). While Class II devices are not required to undergo PMA, the fact remains that 510(k) clearance is not evidence that Defendants satisfied any standard of care in designing the Physiomesh device. By definition, a Class II device is a "[d]evice[] for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance." 21 U.S.C. § 360c(a)(1)(B).

[13] Within a negligence *per se* context, the Fourth Circuit drew an analogy between obtaining 510(k) clearance and having a driver's license – neither says anything about safety. Talley v. Danek Medical, Inc., 179 F.3d 154, 161 (4th Cir. 1999) (holding that requirement for pre-market approval under the MDA "lacks any independent substantive content," failure to comply is "analogous to the failure to have a driver[']s license," and MDA does not establish the standard of care).

In this case, Physiomesh was described to the FDA as a device for the same intended use and with the "same technological characteristics" as its predicates. [Ulatowski Dep. 213-17]. And none of the three predicate devices in the "family tree" of Physiomesh has ever been approved by the FDA or determined by the FDA to be safe and effective. [Ulatowski Dep. 257]. While Defendants argue that 510(k) clearance of Physiomesh is probative, the Seventh Circuit recently explained that, under the "same technological characteristics" avenue for 510(k) clearance, the FDA's "comparison [between the predicates and the proffered new device] ***does not consider safety***." Kaiser, 947 F.3d at 1005; see also Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1369 n.1 (11th Cir. 1999) (emphasizing the limited scope of 510(k) clearance and that focus is on equivalence of preexisting predicate device "regardless of how unsafe or ineffective the grandfathered device happens to be"). Moreover, it is undisputed that the FDA has never adopted special controls for Physiomesh. The Physiomesh 510(k) clearance merely permitted Physiomesh to get in the game and compete. Ethicon asks the Court to ignore the market-driven realities that led to the 510(k) process.

In support of its argument, Ethicon provides a November 2018 publication of the FDA as evidence that the FDA has strengthened its 510(k) requirements. [Doc. 634-15, Defs. Exhibit 14 – *FDA Has Taken Steps to Strengthen The 510(k)*

Program]. The November 2018 publication discusses ways the FDA has clarified its process and implemented attempted improvements between 2014 and 2018.[14] In addition, Ethicon proffers similar FDA guidance materials that pre-date the Physiomesh 510(k) clearance; the most substantive of which was issued on December 27, 2011 (49 pages of "FDA Draft Guidance"). [Docs. 634-12 thru 634-14, Defs. Exhibits 11-13]. However, Physiomesh was cleared in 2010.[15] No matter the steps taken by the FDA *after 2010* to make the 510(k) process more demanding, those increased safety measures had no bearing on the FDA's review of Physiomesh and, therefore, have no relevance here.[16]

Accepting Defendants' proposition that 510(k) clearance for a Class II device has a safety component, the regulatory pathway has little to do with whether Ethicon's Physiomesh design was reasonable. Because the 510(k) clearance

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[14] As for any impact of touted changes prior to 2010, the FDA attributes an increase in the number of pages in 510(k) applications (due to a request for more content). [Defs. Exhibit 14 at 1 ("average number of pages for each 510(k) has increased 150% since 2009")]. There is also mention that "[s]ince 2009, the time spent reviewing each 510(k) submission has increased 32%. . . ." [Defs. Exhibit 14 at 7].

[15] Physiomesh was withdrawn from market by Ethicon in May 2016. Physiomesh was already off the market in 2018 when the FDA published this document.

[16] The November 2018 FDA publication also represents "We [the FDA] also clarified how to incorporate Benefit-Risk Factors into certain 510(k) decisions." [Doc. 634, Exhibit 14 at 1]. The FDA's benefit-risk evaluation *for purposes of 510(k)* could easily be misconstrued by a jury seeking to apply Georgia law.

relevant to Physiomesh does little to inform as to its safety, its probative value is minimal, if any.

Moreover, as discussed below, any probative value is substantially outweighed by the risk of misleading and confusing the jurors.

B. The Probative Value of FDA Evidence Is Substantially Outweighed by the Risk of Unfair Prejudice, Waste of Time, and Misleading and Confusing Jurors

Plaintiffs next contend that FDA evidence is the type of evidence that courts have consistently excluded pursuant to Rule 403 on the grounds of unfair prejudice, waste of time, undue delay, and misleading and confusing jurors. Having surveyed the relevant caselaw, this Court agrees and finds that the risk of misleading and confusing jurors is the most concerning of these potential harms.

As an initial matter, there is a legitimate and weighty concern that jurors might place too much emphasis on the FDA's 510(k) clearance of Physiomesh. Numerous courts, including Ethicon's primary authority, have acknowledged the risk that jurors may place undue weight on FDA evidence or assign an imprimatur of legitimacy to FDA 510(k) clearance. See Eghnayem, 873 F.3d at 1318–19 (affirming trial court's exclusion of evidence relating to 510(k) clearance process under Rule 403 based upon potential for misleading and confusing jury and concern that the jury might think that "general federal regulatory compliance, not

state tort liability, was the core issue"); and see Salinerno, 2019 WL 7753438 at *3 (listing cases).

Speaking directly to 510(k) clearance based upon a post-1976 Class II device, the same regulatory pathway as Physiomesh, federal regulations caution:

> Submission of a premarket notification . . . and a subsequent determination [by the FDA] that the device intended for introduction into commercial distribution is substantially equivalent to a device . . . introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into [C]lass I or II, does not in any way denote official approval of the device. ***Any representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading*** and constitutes misbranding.

21 C.F.R. § 807.97 (emphases added). Here, the Court agrees that evidence regarding Physiomesh's 510(k) process is likely to mislead and/or confuse the jury by suggesting that FDA 510(k) clearance constitutes a certification of safety or by implying that Physiomesh underwent a more rigorous PMA, when in fact the 510(k) clearance only established equivalence to devices that were never tested via FDA's PMA.

Second, introduction of FDA evidence has the potential to lead to a "mini-trial" on the FDA and its processes, with experts battling over the meaning and significance of the FDA processes. This is borne out by the positions asserted by both parties concerning the proffered regulatory experts and their varying "expert"

opinions concerning the value and meaning of obtaining 510(k) clearance.[17] In short, a mini-trial on the FDA 510(k) clearance process and significance of other FDA evidence would be a colossal waste of jury time. The undersigned agrees with the weight of authority on this point.

Furthermore, many courts faced with this issue find that the potential for confusion cannot be remedied through a limiting instruction, as Ethicon suggests. The Eleventh Circuit in Eghnayem rejected the proposition that a limiting instruction could cure any potential harm. 873 F.3d at 1319 (limiting instruction "does not come close to tipping the scale" in the defendant's favor of admitting this evidence). Like this order *in limine*, the Court's decision regarding a limiting instruction is within the Court's "inherent authority to manage the course of trials." Luce, at 463 n.4 (citations omitted).

This Court is confident that exclusion of the FDA evidence will not disserve the parties and will instead allow the jurors to focus on the substantive factual questions that fall within the province of the jury.

[17] The parties' *Daubert* challenges [in large part] are addressed contemporaneously in separate orders.

D. Georgia Law Does Not Dictate A Different Result

Ethicon urges the Court to refrain from issuing an MDL-wide ruling excluding FDA evidence as sought in Plaintiffs' Motion. According to Ethicon, the Court cannot conduct the requisite analysis without considering the governing state law and the specific facts of each individual MDL case. As related to Crumbley, Ethicon refers to Georgia's product liability law, namely, adoption of what is known as the "risk-utility test," which permits jurors to consider Ethicon's compliance with federal standards as one of several factors in determining the reasonableness of the Physiomesh design. Ethicon also argues that its compliance with the FDA is probative concerning Plaintiffs' assertion that Plaintiffs are entitled to recover punitive damages based upon Ethicon's alleged willful and wanton conduct. The Court will briefly address both arguments.

With respect to strict liability defective design, Georgia law is not all that unique. Drawing upon the Third Restatement of Torts, many other states rely upon some form of risk-utility analysis, including as one of several factors, a manufacturer's compliance with federal standards or regulations.[18] See Banks v.

[18] See, e.g., Eghnayem, 873 F.3d 1304 (applying Florida law); Campbell v. Boston Sci. Corp., 882 F.3d 70 (4th Cir. 2018) (applying West Virginia law); Kaiser, 2018 WL 1358407 (applying Indiana law); Lewis, 991 F. Supp. 2d 748 (applying Texas law); Keen, 2020 WL 4818801 (applying Pennsylvania law); Winebarger, 2015 WL 5567578

ICI Americas, Inc., 264 Ga. 732, 734, 450 S.E.2d 671, 673 (1994) (citing, *inter alia*, Preliminary Draft No. 1 (April 20, 1993) Restatement (Third) of Torts: Products Liability, § 101) (adopting risk-utility balancing test for purposes of Georgia design defect cases and observing risk-utility is "general consensus" of other state product liability schemes); see also Lewis, 991 F. Supp. 2d at 754-55 (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998)).[19] According to the Georgia Supreme Court,

> Under the risk-utility test, ***compliance with federal standards or regulations is a factor for the jury to consider in deciding the question of reasonableness***, that is, whether the product design selected was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware. It does not render a manufacturer's choice of design immune from liability. That is not to say that evidence of such compliance is not significant, for it is. But, instead of acting as an impenetrable shield from liability, compliance, more appropriately, is to be a piece of the evidentiary puzzle.

Doyle v. Volkswagenwerk Aktiengesellschaft, 267 Ga. 574, 577, 481 S.E.2d 518, 521 (1997). Notably, Georgia courts acknowledge that a manufacturer's

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(applying North Carolina law); Tingey v. Radionics, 193 Fed. Appx. 747 (10th Cir. 2006) (applying Utah law).

[19] The Restatement provides that "a product's compliance with an applicable product ***safety*** statute or administrative regulation is properly considered in determining whether the product is defective[.]" RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (emphasis added). The comments to the Restatement reinforce that safety is key. Id., cmts. a and c.

compliance with federal standards, *when applicable*, is only one "piece of the evidentiary puzzle." Id. And, a manufacturer's compliance with federal standards or regulations that do not pertain to safety (i.e., FDA 510(k) clearance) are not probative of reasonableness and, therefore, not applicable. Ethicon correctly cites to Georgia law, yet, fails to recognize that Doyle involved substantive, concrete, and specific federal safety standards (i.e., safety belt requirements) – not merely notification or clearance to market a product. The federal standard the jury was allowed to consider as a factor in Doyle was the vehicle manufacturer's design and whether a shoulder harness, the then-existing standard prescribed by the Federal Motor Vehicle Safety Act for seat belts, could be deemed a defective design or support a cognizable defective design claim given expert testimony offered by plaintiff that the absence of a lap belt was a proximate cause of plaintiff's injuries. Doyle, 481 S.E.2d at 521. To the extent Ethicon asserts that Georgia law does not require regulatory compliance to involve *safety* in order to have probative value, that argument has been squarely rejected. See In re C.R. Bard, Inc. Pelvic Repair Syss. Prods. Lia. Litig. (Cisson), 2013 WL 11089794, at *2 (S.D. W.Va. July 1, 2013). The MDL judge in Cisson looked to Georgia's pattern jury instruction on design defect to support its holding that safety was critical to the risk-utility federal standard compliance factor and excluding FDA 510(k) evidence because the

process established equivalence and not safety.[20] Id.; but see In re Bard IVC Filter Prods. Lia. Litig., 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018) (stating minority view in opining that "nothing in Doyle suggests that only safety regulations may be relevant in design defect cases[,]" and finding 510(k) evidence relevant as to reasonableness of manufacturer's design).[21]

Likewise, Plaintiffs' punitive damages claim does not render FDA evidence of Ethicon's regulatory compliance related to Physiomesh admissible. When ruling on post-trial motions in one of the individual MDL Pelvic Repair Systems cases tried applying Georgia law, the MDL Judge rejected defendant's argument that the exclusion of FDA 510(k) evidence deprived it of a fair trial and prevented defendant from defending against claims alleging defective design and seeking punitive damages. See Cisson v. C.R. Bard, Inc., 86 F. Supp.3d 510, 516 (S.D. W.Va. 2015). The court explained in pertinent part:

> Bard's compliance with 510(k) does not make it more or less probable that Bard's conduct justified punitive damages under Georgia law. Georgia's Annotated Code provides for punitive damages when the defendant's actions exhibit "willful misconduct, malice, fraud,

[20] "The Georgia Pattern Jury Instructions state that the jury 'may consider proof of the manufacturer's compliance with federal or state *safety* standards. . . .'" Id. (quoting Georgia Pattern Jury Instruction 62.670) (emphasis added).

[21] Even so, the court recognized that "[t]he 510(k) process may not speak directly to the applicable standard of care under Georgia law. . . ." Id. at 1048.

> wantonness, or oppression." Ga. Code. Ann. § 51–12–5.1(b) (2014). Such conduct is not mitigated by compliance with 510(k), a regulation "intended merely to give manufactures the freedom to compete."

Id. (quoting Lohr, 116 S. Ct. at 2254). This Court finds the rationale in Cisson persuasive and the most consistent with the Supreme Court's teachings and Eleventh Circuit view of FDA evidence, discussed *supra*.

Ethicon cites to In re Bard IVC Filters as its primary authority that 510(k) clearance and other FDA evidence is probative of whether an award of punitive damages can be supported. 289 F. Supp. 3d at 1049. In Bard IVC Filters, there were claims asserted by plaintiffs that defendant "Bard withheld information from the FDA and otherwise failed to fully comply with the 510(k) regulations." Id. at 1049. As a result, the court explained that "[m]any of the relevant events in this case occurred in the context of FDA 510(k) review." Id. Even though the court deemed FDA 510(k) evidence relevant to punitive damages, namely, probative of defendant's "conscious indifference to the dangers posed by its device[,]" the court limited the parties' ability to rely upon the 510(k) clearance.[22] Id. at 1407. The facts of Bard IVC Filters are distinguishable based upon plaintiffs' allegation that

[22] The court restricted FDA evidence in a manner consistent with 21 C.F.R. § 807.97 by precluding evidence or argument by defendant that the 510(k) review process constitutes an approval or finding that the device is "safe and effective" and allowing plaintiffs to present evidence or argument that 510(k) regulations are not safety regulations. Id. at 1047.

Bard withheld information from the FDA and failed to comply with federal regulations. There is no such allegation brought against Ethicon here. Of course, Bard IVC Filters involved a different medical device, possibly calling for a different Rule 403 analysis. See Kaiser, 334 F. Supp. 3d at 938 (explaining why Bard IVC Filters analysis was not persuasive and noting "judgment call" made by trial judge).

Finally, the Court's ruling is bolstered by decisions from courts applying state product liability law of other states that provide for a rebuttable presumption that a device is not defective where a manufacturer complies with federal regulatory or substantive industry safety standards. See Eghnayem, 873 F.3d at 1319 (affirming trial court's exclusion of FDA evidence under Florida product liability law allowing rebuttable presumption product was not defective in favor of manufacturer where 510(k) clearance was only FDA review); accord In re Mentor Corp. Obtape Transobturator Sling Prods. Lia. Litig., 2016 WL 6138253, at *15 (M.D. Ga. October 20, 2016) (trial court applying Florida law did not err in excluding 510(k) evidence pursuant to Rule 403), aff'd sub nom. Taylor v. Mentor Worldwide LLC, 940 F.3d 582 (11th Cir. 2019); and see Tingey, 193 Fed. Appx. at 755 (applying Utah law and finding defendant manufacturer ineligible for rebuttable presumption provided for in strict liability defective design statute based

upon "conformity with government standards established for that industry" where manufacturer sought to rely on FDA 510(k) clearance as proof of conformity).

Notwithstanding application of Georgia law in the Crumbley bellwether trial, the Court finds that any probative value of the FDA 510(k) clearance is substantially outweighed by the risk of unfair prejudice, waste of time, and the likelihood of misleading and confusing jurors. Accordingly, the Court will exclude all FDA evidence related to the Physiomesh regulatory history in Crumbley, and the Court's ruling will apply equally to Plaintiffs and Ethicon.

E. Post-Market FDA Communications & FDA Published Materials on Surgical Mesh

Aside from the 510(k) clearance process, Ethicon contends that it should be able to introduce other FDA-related evidence, including post-market communications Ethicon had with the FDA concerning Physiomesh and FDA materials speaking to the most common and known risks associated with hernia repair, with or without surgical mesh.[23]

[23] Ethicon states that the FDA's review and description of the medical literature and adverse event reports is probative evidence of "the true risks of Physiomesh, the risks of alternatives to Physiomesh, that the risks were commonly known by physicians, and that Ethicon acted in good-faith in drafting its package inserts." [Doc. 634 at 3].

Ethicon contends that certain post-market exchanges and communications with the FDA are also relevant and/or support its defense. For instance, in 2014, approximately four years after Physiomesh was cleared for market, the FDA raised concerns about adverse event reports documenting tears and holes in Physiomesh and requested a three-year trend analysis as well as Ethicon' plan to address the issue. [Doc. 634-7, Defs. Exhibit 6]. Ethicon points to Plaintiffs' general expert Dr. Sean Orenstein and his reliance on the same 2014 correspondence from the FDA as a basis for his opinion that the mesh failure was not rare. [Doc. 634 at 24; Doc. 634-17, Defs. Exhibit 16]. Ethicon asserts that it must be allowed to respond and defend this claim.[24] The Court's ruling will apply to both Plaintiffs and Defendants alike. Plaintiffs (and Plaintiffs' experts) will not be permitted to testify or rely upon FDA evidence either, alleviating the need for Ethicon to respond. [Doc. 635 at 10].

Defendants also produce FDA "statements" concerning hernia mesh generally. Specifically, Defendants produce an FDA "Safety Communication," dated October 28, 2008, excerpts from the FDA website discussing the use of mesh

[24] According to Defendants, Ethicon was able to provide the FDA with its three-year trend analysis showing an overall rate of malfunction at 2.2 occurrences per 10,000 meshes (0.022%) in the past three years; a rate that did not trigger any patient safety signal. [Doc. 634-8, Defs. Exhibit 7].

and hernia repair and a summary of the most common adverse events, and a patient brochure on ventral hernia repair that is merely referenced (but not published) by the FDA. [Defs. Exhibits 8, 9, 10].

For the same reasons detailed, *supra*, the non-510(k) FDA evidence is not probative of the issues for the jurors deciding these product liability claims alleged by Plaintiffs.

CONCLUSION

For the reasons discussed, Plaintiffs' Motion *in Limine* to Exclude FDA Evidence [Doc. 605] is **GRANTED**.

However, because an order *in limine* is a preliminary ruling, "the [Court] is free, in the exercise of sound judicial discretion, to alter [or amend its] previous *in limine* ruling." Luce, 105 S. Ct. at 463; accord Salinero, 2019 WL 7753438, at *1 (citation omitted) ("A ruling in favor of a motion *in limine* can always change at the Court's discretion during the course of trial"). Thus, in the event Plaintiffs offer evidence at trial that opens the door to FDA evidence, the Court may reconsider its ruling.

SO ORDERED this 25th day of November, 2020.

RICHARD W. STORY
United States District Judge