IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DEBRA RUBERTI, Plaintiff, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	)	CASE NO. 2:20-CV-874-WKW [WO]

MEMORANDUM OPINION AND ORDER

Before the court are Plaintiff's motions *in limine* (Doc. # 162)[1] and Defendants' responses (Doc. # 170).[2] For the reasons discussed below, Plaintiffs motions are GRANTED in part, DENIED in part, and DEFERRED in part.[3]

I. Plaintiff's First Motion

In her first motion *in limine*, "Plaintiff seeks to preclude Defendants from offering argument, testimony, or evidence of any type relating to the activities of the" U.S. Food and Drug Administration (FDA) "as it pertains to the" Gynemesh

[1] Although Plaintiff styles this document as a singular "Motion *In Limine,*" it is composed of twenty-five separate motions *in limine*.

[2] All citations use the pagination as designated by the CM/ECF filing system.

[3] As emphasized at the status conference held on November 1, 2022 (Doc. # 174), where other courts have already examined similar motions *in limine*, such prior examination will be viewed as persuasive.

Tension-free Vaginal Tape - Obturator (TVT-O). (Doc. # 162 at 2.) Specifically, Plaintiff seeks to preclude any evidence regarding "the FDA's 510(k) 'clearance process'" because evidence of this process is irrelevant (Fed. R. Evid. 401, 402) and unduly prejudicial (Fed. R. Evid. 403). (Doc. # 162 at 2.)

First, Plaintiff asserts that evidence of the 510(k) process is "not relevant to tort law." (Doc. # 162 at 2 (emphasis omitted).) Plaintiff argues that FDA's 510(k) process allows products "to be marketed based solely on a finding of 'substantial equivalence' to a product on the market prior to 1976, rather than a determination of the product's safety or efficacy." (Doc. # 162 at 3.) "The issues in this case involve the defectiveness of design and/or the adequacy of the warnings of Defendants'" TVT-O "device and whether that product was a cause of Plaintiff's injuries." (Doc. # 162 at 2–3.) As a result, the FDA's 510(k) clearance process is not relevant. (Doc. # 162 at 3.)

Plaintiff relies on the determinations of other courts, primarily the Multi-District Litigation (MDL) court—the United States District Court for the Southern District of West Virginia—to support her argument. The MDL court excluded "all evidence related to the FDA's 510(k) process and enforcement." *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:10-CV-01224, 2013 WL 3282926, at *2 (S.D.W. Va. June 27, 2013), *on reconsideration in part sub nom. In re C.R. Bard, Inc.*, No. 2:10-CV-01224, 2013 WL 11089794 (S.D.W. Va. July 1, 2013), and

aff'd in part, rev'd in part sub nom. In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913 (4th Cir. 2016). In its order addressing defendant's "Motion for Clarification and Reconsideration," the MDL court re-affirmed its exclusion of "all of the evidence related to the 510(k) process and enforcement" because, in part, such evidence was "irrelevant" under Federal Rule of Evidence 402. *In re C.R. Bard, Inc.*, 2013 WL 11089794, at *1–2. The court found that such evidence was irrelevant because, "[u]nder United States Supreme Court precedent the FDA 510(k) process does not go to whether the product is safe and effective." *Id.* at 2.

Before discussing what the cases say, an overview of the statutory scheme is required. Before an entity can introduce "into interstate commerce for commercial distribution . . . a device intended for human use," it must submit a report to the FDA. 21 U.S.C. § 360(k). This reporting process is called the "510(k) process . . . after the number of the section in the original Act." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). In the report, the entity must state, in part, "the class in which the device is classified." 21 U.S.C. § 360(k)(1). There are three classes of devices: class I, class II, and class III. 21 U.S.C. § 360c.

Class I devices are those with the lowest level of accompanying risk that can be effectively regulated by "general controls." 21 U.S.C. § 360(a)(1)(A). Class II devices are those that "cannot be classified as class I [devices] because the general

controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device[s]" and are those that have "sufficient information to establish special controls . . . to provide such assurance." 21 U.S.C. § 360c(a)(1)(B). Class III devices are those that do not fit into either of the first two categories and (1) are "purported or represented to be for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or (2) "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

After the entity has submitted its report, the FDA reviews the report and decides what the initial classification of the device will be. 21 U.S.C. § 360(n)(1). Any device that is introduced after May 28, 1976 "is classified in class III unless" it is (1) a device introduced before May 28, 1976 **or** (2) it is a device introduced after May 28, 1976, and "has been classified in class I or class II" **and** is "*substantially equivalent*[4] to another device within such type." 21 U.S.C. § 360c(f)(1)(A) (emphasis added). If the device is classified within class III, it must receive

[4] "Substantial equivalence" or "substantially equivalent" "means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device . . . **(i)** has the same technological characteristics as the predicate device, **or (ii)** (I) has different technological characteristics and the information submitted that [says] the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary . . . that demonstrates that the device is as safe and effective as a legally marketed device, **and** (II) does not raise different questions of safety and effectiveness than the predicate device." 21 U.S.C.A. § 360c(i)(1)(A) (emphasis added).

"premarket approval" (PMA). 21 U.S.C. §§ 360c(a)(1)(C), 360(e).[5] The TVT-O was cleared for marketing via the 510(k) process. (Doc. # 170-5.)

The Supreme Court has stated that the 510(k) process "imposes a limited form of review on every manufacturer intending to market a new device." *Lohr*, 518 U.S. at 478. But in *Lohr*, the Court noted that the FDA had said, in relation to the device at issue, that a determination of "substantially equivalent" "should not be construed as an endorsement of the [device's] safety." *Id.* at 480. Indeed, "the 510(k) process is focused on *equivalence*, not safety." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (quoting *Lohr*, 518 U.S. at 493). "[D]evices that enter the market through § 510(k) have 'never been formally reviewed . . . for safety or efficacy.'" *Riegel*, 552 U.S. at 323 (quoting *Lohr*, 518 U.S. at 493); *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1317 (11th Cir. 2017) (citations omitted) (quoting *Riegel*, 552 U.S. at 323); *see also Huskey v. Ethicon, Inc.*, 848 F.3d 151, 160 (4th Cir. 2017) (citation omitted) ("[T]he 510(k) process focuses mostly on the equivalence between the product in question and an older one, and only '*tangentially*' examines the safety of the product going through the process."); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001) ("A substantially equivalent device is examined in the § 510(k)

[5] A class III device need not receive PMA approval if it "was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976" or is "substantially equivalent" to another pre-1976 device. 21 U.S.C. § 360e(b)(1); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 345, 349–50 (2001); *Lohr*, 518 U.S. at 477–78.

process only for similarities with existing devices; safety and effectiveness are not the focus.").

As a result, the MDL court was correct that "the 510(k) process does not go to whether the product is safe and effective." *In re C.R. Bard, Inc.*, 2013 WL 11089794, at *2. But this does not automatically mean that all evidence of the 510(k) process ought to be excluded as irrelevant. The MDL court was applying Georgia law which allowed the jury to "consider compliance with federal regulations." *Id.* The relevant *Georgia* law said that a jury could "consider proof of the manufacturer's compliance with federal or state *safety* standards" when determining the reasonableness of the defendant's actions. *Id.* at *1–2 (quoting Georgia Pattern Jury Instructions 62.670). Because a jury was allowed to consider *safety* regulations or statutes, the MDL court reasoned that the 510(k) process, which does not "go to whether . . . products are safe and effective," was inapplicable and irrelevant. *Id.* at *2.

Here, Plaintiff seeks to exclude evidence of the 510(k) process based on the MDL court's reasoning. (Doc. # 162 at 3.) But that will not work because Alabama tort law—not Georgia tort law—governs Plaintiff's claims against Defendants. Defendants mention that the Alabama statutes implicated by this case would make evidence of the 510(k) process relevant. (Doc. # 170 at 1–3.) That may be so. But it may be true that the Alabama statutory provisions at issue are like what the MDL

court applied: the jury may consider safety regulations and statutes, but the 510(k) process does not address safety and so is irrelevant. Plaintiff has provided no argument as to *how* or *why* the relevant Alabama statutes would make this evidence irrelevant. Because of this uncertainty, it is premature to decide whether this evidence is relevant.

Second, Plaintiff argues that, even if evidence of the 510(k) process was relevant, "any probative value that might be garnered through presenting this evidence would be substantially outweighed by the danger of unfair prejudice and the risk of confusing the jury" and so should be excluded under Federal Rule of Evidence 403. (Doc # 162 at 3–4.) Once again, Plaintiff heavily relies on prior determinations of the MDL court. The MDL court has repeatedly said, essentially, the following:

> [E]vidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under Federal Rule of Evidence 403 because of the danger of misleading the jury, confusing the issues, and unfair prejudice. . . . [I]t is abundantly clear that there would be a substantial mini-trial on the 510(k) process and enforcement should it be allowed. In short, this evidence poses a substantial risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims, and if such evidence comes in via expert testimony, the expert would effectively be offering a legal conclusion.

Bellew v. Ethicon, Inc., No. 2:13-CV-22473, 2014 WL 6680356, at *10 (S.D.W. Va. Nov. 25, 2014) (quoting *In re C.R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, 2013 WL 3282926, at *2); *see also Lewis v. Johnson & Johnson*, 991 F. Supp. 2d

748, 754 (S.D.W. Va. 2014). The Eleventh Circuit has found that a district court did not abuse its discretion when it precluded evidence of the 510(k) process for substantially the same reasons articulated by the MDL court in a pelvic mesh litigation case. *Eghnayem*, 873 F.3d at 1318. The district court in *Eghnayem* applied Florida tort law and concluded that 510(k) evidence would be irrelevant and that any probative value would be outweighed by Rule 403 considerations. *Id.* But the analysis may be entirely different here because Alabama law is at issue.

Excluding 510(k) evidence under Rule 403 is not the only path. The District of Arizona recognized the Rule 403 concerns articulated by the MDL court but denied the plaintiff's motion to exclude this evidence. *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1048–49 (D. Ariz. 2018). Instead, the District of Arizona found that defendants could provide testimony about their compliance with the 510(k) process but not that that compliance equaled FDA "approval" or that the device was "safe and effective." *Id.* The court allowed the plaintiff to present "evidence and argument that the 510(k) process is a comparative one that requires only substantial equivalence to a predicate device" and that "510(k) regulations are not safety regulations." *Id.* And "any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process." *Id.*

Because the parties have not addressed how the underlying law in this case interacts with evidence of the 510(k) process, it is premature to determine that this

evidence would be of little probative value. And it is not clear that any potential probative value would be outweighed by undue prejudice, misleading the jury, or confusing the issues.

Based on these considerations, ruling on Plaintiff's first motion *in limine* is RESERVED for trial. If the court deems it necessary, it will order further briefing on this motion to give each party a chance to explain how the Alabama law implicated by Plaintiff's claims interacts with evidence of the 510(k) process.

II. Plaintiff's Second Motion

In her second motion *in limine,* Plaintiff seeks to "bar completely" "Timothy Ulatowski, Ethicon's 'regulatory expert,' . . . from testifying or, at a minimum, [to] have his testimony significantly limited." (Doc. # 162 at 5.) Plaintiff lists fifteen "paraphrased opinions" that she says "do not make it more or less probable that the device was defective in its design . . . [or] bear any connection to whether the device was a cause of Plaintiff's injuries" and "are based on hearsay and speculation." (Doc. # 162 at 5–6.) These opinions include Mr. Ulatowski's assertions that Ethicon complied with FDA regulations. (Doc. # 162 at 5–6.) Defendants respond that "Mr. Ulatowski's opinions about Ethicon's compliance with FDA regulations [are] directly relevant to disputed issues in this case." (Doc. # 170 at 13.)

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579

(1993) (and its progeny). Rule 702 assigns the trial court a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589; *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) ("[T]he Federal Rules of Evidence 'assign to the trial judge the task of ensuring that an expert's testimony rests both on a reliable foundation and is relevant to the task at hand.'" (quoting *Daubert*, 509 U.S. at 597)). This gatekeeping responsibility is the same when the trial court is considering the admissibility of "testimony based upon 'technical' and 'other specialized knowledge.'" *Kumho Tire Co.*, 526 U.S. at 141 (quoting Fed. R. Evid. 702).

Considering *Daubert*'s "gatekeeping requirement," the Eleventh Circuit requires district courts to engage in a "rigorous three-part inquiry" for assessing the admissibility of expert testimony under Rule 702:

> Trial courts must consider whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue."

United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). These requirements are known as the "qualification," "reliability," and "helpfulness" prongs. *See id.*

Plaintiff does not challenge Mr. Ulatowski's qualifications or the reliability of the methodology he used to reach his conclusions. She only challenges the helpfulness of his opinions (*e.g.*, they are irrelevant). As a result, it would be improper to exclude Mr. Ulatowski's testimony under *Daubert* at this time.

When faced with a similar motion *in limine*, the MDL court excluded all of Mr. Ulatowski's opinions related to "the 510(k) clearance process" and his opinions as they "relate to FDA regulations or procedures, FDA decision-making, FDA communications, or Ethicon's compliance with such"—"any opinion testimony on matters of the FDA." *Bellew*, 2014 WL 6680356, at *10; *see also Barron v. Atrium Med. Corp.*, No. 17-CV-742-LM, 2021 WL 6884622, at *1 (D.N.H. May 14, 2021) (limiting the testimony Mr. Ulatowski could give regarding the FDA). This ruling was based on the court's "concern with the risks of leading the jury into the confusing domain of the FDA." *Bellew*, 2014 WL 6680356, at *10. While this court understands the MDL court's concerns, such potential confusion can be mitigated through an appropriate limiting instruction at trial. For these reasons, ruling on Plaintiff's second motion *in limine* is RESERVED for trial.

III. Plaintiff's Third Motion

In her third motion *in limine*, Plaintiff seeks to exclude "evidence related to the history of polypropylene use in the human body," including evidence about "the safety of other products," besides the TVT-O, that use polypropylene. (Doc. # 162

at 7.) Plaintiff seeks to exclude this evidence under Rule 403 because it "would implicate massive, imprecise hearsay, which would require extensive cross-examination and rebuttal evidence" in response which would "divert the jury's attention from the relevant issues, confuse and mislead the jury, and create a 'mini trial.'" (Doc. # 162 at 7.) Defendants respond that they "must be allowed to offer evidence that both polypropylene (generally) and Ethicon's Prolene (specifically) have a long history of safe and effective use in the human body" to "defend against" Plaintiff's likely argument "that TVT-O is defective because it is made of polypropylene." (Doc. # 170 at 13.)

Addressing similar arguments, the District of Kansas found that "defendants should be allowed to offer evidence that both polypropylene and Prolene have a long history of safe and effective use in the human body, and that polypropylene is used in many other permanent medical implants." *Kieffaber v. Ethicon, Inc.*, No. CV 20-1177-KHV, 2021 WL 1177914, at *3 (D. Kan. Mar. 26, 2021). Plaintiff's third motion *in limine* is DENIED.

IV. Plaintiff's Fourth Motion

In her fourth motion *in limine*, Plaintiff seeks to exclude "any testimony or evidence that alleges that the TVT line of products, or the TVT-O in particular, is the 'gold standard' for treating SUI [stress urinary incontinence]" because it is a statement that "constitutes pure speculation" (Fed. R. Evid. 602) and its prejudicial

effect "far outweigh[s] any probative value" (Fed. R. Evid. 403). (Doc. # 162 at 9.) Defendants respond that "[e]vidence that polypropylene midurethral slings like TVT and TVT-O are considered the gold standard for treating SUI cuts to the heart of Plaintiff's claims" and "[e]vidence that the medical community considered polypropylene mesh slings to be within the standard of care, *i.e.*, reasonable and appropriate treatment methods for SUI, is probative of Ethicon's defense that it did not act with the type of culpability required to impose punitive damages." (Doc. # 170 at 15–16.)

Several courts have found that this evidence is admissible. The MDL court said the following:

> Whether the TVT–O is regarded as the "gold standard" is highly probative: it goes to the very essence of whether the TVT–O is unreasonably dangerous and whether there existed safer alternative designs. If the plaintiffs believe that "gold standard" is imprecise, inaccurate, or confusing, they may vigorously cross-examine witnesses.

Huskey v. Ethicon, Inc., No. 2:12-CV-05201, 2014 WL 3861778, at *2 (S.D.W. Va. Aug. 6, 2014) (citation omitted); *see also In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 505234, at *3 (S.D.W. Va. Feb. 5, 2014) (*Lewis*) (saying the same regarding the TVT). And, dealing with a different Ethicon mesh product, the Southern District of Florida said it "agrees with . . . the MDL Court that evidence about the 'gold standard' or 'standard of care' . . . is directly relevant to the issues of [the product's] allegedly defective design and

alleged foreseeable dangers arising from" implantation of the product and that "such evidence's probative value outweighs any arguable unfair prejudice." *Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753438, at *10 (S.D. Fla. Sept. 25, 2019).

Plaintiff has not offered any persuasive arguments to the contrary. Any concerns that Plaintiff has about the speculative nature of the term "gold standard" can be addressed on cross-examination. Plaintiff's fourth motion *in limine* is DENIED.

V. Plaintiff's Fifth Motion

In her fifth motion *in limine*, Plaintiff seeks to prevent any "defense witness or attorney" from making assertions about "the supposed 'rarity' of the complications" associated with the TVT-O because it is "purely speculative and wholly improper" (Fed. R. Evid. 602, 701). (Doc. # 162 at 10.) If Plaintiff takes issue with the use of the words "rare" or "very rare" by Ethicon's witnesses and believes that such a that statement is contradicted by other testimony (Doc. # 162 at 10), the solution is to bring these issues up on cross-examination, not to exclude Defendants from eliciting these statements on direct examination. (*See* Doc. # 170-10 ("If Plaintiff disagrees with a witness's testimony, the remedy is cross examination and opposing evidence.").) Plaintiff's fifth motion *in limine* is DENIED.

VI. Plaintiff's Sixth Motion

In her sixth motion *in limine*, Plaintiff seeks to prevent Defendants from "submit[ting] evidence regarding the safety and efficacy of, medical literature regarding, and anecdotal evidence related to, other devices (e.g., Prolift, Prolift+M, etc.)" under Federal Rules of Evidence 401 and 403. (Doc. # 162 at 11.) Defendants state that they do not "intend to introduce evidence comparing TVT-O to pelvic organ prolapse mesh products" and assert that "neither party should be permitted to introduce evidence relating to pelvic organ prolapse mesh products." (Doc. # 170 at 17–18.) Plaintiff's sixth motion *in limine* is GRANTED. Neither party will be allowed to offer evidence regarding devices used for the treatment of pelvic organ prolapse.

VII. Plaintiff's Seventh Motion

In her seventh motion *in limine*, Plaintiff seeks to "exclude evidence and testimony related to what was taught to physicians in 'professional education'" since "it would be irrelevant and blatant hearsay, without any specificity or reliability" under Federal Rules of Evidence 401 and 802. (Doc. # 162 at 13.) Defendants respond that "[t]he duty to warn imposed by the AEMLD [Alabama Extended Manufacturer's Liability Doctrine] takes into account the user's awareness of the risk in question, meaning manufacturers like Ethicon are not required to warn of risks that are known to the ordinary users of their products." (Doc. # 170 at 18.)

According to Defendants, "[o]ne way to establish the common knowledge of the ordinary users of TVT-O (pelvic surgeons) is to show what they are taught in medical school, tested on when they become board certified, and taught in professional education courses." (Doc. # 170 at 18.)

Plaintiff's seventh motion *in limine* is DENIED to the extent that Defendants can lay a proper foundation, with sufficient specificity, for what users of the TVT-O would know.

VIII. Plaintiff's Eighth Motion

In her eighth motion *in limine*, Plaintiff seeks "[t]o exclude evidence and testimony related to what 'pelvic surgeons know' regarding risks or benefits" of the TVT-O because it "is based entirely on inadmissible hearsay and blatant speculation" (Fed. R. Evid. 602, 802) and "any probative value that might possibly be attached to this evidence would be substantially outweighed by its unfairly prejudicial effect and the risk that this evidence would cause confusion among the jury" (Fed. R. Evid. 403). (Doc. # 162 at 14.)

In *Robinson v. Ethicon, Inc.*, the Southern District of Texas addressed a similar motion "to exclude evidence as to what pelvic surgeons knew and understood with respect to the risks of the TVM devices and pelvic surgery." (Doc. # 170-4 at 12.) But the court denied this motion *in limine* because "[t]his evidence would be directly relevant to a failure-to-warn claim, since there is no duty to warn of risks

that are within the common knowledge of that audience." (Doc. # 170-4 at 12.) While the Southern District of Texas was applying Texas law, this reasoning may apply to Plaintiff's claim against Defendants for failure to warn (Doc. # 1 at 4) since evidence regarding what users know regarding risks and benefits is relevant to Defendants' duty to warn. *See Ex parte Chevron Chem. Co.*, 720 So. 2d 922, 927–29 (Ala. 1998). Plaintiff has not offered a persuasive argument to the contrary. Plaintiff's eighth motion *in limine* is DENIED.

IX. Plaintiff's Ninth Motion

In her ninth motion *in limine*, Plaintiff seeks to preclude Defendants from introducing any evidence of "good reputation" or "good acts" ("e.g., community employment, charitable donations of money, and medical contributions, such as the development of new products") "that are wholly unrelated to the TVT-O, or this case," since such evidence is irrelevant to Plaintiff's claims against Defendants (Fed R. Evid. 401), "is unduly prejudicial, confuses the issues, and is likely to mislead the jury" (Fed. R. Evid. 403), and is "improper propensity evidence" (Fed. R. Evid. 404). (Doc. # 162 at 15–18.) Defendants respond by arguing, first, that Plaintiff's motion "is impermissibly vague and seeks to exclude overly broad categories of evidence rather than specific items" and, second, that "the motion should be denied to the extent Plaintiff seeks to exclude admissible background information on Defendants

and their pelvic mesh products, particularly related to the development of TVT-O." (Doc. # 170 at 19–20.)

Plaintiff's ninth motion *in limine* is GRANTED as to evidence regarding Defendants' community employment, charitable donations, and medical contributions. But ruling on Plaintiff's ninth motion *in limine* as to Defendants' product development is RESERVED for trial. *See Bellew*, 2014 WL 6680356, at *7.

X. Plaintiff's Tenth Motion

In her tenth motion *in limine*, Plaintiff seeks to prevent Defendants from "mak[ing] claims regarding the number of randomized controlled trials [RCTs] that purportedly support the safety and efficacy of TVT-O for the treatment of SUI" because "evidence or argument advancing such claims" is "inadmissible hearsay" (Fed. R. Evid. 801) and is "confusing to the jury, a waste of time, and unfairly prejudicial" (Fed. R. Evid. 403). (Doc. # 162 at 19.) Defendants respond by stating that other courts have rejected arguments identical to Plaintiff's, that the "number of RCT's supporting the safety of TVT-O is not hearsay," that Plaintiff does not meet her burden under Rule 403, and that "[e]vidence concerning Ethicon's post-market surveillance of its products, including its review of newly published RCTs, is directly relevant to Plaintiff's claim for punitive damages." (Doc. # 170 at 21–22.)

Plaintiff's tenth motion *in limine* is GRANTED as to evidence regarding the *number* of RCTs, but it is DENIED as to evidence of specific RCTs and as to

evidence of how expert opinions were informed by certain RCTs. *See Lewis*, 2014 WL 505234, at *1.

XI. Plaintiff's Eleventh Motion

In her eleventh motion *in limine*, Plaintiff seeks to prevent Defendants from submitting "evidence or testimony related to the number of TVT devices (or TVT-O specifically) that have been sold to healthcare providers and facilities in an effort to signal to the jury that a vast quantity of these devices have been used to treat women." (Doc. # 162 at 21.) Plaintiff argues that such evidence is misleading because the number of units sold does not equal the number of devices implanted or used, and, so, it would be speculative for Defendants to make this argument and "unfairly prejudicial" (Fed. R. Evid. 403). (Doc. # 162 at 21.) And "the number of units/devices sold is not relevant to the particular issues raised" in this case (Fed. R. Evid. 402). (Doc. # 162 at 21.)

Defendants respond that "[e]vidence concerning the number of women who have been implanted with pelvic mesh to treat stress urinary incontinence is highly relevant to Plaintiff's claims" and that "its probative value is not outweighed by the danger of any alleged unfair prejudice." (Doc. # 170 at 22–23.) The Northern District of West Virginia previously denied a similar motion in *Smallridge v. Johnson & Johnson*. (Doc. # 170-1 at 9 ("The number of women treated with pelvic

mesh and the number of units sold is probative on the issue of whether the TVT-O was reasonably safe.").) Plaintiff's eleventh motion *in limine* is DENIED.

XII. Plaintiff's Twelfth Motion

In her twelfth motion *in limine*, Plaintiff seeks to exclude "any testimony or evidence offered to claim that the" TVT-O "has been 'implanted in millions of women around the world'" because this evidence is "wholly irrelevant and the prejudicial effect of such testimony would substantially outweigh any probative value" (Fed. R. Evid. 401, 403). (Doc. # 162 at 22.) And since Defendants "cannot possibly evaluate the effect of the device on those women[,] . . . any reference or inference that could be derived from such evidence would be skewed by this hinderance and thus would be unfairly prejudicial and would invariably mislead and confuse the jury" (Fed. R. Evid. 403). (Doc. # 162 at 22.) Defendants say this motion should be denied for the same reasons they said Plaintiff's eleventh motion *in limine* should have been denied. (Doc. # 170 at 23.) Plaintiff's twelfth motion *in limine* is DENIED.

XIII. Plaintiff's Thirteenth Motion

In her thirteenth motion *in limine*, Plaintiff seeks to exclude "any suggestion that the TVT-O is still on the market" since this evidence would give the impression that the TVT-O has "FDA endorsement." (Doc. # 162 at 23–24.) According to Plaintiff, "the prejudice inherent in" "statements about the product remaining on the

market" "outweighs their probative value" (Fed. R. Evid. 403). (Doc. # 162 at 25.) And if statements about the TVT-O remaining on the market "were allowed," Plaintiff asserts that she "would . . . be entitled to counter those statements by showing that the warnings that now accompany the TVT products are far stronger than they were when the product was originally cleared" and should be allowed to introduce evidence that "the 510(k) process . . . says nothing about the product's safety and efficacy." (Doc. # 162 at 24.) In response, Defendants argue that the fact that "doctors regularly use TVT-O *today* directly contradicts Plaintiff's experts' opinions that TVT-O is defectively designed and exposes women to unreasonable and foreseeable risks" and that "evidence that TVT-O is still used to treat SUI is relevant to refute Plaintiff's punitive damages claim." (Doc. # 170 at 24–25.)

Evidence that the TVT-O is still on the market is likely probative of Plaintiff's claim for punitive damages. (Doc. # 1 at 5.) And in *Robinson*, the Southern District of Texas denied a motion *in limine* that was nearly identical to Plaintiff's. (Doc. # 170-4 at 7 ("The plaintiff seeks to exclude evidence that the TVT-O product line is still on the market. . . . [T]his evidence is admissible.).) Plaintiff's thirteenth motion *in limine* is DENIED.

XIV. Plaintiff's Fourteenth Motion

In her fourteenth motion *in limine*, Plaintiff seeks to "preclude any argument, evidence[,] or testimony relating to the" American Urogynecologic Society (AUGS)

and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)'s "Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence" (Position Statement) (Doc. # 162-12). (Doc. # 162 at 26.) She argues that the Position Statement is a "wholly irrelevant, litigation-driven, rank hearsay, and [an] admittedly unscientific" document that "would also usurp the role of the jurors that will decide this case." (Doc. # 162 at 27–28.)

Defendants respond that the Position Statement says that "[t]he polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women." (Doc. # 170 at 25 (quoting Doc. # 170-18 at 2).) According to Defendants, "[t]he Position Statement is highly probative of Plaintiff's claims, as it directly addresses the medical community's endorsement of the safety and efficacy of the class of products to which TVT-O belongs"; "[t]he Position Statement is . . . directly relevant to the credibility of Plaintiff's experts; the Position Statement is not inadmissible hearsay; the Position Statement does not "supplant the legal standard of care"; and Plaintiff is incorrect "that position statements are inadmissible simply because, in her view, they were not written from an 'objective' perspective." (Doc. # 170 at 25–28.)

Evidence from a position statement that was produced by a trade association to which a defendant belonged is excludable under Federal Rule of Evidence 403.

Defendants' reliance on the Position Statement to demonstrate the safety of the TVT-O runs the risk of confusing and misleading the jury, and any probative value would be outweighed by undue prejudice. Fed. R. Evid. 403. In addition, addressing the objections to this Position Statement and resolving the parties' concerns at trial would likely lead to a side show that would cause "undue delay" and "wast[e] time." Fed. R. Evid. 403.

An example will illustrate the court's concerns. Suppose there was a case where the defendant was that venerable American institution: McDonald's. The plaintiff sues McDonald's over its unsafe burgers and fries (according to the plaintiff, they cause high cholesterol, diabetes, heart disease, and are generally ill-suited to the human body). McDonald's defends and seeks to prove that its food is safe based on a report produced by a national, restaurant association of which McDonald's is a contributing member. Contrary to the plaintiff's assertions, the report says that McDonald's cuisine is internationally recognized as healthful and essential to a well-balanced diet. Can McDonald's rely on this evidence to prove the safety of its food? The answer is clearly not. Any probative value from the association's report would be outweighed by the risk of prejudice, distracting the jurors, and wasting the court's time. Like McDonald's, Defendants cannot rely on a facially self-interested report to prove the safety of the TVT-O.

For these reasons, Plaintiff's fourteenth motion *in limine* is GRANTED.

XV. Plaintiff's Fifteenth Motion

In her fifteenth motion *in limine*, Plaintiff seeks "[t]o preclude Defendants from offering argument, evidence, or testimony referencing any [FDA] Advisory Committee recommendations" because they are irrelevant (Fed. R. Evid. 402) and "reference to any such recommendations would be unduly prejudicial and confusing to the jury and would result in a 'trial within a trial'" (Fed. R. Evid. 403). (Doc. # 162 at 30.) Ruling on Plaintiff's fifteenth motion *in limine* is RESERVED for trial. Before seeking to introduce evidence regarding Advisory Committee recommendations at trial, the parties are directed to raise the matter with the court.

XVI. Plaintiff's Sixteenth Motion

In her sixteenth motion *in limine*, Plaintiff seeks "[t]o exclude argument or testimony related to the . . . 'Time to Rethink' article" (Doc. # 162-20) because this article—"an unscientific, propaganda piece"—"is wholly irrelevant" (Fed. R. Evid. 401, 402) and "misleading and confusing" (Fed. R. Evid. 403). (Doc. # 162 at 31.) Specifically, this article utilized a "petition that was signed by 600 doctors confirming that they agree [that] mesh in general should not be completely banned." (Doc. # 162 at 31.) Plaintiff asserts that "[p]resenting evidence to the jury that 600 doctors merely signed a petition, without additional support or information, lacks foundation and would be very misleading and unduly prejudicial to" her. (Doc.

162 at 31.) Defendants respond that they "do not intend to introduce the 'Time to Rethink' article." (Doc. # 170 at 30.)

The "Time to Rethink" article lacks proper foundation and would mislead and confuse the jury. Fed. R. Evid. 403. Therefore, Plaintiff's sixteenth motion *in limine* is GRANTED.

XVII. Plaintiff's Seventeenth Motion

In her seventeenth motion *in limine*, Plaintiff seeks to "preclude any argument, testimony, or evidence of any type relating to any patient-specific evidence" ("such as co-morbidities, pre-existing health or medical conditions, patient lifestyle or conduct") "or physician conduct" "as irrelevant and unfairly prejudicial under Federal Rules of Evidence 401 and 403." (Doc. # 162 at 33.) In addition, Plaintiff asserts that "there is no expert opinion or competent evidence that [she] was negligent in any way in this case. Therefore, no suggestions should be made that the Plaintiff was comparatively at fault or responsible for her injuries." (Doc. # 162 at 33.)

Ruling on Plaintiff's seventeenth motion *in limine* is RESERVED for trial. Negligence is still at issue (Doc. # 1 at 4), and evidence of Plaintiff's pre-existing conditions may be relevant for determining whether Defendants were negligent. But Defendants must lay a proper foundation for discussing Plaintiff's pre-existing conditions.

XVIII. Plaintiff's Eighteenth Motion

In her eighteenth motion *in limine*, Plaintiff seeks "[t]o exclude any evidence of payments which have been or may have been made by health insurers or others of medical bills or of [a] wage[-]related benefit or payment" since "[s]uch payments constitute collateral source evidence and thus may not be mentioned." (Doc. # 162 at 35.) But Plaintiff is incorrect because, under Alabama law, "[i]n all civil actions where damages for any medical or hospital expenses are claimed and are legally recoverable for personal injury or death, evidence that the plaintiff's medical or hospital expenses have been or will be paid or reimbursed shall be admissible as competent evidence." Ala. Code § 12-21-45(a). Plaintiff's eighteenth motion *in limine* is DENIED.

XIX. Plaintiff's Nineteenth Motion

In her nineteenth motion *in limine*, Plaintiff seeks "[t]o preclude Defendants . . . from presenting evidence related to personal problems that Ms. Ruberti experienced throughout the course of her life." (Doc. # 162 at 36.) From the context, these "personal problems" appear to be about prior mental health or psychiatric issues. (Doc. # 162 at 36.) Plaintiff states that "these events are far too temporarily distant to be relevant to any claim"; that Plaintiff's claim is for "mental anguish or 'garden variety' emotional distress" accompanying "the kind of severe physical pain caused by the injuries she suffers" and not for a "psychic injury or psychiatric

disorder caused by her use of the TVT-O, such that other possible causes of such mental illness might somehow come into play"; and that this "evidence is far too prejudicial to be admissible, even if it were somehow tangentially related to Plaintiff's damages" (Fed. R. Evid. 403). (Doc. # 162 at 36.)

Ruling on Plaintiff's nineteenth motion *in limine* is RESERVED for trial.

XX. Plaintiff's Twentieth Motion

In her twentieth motion *in limine*, Plaintiff seeks "[t]o preclude Defendants . . . from providing evidence or testimony related to Plaintiff's mental health records or treatment . . . without a particularized showing of justification . . . pursuant to" Federal Rules of Evidence 401 and 403. (Doc. # 162 at 37.) Like her nineteenth motion *in limine*, Plaintiff says that she "is claiming only mental anguish/garden variety emotional distress. She claims only the anguish that ordinarily accompanies severe physical pain." (Doc. # 162 at 37.) Defendants respond that "Plaintiff's . . . mental health history is directly relevant to the cause and extent of her alleged injuries and damages in this case." (Doc. # 170 at 34.) And, since "[P]laintiff alleges emotional injuries as a result of" Defendants' "conduct," Defendants are "entitled to present evidence of alternative sources that may have caused those injuries." (Doc. # 170 at 34.)

Ruling on Plaintiff's twentieth motion *in limine* is RESERVED for trial.

XXI. Plaintiff's Twenty-First Motion

In her twenty-first motion *in limine*, Plaintiff seeks to exclude all "[e]vidence of her filing . . . disability claims with her insurance provider and through" the Social Security Administration (SSA). (Doc. # 162 at 38.) She argues that such evidence would "prejudice the jury into believing [P]laintiff is litigious," the "applications and subsequent decisions" of her insurance provider and the SSA "have no bearing on the validity and severity of [her] injuries related to the TVT-O," and "any argument regarding" what the SSA and the insurance company's actions regarding her disability claims "might mean" would be speculative and hearsay and would distract the jury and waste its time (Fed. R. Evid. 401, 402, 403, 802). (Doc. # 162 at 38.)

Defendants respond that "[t]he basis for Plaintiff's application for Social Security benefits is directly relevant to disputed issues in this case, including the potential causes of Plaintiff's alleged injuries and the nature and extent of her damages." (Doc. # 170 at 35.) Defendants seek to "rely on Plaintiff's representations in her disability applications to show how she described her medical condition at that time." (Doc. # 170 at 36.)

First, as to Plaintiff's hearsay objection, evidence regarding Plaintiff's applications for disability is not hearsay if it qualifies as a prior inconsistent statement. *See* Fed. R. Evid. 801(d)(1)(A); *Chisolm v. Michigan AFSCME Council*

25, 218 F. Supp. 2d 855, 864–65 (E.D. Mich. 2002) (noting that "[e]vidence of the inconsistency" between plaintiff's "deposition testimony" and plaintiff's "Social Security disability benefits" application "may be relevant for impeachment purposes"); *Geiger v. United States*, No. 2:19-CV-1188-BJR, 2021 WL 977703, at *2 (W.D. Wash. Mar. 16, 2021) (noting that the plaintiff's "credibility was impeached on multiple occasions during cross-examination" and that such "impeachment evidence" included "inconsistencies between [plaintiff's] "testimony at trial and her sworn representations in her applications for Social Security disability benefits").

From the current record, it is not clear if Plaintiff's Social Security disability claim and disability claim to the insurance company were made under penalty of perjury. Fed. R. Evid. 801(d)(1)(A). Neither party has made that assertion, and a copy of Plaintiffs' claims are not in the record for the court's examination.

In addition, Plaintiff's prior Social Security and insurance disability claims could be introduced as an opposing party's statement. Fed. R. Evid. 801(d)(2)(A)-(B). Such claims would have been made by Plaintiff in her individual capacity, Fed. R. Evid. 801(d)(2)(A), and would likely have been "one that [Plaintiff] manifested [she] adopted or believed to be true," Fed. R. Evid. 801(d)(2)(B); *see In re Amtrak "Sunset Limited" Train Crash in Bayou Canot, AL on Sept. 22, 1993*, 136 F. Supp. 2d 1251, 1261 (S.D. Ala.), *aff'd sub nom. In re Amtrak*, 29 F. App'x 575 (11th Cir.

2001) (finding that a statement made on a Social Security benefits application regarding the individual's disability was "clearly" a statement of a party opponent). If the evidence from the disability claims were admitted under this rule, it would not be hearsay. Fed. R. Evid. 801(d).

But neither party has addressed whether these disability claims should be admitted as prior inconsistent statements or as statements of an opposing party. And whether these disability claims would count as prior inconsistent statements depends on the factual circumstances surrounding these claims, which is unclear from the record. So, the court declines to rule on the admissibility of this evidence at this time.

Second, under Rules 401, 402, and 403, it is within this court's discretion to determine whether Plaintiff's prior disability claims should be admitted as evidence. For example, in *Saunders v. Wal-Mart Stores, Inc.*, the Eleventh Circuit held that the "district court did not abuse its discretion" by "allowing Wal-Mart to present evidence regarding Saunders's application for Social Security disability benefits." *Saunders v. Wal-Mart Stores, Inc.*, 300 F. App'x 697, 698 (11th Cir. 2008); *see also Calhoun v. Ramsey*, 408 F.3d 375, 381–82 (7th Cir. 2005) (reviewing the district court's decision to admit "sworn statements" that the respondent "had made to the Social Security Administration in an application for disability benefits," finding that these statements "were admissible" because "[t]hey threw light on a material issue

in the case," and holding that "the district court did not abuse its discretion in admitting this evidence"). The exercise of discretion will be reserved for the development of factual context at trial.

Ruling on Plaintiff's twenty-first motion *in limine* is RESERVED for trial.

XXII. Plaintiff's Twenty-Second Motion

In her twenty-second motion *in limine*, Plaintiff seeks to prevent Defendants from referencing "other medical conditions of Plaintiff's without competent evidence, based on reasonable medical probability, that the conditions caused the injuries at issue in this case." (Doc. # 162 at 39.) Plaintiff argues that "[n]one of these medical conditions" are "relevant to the issues in this case," such evidence would "confuse or mislead the jury with discussion of these unrelated conditions and the treatment thereof," and any reference to a causal connection between these past medical conditions and Plaintiff's claims regarding the TVT-O would be irrelevant and "unfairly prejudicial" (Fed. R. Evid. 401, 403). (Doc. # 162 at 39.)

Ruling on Plaintiff's twenty-second motion *in limine* is RESERVED for trial.

XXIII. Plaintiff's Twenty-Third Motion

In her twenty-third motion *in limine*, Plaintiff seeks to prevent Defendants from, first, "affirmatively designating deposition testimony of available witnesses" and from, second, "counter-designating deposition testimony, unless narrowly limited to testimony necessary for completeness and context of the Plaintiff's

affirmative designations." (Doc. # 162 at 40.) Defendants respond that Plaintiff has failed to "identif[y] any of Defendants' designations that she believes to be improper" and that they cannot "reasonably respond to Plaintiff's arguments in the abstract." (Doc. # 170 at 36.) According to Defendants, "[t]he matters raised in this motion should be addressed through objections to deposition designations." (Doc. # 170 at 36.) Plaintiff's twenty-third motion *in limine* is DENIED.

XXIV. Plaintiff's Twenty-Fourth Motion

In her twenty-fourth motion *in limine*, Plaintiff seeks to exclude all "argument, evidence, or testimony referring to" the fee agreements with her attorneys, whether another attorney referred her to her current attorneys, "the date or circumstances under which Plaintiff employed her attorneys," "the name of any other lawyer retained or consulted by Plaintiff," and "whether or not such lawyers were the original attorneys of record." (Doc. # 162 at 41.) Defendants respond that they "do not intend to introduce evidence of Plaintiff's fee agreement with her counsel or whether her current counsel were [the] original counsel of record in this case," so those "aspects of Plaintiff's motion should be denied as moot." (Doc. # 170 at 36.) But Defendants say that "the circumstances under which" Plaintiff "hired her attorneys . . . are relevant to Plaintiff's credibility with respect to her injuries and damages." (Doc. # 170 at 37.)

Plaintiff's twenty-fourth motion *in limine* is GRANTED to the extent that evidence or arguments about her fee arrangements with her lawyers is excluded. But ruling on the other aspects of Plaintiff's twenty-fourth motion *in limine* is RESERVED for trial.

XXV. Plaintiff's Twenty-Fifth Motion

In her twenty-fifth motion *in limine*, Plaintiff seeks to exclude "any statements" that "attack[] counsel personally . . . or suggest[] that counsel has driven this litigation through lawyer advertisements" since this "would be irrelevant and inherently prejudicial, given jurors' inherent distrust of lawyers" (Fed. R. Evid. 401, 402, 403). (Doc. # 162 at 42.) In response, Defendants state that they "do not intend to argue as a general matter that pelvic mesh litigation is 'attorney driven.'" (Doc. # 170 at 37.) Rather, they say that "evidence that Plaintiff's counsel influenced her medical treatment is relevant to her credibility and should not be excluded." (Doc. # 170 at 37.)

Plaintiff's twenty-fifth motion *in limine* is GRANTED, subject to Defendants having an opportunity at trial to establish the relevance of this evidence in a hearing outside the presence of the jury.

CONCLUSION

For the reasons provided above, it is ORDERED that Plaintiff's motions *in limine* (Doc. # 162) are GRANTED in part, DENIED in part, and DEFERRED in part.

DONE this 22nd day of December, 2022.

/s/ W. Keith Watkins
UNITED STATES DISTRICT JUDGE