IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

ROMONA WINEBARGER, and REX WINEBARGER, Plaintiffs,	)	
v.	)	**O R D E R**
BOSTON SCIENTIFIC CORPORATION, Defendant.	)	**Motions in Limine**

MARTHA CARLSON, Plaintiff,	)	
v.	)	
BOSTON SCIENTIFIC CORPORATION, Defendant.	)	

THIS MATTER is before the Court on motions in limine filed by the parties and all related filings. (Docs. 173−75, 177−79, 185, 199).

The above-referenced causes of action brought by Plaintiffs Romona and Rex Winebarger and Plaintiff Martha Carlson against Defendant Boston Scientific Corporation (BSC) were remanded to the Western District of North Carolina from the Southern District of West Virginia for trial. See In Re Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, MDL No. 2326.

On May 15, 2015, the claims were consolidated for trial by this Court. (Doc. 108). Jury trial is scheduled to begin October 5, 2015. (Doc. 111).

On September 16, 2015, the Court was informed by counsel that the Winebarger Plaintiffs and BSC had reached a settlement in principal. On September 18, 2015, the Winebarger Plaintiffs filed a Stipulation of Dismissal dismissing all of their claims against BSC without prejudice. (Doc. 198). For this reason, the instant Order addresses only the pending motions related to Plaintiff Carlson's claims against BSC.[1]

In 2010, Plaintiff Martha Carlson underwent a surgical procedure in North Carolina to treat pelvic organ prolapse and / or stress urinary incontinence. Dr. Kennelly, Carlson's surgeon, selected BSC's Uphold Vaginal Support System (Uphold), a pelvic or transvaginal mesh product, for implantation. Plaintiff Carlson's claims surviving summary judgment include: Negligent Design, N.C. Gen. Stat. § 99B-6 and Breach of Implied Warranty, N. C. Gen. Stat. §§ 25-2-314(1) and (2). Plaintiff also seeks to recover punitive damages.

The motions in limine tend to fall into one of several categories, with the majority having been previously addressed in MDL 2326 consolidated pretrial proceedings and/or in select bellwether trials before The Honorable Joseph R. Goodwin, U.S. District Judge, Southern District of West Virginia ("MDL Judge").[2] A significant number of the motions in limine were considered premature and denied without prejudice by the MDL Judge subject to specific

[1] Plaintiffs' Motion in Limine No. 2 seeking to exclude evidence related to Romona Winebarger's prior criminal convictions (Doc. 173) is rendered moot. Defendant's contention that its Motions in Limine Nos. 2, 5, 18, 19, 25, and 26 are also rendered moot is not as obvious. (Doc. 199). The Court's evaluation of BSC's Motions in Limine is frustrated by the overall lack of specificity of certain motions and BSC's proposal that broad categories of evidence be excluded altogether. More importantly, BSC glosses over the fact that much of the evidence placed at issue by BSC's motions is offered by Plaintiff for multiple purposes, including notice to BSC of the inadequacy of its design, feasibility of an alternative design, the severity of potential injuries, and / or punitive damages. For this reason, many of these evidentiary issues will necessarily depend upon the specific objection made at trial.

[2] MDL 2326 is one of seven multidistrict cases assigned to Judge Goodwin that involve pelvic or transvaginal mesh devices. See generally Transfer Orders from MDL Judge. (Docs. 102 / Exh. 1). A more detailed factual background of Plaintiff's claims may be found in the Memorandum and Opinion and Order resolving the parties' respective summary judgment motions. (Carlson Docs. 98, 101).

objection at trial and the benefit of both context and proper evidentiary foundation. In fact, it is the practice of this Court to defer ruling on motions in limine raising evidentiary issues until the evidence is underway and the question of admissibility is squarely presented at trial. Notwithstanding the usual practice, to the extent deemed appropriate, the undersigned will attempt to provide counsel some guidance in advance of trial on the subjects raised in the parties' respective motions.

I. Prior MDL 2326 Rulings On Evidentiary Matters

Given the procedural posture, the Court first addresses BSC's contention that the MDL Judge's motion in limine rulings are not binding on this Court and likewise that the MDL Judge's decisions should not be considered persuasive authority.[3] BSC asks this Court to look at many issues afresh while Plaintiff accuses BSC of attempting a "fourth bite at the apple." BSC further suggests that authority relied upon by Plaintiff involves different products or devices, different state law schemes, and, in some instances, the authority relied upon does not involve claims brought against BSC but rather other pelvic mesh product manufacturers.

Since Plaintiff Carlson's implant procedure occurred in North Carolina, her substantive claims are governed by North Carolina law, namely, the North Carolina Product Liability Act, Chapter 99B, and the North Carolina Commercial Code, Chapter 25.[4] Despite the lack of a

[3] See Eghnayem v. Boston Scientific Corp., No. 2:12CV7965 (S.D.W.Va. October 28, 2014) (involving the Pinnacle Pelvic Floor Repair Kit ("Pinnacle")); Sanchez v. Boston Scientific Corp., No. 2:12CV5762 (S.D.W.Va. February 12, 2015)(involving implant of 2 devices – Pinnacle Pelvic Floor Repair Kit ("Pinnacle") and Advantage Fit Transvaginal Mid-Urethral Sling System ("Advantage")); Hall v. Boston Scientific Corp., No. 2:12CV8186 (S.D.W.Va. February 27, 2015) (involving the Obtryx Transobturator Mid-Urethral Sling System ("Obstryx")); and Tyree, et al. v. Boston Scientific Corp., No. 2:12CV8633 (S.D.W.Va. October 17, 2014) (("Obstryx").

[4] See April 2015 MDL Memorandum Opinion and Orders – Defendant's Motion for Summary Judgment setting out choice of law principles and rationale, namely, the doctrine of lex loci delicti, for applying North Carolina substantive law to the Winebargers' claims (MDL 2326 No. 2:13CV5475; Doc. 97) and Carlson's claims (MDL 2326 No. 2:13CV28892; Doc. 37).

Model Uniform Products Liability Act, all of the divergent statute product liability schemes are grounded in tort / negligence.[5] For this reason, there are essential common law principles that apply no matter the state law.

Likewise, it is true that the bellwether cases that proceeded to trial did not involve the Uphold, the specific pelvic mesh product at issue in these actions. However, the Uphold, and all of the other BSC pelvic mesh products, are manufactured using monofilament polypropylene mesh, and all are intended for use via permanent implantation in the human body. (Master Compl., ¶ 9). The heart of the negligent design claims brought by Plaintiff is that the polypropylene mesh used by BSC is "biologically incompatible with human tissue and promotes a negative immune response" causing injury after implantation. (Master Compl., ¶ 27). Thus, there are impactful evidentiary issues that have already been extensively litigated before the MDL Judge.[6]

Finally, notwithstanding BSC's persistence, the undersigned does not intend to re-litigate every issue one of the parties is unhappy with. To do so would defeat the purpose of the MDL consolidated pretrial proceedings and deprive this trial court of the benefit of the MDL Judge's expertise managing these complex product liability cases. See MANUAL FOR COMPLEX LITIGATION, FOURTH § 20.131 ("The objective of transfer is to eliminate duplication in

[5] Although several versions of the Model Uniform Products Liability Act ("MUPLA") were presented to the U.S. Congress between 1976 and the early 1980's, it was never enacted into law. See generally, Seals v. Sears, Roebuck and Co., Inc., 688 F.Supp. 1252, 1261 n. 6 (E.D.Tn. 1988) (internal citations omitted).

[6] In each of these motion in limine decisions, the MDL Judge applied the specific state law that governed the substantive product liability claims. In ruling on motions in limine, the MDL Judge relies heavily on his decision in one of the first bellwether trials in MDL 2327, which is one of the seven multidistrict cases assigned to Judge Goodwin that involve pelvic mesh devices. See Lewis v. Johnson & Johnson, 991 F. Supp.2d 748, 754 (S.D.W.Va. 2014) (MDL 2327, In re Ethicon, Inc.; Gynecare TVT ("TVT") surgical mesh product used to treat pelvic organ prolapse and stress urinary incontinence).

discovery, avoid conflicting rulings and schedules, reduce litigation cost, and save time and effort of the parties, the attorneys, the witnesses, and the courts.").

II. Plaintiff's Motion in Limine No. 1 − To Exclude Evidence Related to the FDA's 510(k) Process (Doc. 174)

Here, Defendant BSC pursued and obtained FDA 510(k) clearance for its Uphold product. Plaintiffs seek to exclude evidence related to the FDA's 510(k) clearance process pursuant to Rules 401, 402 and 403 of the Federal Rules of Evidence.

A basic understanding of the regulatory background is necessary to application of the federal rules.

> Before 1976, the Food and Drug Administration (FDA)'s rigorous premarketing approval did not extend to medical devices. The Dalkon Shield disaster, among others, prompted Congress to change that. . . . Today, the maker of a new "Class III" device-the most potentially dangerous-must apply for FDA approval and must cool its heels while the FDA thoroughly investigates the device's effectiveness. 21 U.S.C. § 360e(d)(2).
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> Because the 1976 amendments so abruptly changed the status quo, Congress was compelled to take the existing market into account. Any device on the market at the time was permitted to stay on the market until and unless the FDA, after conducting a review like that for new devices, ordered otherwise. 21 U.S.C. § 360e(b)(1)(A).
>
> This grandfather clause took care of assuring the continued availability of necessary equipment; on the other hand, it locked up market power in the current manufacturers, and it posed a risk that, if the manufacturer of some device went out of business, a much-needed product might be unavailable during the time it would take a new manufacturer to go through the FDA premarket approval process. Accordingly, Congress also exempted from premarket approval "substantially equivalent devices" to those on the market in 1976. 21 U.S.C. § 360e(b)(1)(B). Under this exemption, a manufacturer need only notify the FDA of its intent to market a device. If the FDA concludes that the device is "substantially equivalent," it notifies the manufacturer, which is then free to market its product. This limited FDA review is called "510(k)" after its section number in the original act [21 U.S.C. § 360(k)].[7]

[7] 21 U.S.C. § 360k(a) reads:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2)

Martin v. American Medical Syss., Inc., 116 F.3d 102, 103−04 (1997). "The [FDA]'s review of devices for substantial equivalence is known as the § 510(k) process . . . ." Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008).

The FDA 510(k) process was a response to codification of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq. See 21 U.S.C. § 360(k); 21 C.F.R. § 807.92 (outlining content and format of 510(k) summary). Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Medtronic v. Lohr, 518 U.S. 470, 474 (1996) (internal citation omitted). The MDA "established various levels of oversight for medical devices, depending on the risks they present." Riegel, 552 U.S. at 323. Class I devices are "subject to the lowest level of oversight: "general controls," such as labeling requirements." Riegel, 552 U.S. at 323 (internal citation omitted). In addition to meeting the Class I device "general controls," Class II devices are subject to ""special controls" such as performance standards and postmarket surveillance measures, § 360c(1)(1)(B)." Id. Class III devices "receiv[e] the most federal oversight."[8] Id. Only Class III devices require premarket approval ("PMA") by the FDA. Under the existing regulatory framework, most new Class III devices go to market via compliance with FDA 510(k).

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which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

[8] "In general, 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." Id. (quoting § 360c(a)(1)(C)(ii)).

Significantly, the FDA 510(k) and FDA premarket approval of a product are different processes. In Medtronic v. Lohr, a preemption case decided after codification of the MDA, 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."

518 U.S. 470, 478−79 (1996) (considering scope of express preemption language within 21 U.S.C. § 360k(a) [510(k)]; holding that not all common law negligence claims and state law product liability claims are preempted by § 360k(a); only those claims that are "different from, or in addition to" the requirements imposed by federal law are preempted) (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 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. Riegel, 552 U.S. at 317−18. 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., at 318 (quoting § 360c(a)(2)(C)).

The pelvic mesh products at issue in MDL 2326, including the Uphold, are all Class II medical devices.[9] (Master Compl., ¶ 10). As such, no formal review for safety or efficacy is required by the FDA. The only premarket hurdle is to comply with 510(k). In previous MDL 2326 rulings, the MDL Judge, Judge Goodwin, has consistently excluded all evidence pertaining to the 510(k) process based in part upon the Supreme Court's characterization of the 510(k) process in Medtronic as contemplating equivalency as opposed to safety. See e.g., Medtronic, 518 U.S. at 478−79; see also Riegel, 552 U.S. at 323 ("While 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence.") (internal quotation omitted); Martin, 116 F.3d at 104. The MDL Judge has also observed that FDA regulations view 510(k) in this manner and expressly state that 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97 (2012). The MDL Judge's rationale is as follows:

> I FIND that evidence of FDA clearance and enforcement should be excluded under Federal Rules of Evidence 402 and 403.
>
> Rule 403 provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Evidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value.

[9] On May 1, 2014, the FDA adopted a recommendation from the FDA Obstetrics & Gynecology Devices Advisory Committee to reclassify all pelvic organ prolapse devices as Class III. See http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM270402.pdf (last viewed 9/18/15).

Lewis v. Johnson & Johnson, et al., 991 F.Supp.2d 748, 754 (S.D.W.Va. January 15, 2014) (applying Texas state law).[10] Similarly, when ruling on BSC's Motion for Summary Judgment of Plaintiff's inadequate design claim, the MDL Judge emphasized his previous rulings that "510(k) clearance from the FDA is not relevant to state tort law." (Doc. 97, 10; Doc. 101, 9 n. 2).

The question here is whether the North Carolina Products Liability Act warrants a different result. BSC contends that for purposes of Plaintiff's inadequate or negligent design claim, pursuant to N. C. Gen. Stat. § 99B-6(b)(3), one of the factors that the jury must consider is whether BSC complied with "any applicable government standard."[11] BSC asserts that this language encompasses the FDA 510(k) process − that to preclude admission of any of this evidence would amount to error. According to Plaintiffs, the statutory language cited by BSC, read in context, refers only to "any applicable government standard" capable of informing the actual materials used in, and mechanics of the device design. Plaintiffs contend that the aim of §

[10] Relevant to BSC's argument that it should be able to introduce evidence that the FDA never pursued any enforcement actions against BSC with reference to the MDL 2326 devices, the Lewis decision precludes FDA 510(k) clearance evidence but also precludes evidence of FDA enforcement action on the same grounds. According to Lewis, FDA enforcement evidence "runs the same risk of misleading the jury" in that "[j]urors are likely to believe that FDA enforcement relates to the validity of plaintiffs' state law tort claims . . . ." Id., 991 F.Supp.2d at 755.

[11] In two of the MDL 2326 cases, the MDL Judge was asked whether 510(k) was a relevant "standard." In Hovey v. Cook, under Texas law, the MDL Judge opined that 510(k) clearance is not akin to a government safety standard, nor does it have any bearing on the industry standard. 2015 WL 1405558, * 4 (S.D.W.Va.). Instead, the MDL Judge stated that 510(k) is simply a process for determining substantial equivalency to a predicate device. Similarly, in Hall, the MDL Judge rejected the argument advanced by BSC that the 510(k) process was a "relevant standard" as contemplated by the Wisconsin statute. The statutory provision in Hall identified factors relevant to determining whether a defect rendered a product "unreasonably dangerous." The Wisconsin statutory scheme gave rise to a rebuttable presumption that a product was not defective given "[e]vidence that the product, at the time of sale, complied in material respects with **relevant standards**, conditions, or specifications adopted or approved by a federal or state law or agency . . . ." (Hall MIL, 3) (emphasis added). Admittedly, the statutory language in Hall is different than the North Carolina 99B-6(b)(3), but BSC's argument was essentially the same as in this case.

99B-6(b)(3) is safety and that "any applicable government standard" would logically speak to safety and efficacy as opposed to compliance with the FDA.

"Under North Carolina law, a products liability action based upon negligence requires the plaintiff to prove the following essential elements: (1) duty; (2) breach; (3) causation; and (4) damages." Durkee v. C.H. Robinson Worldwide, Inc., 765 F.Supp.2d 742, 748 (W.D.N.C. January 28, 2011) (quoting Smith v. Wyeth–Ayerst Laboratories Co., 278 F.Supp.2d 684, 706 (W.D.N.C. 2003)). "The products liability statute also provides:

> (a) No manufacturer of a product shall be held liable in any product liability action for the inadequate design or formulation of the product unless the claimant proves that at the time of its manufacture the manufacturer acted unreasonably in designing or formulating the product, that this conduct was a proximate cause of the harm for which damages are sought and also proves ... [that] at the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design ... that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
>
> (b) In determining whether the manufacturer acted unreasonably under subsection (a) of this section, the factors to be considered shall include, but are not limited to, the following:
>
> > (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product.
> >
> > (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm.
> >
> > (3) The extent to which the design or formulation conformed to **any applicable government standard** that was in effect when the product left the control of its manufacturer.
> >
> > (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to any applicable government or private standard that was in effect when the product left the control of its manufacturer.

> (5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation.
>
> (6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture.
>
> (7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

N. C. Gen. Stat. § 99B-6(a) and (b)(2015). The ruling on this issue depends upon whether the 510(k) clearance process is "any applicable government standard" for purposes of § 99B-6(b)(3). Chapter 99B does not define the statutory phrase "any applicable government standard," N.C. Gen. Stat. § 99B-1, and no North Carolina case has interpreted this phrase. The undersigned must attempt to discern how the Supreme Court of North Carolina would decide this issue. See Fontenot v. Taser Intern., Inc., 736 F.3d 318, 326 (4th Cir. 2013) (internal citation omitted).

"[A] court must read statutory provisions in light of the whole statute and the objects and policy of that statute." Blakely v. Wards, 738 F.3d 607, 629 (4th Cir. 2013) (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000)) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."; citing Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687, 698–700 (1995) (emphasizing that we must read a statute in light of its underlying purpose)).

The Court begins by considering the plain language of Section 99B–6(b)(3) and finds that the relevant phrase, "any applicable government standard," is unambiguous on its face. See e.g., Fontenot, 736 F.3d at 327 (citing Frye Reg'l Med. Ctr., Inc. v. Hunt, 510 S.E.2d 159, 163 (N.C. 1999)). While the "any applicable government standard" language is certainly broad, the law of the case in MDL 2326 is that 510(k) is not at all a "standard" and thus has no bearing on the reasonableness of the Uphold product design. Absent guidance from Chapter 99B, the Court

looks to the ordinary, everyday meaning of the term "standard." Black's Law Dictionary defines the term "standard" as "1. A model accepted as correct by custom, consent, or authority. [] 2. A criterion for measuring acceptability, quality, or accuracy." BLACK'S LAW DICTIONARY, TENTH, 1624 (2014). The Court also notes that use of the word "any" within § 99B-6(b)(3) suggests there are no limitations as to the "applicable government standard."

The Court must also consider whether construing § 99B-6(b)(3) as suggested by BSC is consistent with § 99B-6 as a whole. Blakely, 738 F.3d at 629. BSC maintains that "510(k) is the standard" and insists that the underlying premise of any form or level of premarket approval is safety. BSC cites the FDA website for this proposition, which states that under 510(k) clearance, the manufacturer must demonstrate that the proposed device: (1) "does not raise new questions of safety and effectiveness" and (2) "is at least as safe and effective as the legally marketed device."[12] Contrast BSC's position concerning 510(k) and safety with the Supreme Court's comment:

> "Substantial equivalence determinations provide little protection to the public. These determinations simply compare a post–1976 device to a pre–1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective."

Medtronic, 518 U.S. at 492−93 (criticizing defense for manufacturer of pacemaker for exaggerating the importance of the § 510(k) process and the FDA letter to the defendant-company regarding the medical device's substantial equivalence to a grandfathered device) (internal citation omitted).

[12] See "Premarket Notification (510k), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (August 2015).

Like the MDL Judge, the undersigned is not persuaded that 510(k) clearance speaks directly to the applicable standard of care.[13] See generally, Talley v. Danek Medical, Inc., 179 F.3d 154, 161 (4th Cir. 1999) (considering whether violation of federal regulatory statute constitutes negligence per se under Virginia state law and drawing distinction between administrative statutory requirement and standard of care for purposes of negligence action). Based upon the nature and purpose of 510(k) clearance, safety and efficacy is secondary to the primary purpose of the 510(k) limited review, which is to merely allow the manufacturer to engage in competition within the product market. Even so, FDA 510(k) is the only premarket "criterion for measuring acceptability, quality, or accuracy" for a Class II device such as the Uphold. The fact that BSC followed the requisite 510(k) protocol – limited as it is – prior to marketing its Uphold device has minimal probative value regarding BSC's efforts to adhere to FDA processes and procedure generally. However, the risk of misleading and confusing the jury is also great. A mini-trial on the FDA 510(k) clearance process would be a waste of time. There is also a legitimate concern that jurors might place too much emphasis on the 510(k) clearance. Admissibility might depend upon a limiting instruction that 510(k) clearance is not to be considered as evidence that the FDA authorized the Uphold as safe and approved its intended use as such; that 510(k) clearance is not evidence that BSC satisfied any standard of care in designing the Uphold device. For these reasons, the Court's preliminary ruling on Plaintiff's motion is that the 510(k) clearance process is admissible subject to a limiting instruction consistent with the terms of the instant Order.

[13] On September 16, 2015, in Cisson v. C.R. Bard, Inc., COA No. 15-1102, another transvaginal mesh multidistrict case which arose out of MDL 2187 (one of the seven assigned to Judge Goodwin), the Fourth Circuit heard oral arguments concerning the admissibility of evidence about the FDA 510(k) clearance process. Georgia law governs the product liability claims in Cisson.

III. Defendant's Motions in Limine

A. BSC's Motion in Limine to Exclude Material Safety Data Sheets

BSC seeks to exclude evidence of Material Safety Data Sheets ("MSDS") issued by producers / sellers of synthetic polypropylene purchased by BSC. BSC used synthetic polypropylene in making its pelvic mesh products, including the Uphold. The Material Safety Data Sheets generally address potential safety concerns when using Marlex polypropylene as a raw material in a permanent implant. Specifically, the MSDS medical application caution warns that Marlex polypropylene may be unsafe if implanted into the human body. For example, the MSDS for the polypropylene BSC chose for its Uphold device reads:

> MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP Material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluid or tissues.

(Doc. 177 / Exh. 1). In connection with its 2004 purchase of Marlex polypropylene from Phillips Sumika Polypropylene Company ("PSPC"), the sales contract included the following provision:

> BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE MARKET SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

(Doc. 177 / Exh. 3).

Plaintiff claims that the MSDS is probative of its § 99B-6 negligent design claim and "primarily offered as evidence of notice regarding the suitability of Marlex polypropylene as a permanent implant." (Master Compl., ¶ 61(a); Doc. 177, 6). More specifically, Plaintiff alleges

that BSC should not have elected to use Marlex polypropylene in light of the medical application caution addressing its suitability for use in an implant, that BSC should have heeded the warning in the MSDS and conducted additional testing to ensure safety for this specific intended use, and that BSC should have shared what it knew about Marlex polypropylene and warned the relevant audience. (Master Compl., ¶ 56(C)). Plaintiff proffers expert testimony – testimony that has survived Daubert scrutiny − discussing the MSDS and polypropylene and its appropriateness as a permanent implant. BSC proffers its own expert in an effort to minimize the MSDS by contending that the medical application caution is so vague that no affirmative action was warranted by BSC. These determinations will be for the jury.

The MDL Judge has consistently rejected BSC's motions in limine seeking to exclude MSDS evidence, finding BSC's argument "wholly unconvincing."[14] According to the MDL Judge, the MSDS evidence is relevant to Plaintiffs' substantive claims as well as Plaintiffs' claim for punitive damages. This Court agrees. At minimum, the Court finds that the MSDS for Marlex polypropylene is highly probative concerning the notice to BSC that polypropylene may be unsafe for BSC's intended use. At this stage, the Court need not identify every proper purpose for introduction of the MSDS evidence nor identify every conceivable exception to the hearsay rule that might hypothetically permit its admissibility. BSC's Motion in limine will be **DENIED**.

[14] See MDL Judge's rulings in Sanchez, Eghnayem, and Tyree.

IV. ORDER

IT IS, THEREFORE, ORDERED THAT:

1) Plaintiffs' Motion in Limine No. 1 to Exclude Evidence Related to the FDA's 510(k) Process (Doc. 174) is **DENIED, however, any such evidence will be subject to a limiting instruction consistent with the terms of the instant Order**;

2) Plaintiffs' Motion in Limine to Exclude Evidence Related to Romona Winebarger's Criminal Record (Doc. 173) is **DENIED as moot**; and

IT IS FURTHER ORDERED THAT:

In connection with BSC's multi-part Motion in Limine (Doc. 175),

1) BSC's Motion to Preclude Evidence or Argument Regarding Fraud on the FDA or Alleged Misbranding is unopposed and **DENIED as moot**;

2) BSC's Motion to Preclude Evidence Concerning Material Safety Data Sheets is **DENIED**;

3) BSC's Motion to Preclude Evidence Concerning Polyethylene Material Safety Data Sheets is unopposed and **DENIED as moot**;

4) BSC's Motion to Preclude Evidence of BSC's Procurement of Polypropylene Resin is **DENIED without prejudice subject to a specific objection at trial**;

5) BSC's Motion to Preclude Evidence or Argument Concerning Foreign Regulatory Actions is **DENIED without prejudice subject to a specific objection at trial**;

6) BSC's Motion to Preclude Evidence or Argument Concerning BSC's Intent, Motives, or Ethics is **DENIED without prejudice subject to a specific objection at trial**;

7) BSC's Motion to Preclude Evidence or Argument Concerning BSC's Decision to Stop Selling the Uphold Device or Suggesting that the Uphold Device was Recalled

or Withdrawn is **DENIED without prejudice subject to a specific objection at trial**;

8) BSC's Motion to Preclude Evidence or Argument concerning BSC's Decision to Stop Selling the Pinnacle Device or Suggesting that the Pinnacle Device was Recalled or Withdrawn is **DENIED without prejudice subject to a specific objection at trial**;

9) BSC's Motion to Preclude Evidence Regarding the ProteGen Device is **DENIED without prejudice subject to a specific objection at trial**;

10) BSC's Motion to Preclude Evidence or Argument Concerning BSC's Post-Implant Product Innovations Including LITE Mesh and Colored Mesh is **DENIED without prejudice subject to a specific objection at trial**;

11) BSC's Motion to Preclude Evidence or Argument that BSC Owed or Breached a Duty to Warn Plaintiffs Directly is **DENIED as moot**;

12) BSC's Motion to Preclude Evidence or Argument that BSC Owed or Breached a Duty to Train Plaintiffs' Physicians is **DENIED as moot**;

13) BSC's Motion to Preclude Product Complaints, Adverse Event Reports, and Medical Device Reports Concerning Patients Other than Plaintiffs is **DENIED without prejudice subject to a specific objection at trial**;

14) BSC's Motion to Preclude any Evidence or Argument Concerning Lawsuits Against Other Manufacturers of Pelvic Mesh Devices is **GRANTED**;

15) BSC's Motion to Preclude any Evidence or Argument that Pelvic Mesh Can Cause Complications not Experienced by Plaintiffs is **DENIED without prejudice subject to a specific objection at trial**;

16) BSC's Motion to Preclude "Reptile" Litigation Tactics is **DENIED**;

17) BSC's Motion to Preclude Inflammatory References to Plaintiffs or to Boston Scientific's Pelvic Mesh Devices is **DENIED without prejudice subject to a specific objection at trial**;

18) BSC's Motion to Preclude any Evidence or Argument Concerning Boston Scientific's Marketing Materials is **DENIED without prejudice subject to a specific objection at trial**;

19) BSC's Motion to Preclude any Evidence or Argument Concerning Materials not Relied on by Plaintiffs or their Physicians is **DENIED without prejudice subject to a specific objection at trial**;

20) BSC's Motion to Preclude any Evidence or Argument Concerning Other Mesh Lawsuits, Investigations, Claims, Verdicts, and Trials against Boston Scientific is unopposed and **DENIED as moot** concerning lawsuits, verdicts, settlements or trials; with respect to investigations or other regulatory actions **DENIED without prejudice subject to specific objection at trial**;

21) BSC's Motion to Preclude any Evidence or Argument Concerning Unrelated FDA Corporate Warning and 483 Letters Pertaining to Cardiac Devices is unopposed and **DENIED as moot**;

22) BSC's Motion to Preclude any Evidence or Argument Concerning the Parties' Litigation Conduct is **GRANTED**;

23) BSC's Motion to Preclude any Evidence or Argument Concerning Boston Scientific's Finances is **GRANTED** except as it might relate to a punitive damages award;

24) BSC's Motion to Preclude any Evidence or Argument Concerning Boston Scientific's Employment Decisions is **GRANTED** except as it might relate to a punitive damages award;

25) BSC's Motion to Preclude any Evidence or Argument Concerning Plaintiff's Physicians' Decisions to Discontinue Using Pelvic Mesh Devices Generally, or Boston Scientific Devices Specifically is **DENIED as moot**;

26) BSC's Motion to Exclude Testimony Relating to Boston Scientific Corporation's Legal Duty is **DENIED as moot**;

SO ORDERED.

Signed: September 21, 2015

Richard L. Voorhees
United States District Judge