IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

SHARON CARLINO AND CHARLES CARLINO,	:	June Term 2013 No. 03470
Plaintiffs,	:	1129 EDA 2016 1294 EDA 2016
v.	:	
ETHICON, INC., et al.,	:	
Defendants	:	

OPINION

POWELL, JR. KENNETH J., J. **January 3, 2017**

I. Procedural History

On June 26, 2013, the Plaintiffs, Sharon and Charles Carlino, commenced this action by filing a complaint against Ethicon, Inc. ("Ethicon"), as well as numerous other defendants. On October 7, 2014, in response to a case management order, the Plaintiffs filed a short-form complaint clarifying that their action was against Ethicon, Johnson and Johnson ("J&J"), Secant Medical, Inc., Secant Medical, LLC (collectively, hereinafter "Secant"), and Prodesco, Inc. ("Prodesco"). The complaint arises from the implantation of Tension-free Vaginal Tape, or TVT, a transvaginal mesh product, which was surgically implanted in Ms. Carlino on August 18, 2005.

The complaint brought numerous claims based in New Jersey product liability law. Ultimately, the jury found that Ms. Carlino's TVT has a design defect that was a cause of her injuries, and further found that Ethicon failed adequately to warn of TVT's medical risks, and that the failure to warn was also a cause of Ms. Carlino's injuries. On February 10, 2016, after a fourteen-day trial, the jury awarded $3.25 million in compensatory damages to Ms. Carlino,

$250,000 to Mr. Carlino for loss of consortium, and punitive damages of $10 million. The total verdict was thus $13.5 million for the plaintiffs.

On February 22, 2016, Ethicon and J&J filed a post-sentence motion, which this Court denied on March 23, 2016. On March 15, 2016, this Court granted in part and denied in part the Plaintiffs' motion for delay damages, molding the gross verdict of $13,500,000 to add delay damages in the amount of $239,119.48, for a total judgment of $13,738,119.48. On April 1, 2016, the parties stipulated to entry of judgment in that amount and this Court approved the parties' stipulation, which further stated that Plaintiffs will not seek to execute on the judgment during the pendency of the appeal. On that same date, the Defendants filed a notice of appeal to the Superior Court. On April 12, 2016, the Plaintiffs filed a cross-appeal. Both parties filed timely statements pursuant to Pa.R.A.P. 1925(b).

II. Facts

Ms. Carlino, a fifty-eight year old services coordinator for Monmouth University's Registrar's Office, was suffering from back pain caused by uterine fibroids and stress urinary incontinence ("SUI"), and her gynecologist referred her to Dr. Andrew Blechman for surgery. Dr. Blechman suggested that she receive a laparoscopic hysterectomy and bilateral salpingo-oophorectomy with bladder sling procedure to alleviate her pain and SUI. On August 18, 2005, Dr. Blechman implanted the Plaintiffs' TVT during the bladder sling procedure. Her hysterectomy was effective in alleviating her back pain, and initially it seemed that the TVT implantation was also successful. N.T. January 27, 2016, a.m., pp. 57-100.

However, in 2007, she noticed a sharp foreign body penetrating her right vaginal wall from within her body. She returned to Dr. Blechman, who removed that portion of the TVT and repaired her vaginal wall. In 2010, she again felt a sharp foreign body penetrating her vaginal

wall from inside her body. She returned to Dr. Blechman, who told her he was hesitant to perform a third procedure and referred her to a colleague, Dr. Conner. Dr. Conner removed the right side of the TVT. Ms. Carlino's incontinence returned, but she elected to endure it rather than risk another TVT implantation. *Id.* at 100-104.

For a time, it seemed as if her problems with the TVT had ended. But in late 2011 and early 2012, she began to experience a dramatic intensification of her incontinence, pain and swelling in her vagina, pain during sex, and a sensation of pulling across her leg. At the time of trial, she was experiencing pain most of the time, on the right side at the site of her corrective surgeries and in her left pelvic area. She takes gabapentin, which is used to treat neuropathic pain (among other conditions). The pain she experiences during and after sexual intercourse severely limits her ability to tolerate penetration. Before 2012, she and her husband had intercourse approximately four times a week; by the time of trial, they had intercourse two or three times per month, in a way that is very limited because of her pain. Her injuries have diminished their sexual relationship, and they discuss the issue of her injuries and their impact in their lives and marriage on a daily basis. Because she has constant pain at the site of her rescission, penetration is difficult for her to endure. She feels guilty that she can no longer engage with her husband the way she was able to in the past due to her injuries. *Id.* at 105-112; 118-119. Her husband testified that they can no longer be spontaneous with each other sexually, and that they spend a lot of time discussing her pain and its impact on their lives. He said that it has limited many of their other joint activities, such as working out together at the gym, and that it has dampened their visions of their joint retirement. N.T. February 2, 2016, p.m., pp. 11-20.

The Plaintiffs filed suit against the Defendants on June 26, 2013. N.T. January 27, 2016, a.m., p. 115.

Ms. Carlino testified that if she had been warned about the risks of the TVT implantation (including inflammation, erosion of the TVT into the vaginal canal, degrading of the TVT in the body, mechanically-cut TVT giving off fragments, and pain during sex), she would not have consented to the procedure because the risks would have been far too great given the scope of the problem posed by her SUI. *Id.* at 97-98.

Dr. Blechman testified that, had he known of the full panoply of risks that came with TVT implantation, such as chronic foreign body response, degradation of the mesh material, and permanent pain (including pain during intercourse), he would have warned Ms. Carlino of those risks, and would not have recommended the implantation procedure to her, or to any patient. *See* Deposition of Andrew Blechman, M.D., January 30, 2016, pp. 42-59.

Dr. Michael Margolis gave expert testimony as to urogynecology and pelvic reconstruction surgery. He is a surgeon who performs pelvic surgeries, including sling surgeries, though he only implants organic materials rather than TVT. He has performed surgeries in order to remove TVT. SUI is the most common condition he treats, and he explained that condition. He also explained the procedures by which the TVT was implanted and then removed from Ms. Carlino's body. He testified, based on his examination of her, that TVT is the cause of Ms. Carlino's injuries, and that it will continue to cause irreversible injury in perpetuity. January 27, 2016 p.m., pp. 83-123; January 28, 2016, pp. 18-36.

Dr. Margolis also testified that the remaining TVT sling cannot be safely removed from Ms. Carlino's body, and that even if it could be safely removed, she would still have a permanent painful condition. She has, and will continue to have, inflammation and scarring due to the TVT, along the tract of implantation. He also confirmed that the remaining TVT material is palpable, and will very likely erode through her left vaginal wall, as the prior pieces of TVT did on the

other side. Her body is responding to the TVT by rejecting it as foreign, which is causing continuous inflammation which will likely eventually result in her body pushing out the TVT. Dr. Margolis testified that the TVT's heavy weight, small pore size, and cytotoxicity all contribute to its damaging impact in Ms. Carlino's body. *Id.* at 36-52.

When the 2.4 centimeter section of TVT was removed in 2010, the tissue was sent to a pathologist for examination. The pathology report documented "[f]ragments of fibroconnective tissue with mild chronic inflammation and foreign body giant cell reaction to foreign material." Fibroconnective tissue is scar tissue. Giant cells are indicative of a continuous, aggressive immune reaction to the foreign material. *Id.* at 60-62, Plaintiff Exh. 44. The pathology report indicated that Ms. Carlino's body is continuing to attack the remaining TVT, sending potent immune cells and attempting to wall the TVT off behind scar tissue. In response, the TVT contracts, potentially creating or contributing to the pulling sensation of pain that Ms. Carlino experiences. *Id.* at 62-65.

The "Instructions For Use," or IFU, in use at the time the TVT was implanted listed transitory local irritation and transitory foreign body response among its potential adverse reactions. Ms. Carlino's experiences were not described in the listing of adverse reactions, but Dr. Margolis testified that they should have been, because doctors and patients should be able to rely on notifications of adverse reactions to understand the potential risks of procedures before they agree to them, and because these adverse reactions were known to Ethicon at the time of Ms. Carlino's surgery in 2005. *Id.* at 78-84.

Dr. Margolis' examination of Ms. Carlino confirmed that the remaining sling material has "shrunk up and rolled" on the left side, and she has palpable scar tissue on the right side, where the sling used to be. He identified her options for treatment as a very invasive surgical procedure

aimed at removing all remaining material (though he cautioned that such a surgery would not be successful in removing all material), or treatment that would destroy the nerves of the vagina. Pain medication is a third option. *Id.* at 85-88. Dr. Margolis concluded to a reasonable degree of medical certainty that Ms. Carlino's symptoms are caused by the TVT implantation and subsequent inflammation and surgeries caused by the implant's failure. *Id.* at 94-98.

Piet Hinoul, M.D., Ethicon worldwide medical director and designated medical affairs corporate representative, acknowledged that the TVT product has a number of serious complications, including erosion, pain, scarring, mesh contracture, pain during intercourse, and the potential necessity of subsequent surgeries to remove mesh that was malfunctioning or causing harm. *See* Deposition of Piet Hinoul, M.D., June 27, 2013, at pp. 548-550. He also confirmed that these risks were known to Ethicon at the time they launched the TVT product. *See id.* at pp. 551-55. Ethicon Medical Director Dr. Martin Weisberg gave similar testimony, confirming that the risk of lifelong pain and additional surgeries was known to Ethicon, but was not included in the IFU. *See* Deposition of Martin Weisberg, M.D., August 9, 2013, at pp. 968-69. Former Ethicon Medical Director, Dr. David Robinson, testified that that there is lifelong risk of erosion as long as the foreign body remains in place, but that Ethicon did not warn of the lifelong risk of erosion, the possibility of multiple surgeries, or permanent painful sexual intercourse in the IFU or patient brochure. *See* Deposition of David Robinson, M.D., September 11, 2013, at pp. 1139-1140.

III. Issues

Plaintiff raises the following issue:

1. On March 15, 2016, the trial court granted in part and denied in part Plaintiff's Motion for delay damages. This motion sought delay damages on the entirety of the jury's verdict – both the compensatory award and the punitive damages award. The trial court molded the

jury's gross verdict of $13,500,000.00 to add delay damages of $238,119.48 for a total judgment of $13,738,119.48. In doing so, the trial court calculated delay damages only on the compensatory damages portion of the jury's verdict. The trial court denied Plaintiff's request that delay damages be calculated based on the punitive damages award as well. Did the trial court misinterpret Pa.R.C.P. 238 and err by refusing to calculate delay damages based on the entire verdict, including the punitive award?

Defendant raises the following issues:

1. The Court erred in permitting Plaintiffs to litigate their claims because the Court lacks personal jurisdiction over Defendants. Plaintiffs reside in New Jersey, yet the Court allowed them to litigate claims in Pennsylvania under New Jersey law against New Jersey defendants about conduct that occurred entirely in New Jersey. As a result, both specific jurisdiction and general jurisdiction were lacking under 42 Pa.C.S. § 5322 and the federal Constitution. *See* Defs.' Ethicon, Inc. and Johnson & Johnson's Mot. for Post-Trial Relief Pursuant to Pa.R.C.P. No. 227.1 ("Post-Trial Mot.") at 1–2.

2. The Court erred in denying Defendants' motions for directed verdict and post-trial relief, including jnov, and Defendants' oral motion for mistrial and other curative measures, on the basis of preemption because Plaintiffs' claims are preempted insofar as they are based on (a) a state-law duty to sell an alternative design that required, but had not received, FDA's permission by the time of Ms. Carlino's TVT surgery; (b) a challenge to the information on which the FDA based its decision to permit the marketing of the product and the scope and content of the product's warnings; or (c) Plaintiffs' suggestion that Defendants had a duty not to sell TVT or to stop selling TVT altogether. *See* Post-Trial Mot. 17–18, 26–27, 84–86 (*citing, e.g., Wyeth v. Levine*, 555 U.S. 555 (2009), *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)).

3. Plaintiffs did not bring suit within two years of the accrual of their claims. Accordingly, under either New Jersey or Pennsylvania law, these claims were barred, and the Court erred in permitting them to go forward and in denying Defendants' motions for directed verdict and jnov, in permitting improper argument on the issue, and in failing to properly charge the jury on the issue. *See* Post-Trial Mot. 7–16. In particular:

    A. The Court erred in denying Defendants' motions for directed verdict and jnov because Plaintiffs' claims are time-barred. First, given Pennsylvania's borrowing statute, New Jersey law governs the issue, and it should have been resolved as a matter of law in Defendants' favor. By applying Pennsylvania law on this issue and allowing the jury to decide it, the Court improperly gave Plaintiffs greater rights than those available in the state where the cause of action arose. Under New Jersey law, Plaintiffs' claims were time-barred because they failed to present evidence sufficient to carry their burden of proving that the discovery rule rendered their claims timely. Second, even under Pennsylvania law, Plaintiffs' claims were time-barred because they failed to present evidence sufficient to carry their burden of proving that the discovery rule rendered their claims timely. In particular, Ms. Carlino was prescribed

TVT in August 2005, but Plaintiffs did not file suit until June 2013, even though she underwent revision surgeries in 2007 and 2010 to remove portions of the TVT that had become exposed in her vagina and, she says, caused her sharp vaginal pain. Given Plaintiffs' and their counsel's judicial admissions, Ms. Carlino could not rely on the discovery rule. It is no excuse to say that she did not know the full extent of her injuries or what about the mesh caused them; she was obligated to exercise reasonable diligence to determine any details she was lacking, yet Plaintiffs failed to present sufficient evidence that she did so. *See* Post-Trial Mot. 7–16.

B. In giving the case to the jury, the Court erred in not enforcing—despite Defendants' objections—its own ruling on nonsuit that Plaintiffs could not avoid the statute of limitations by claiming that they were not seeking damages from the 2007 and 2010 manifestations of the claimed injury. By allowing Plaintiffs to argue precisely that in closing, Defendants were prejudiced and a new trial is necessary. *See* Post-Trial Mot. 9–10, 13–14, 84–85. In addition, the Court erroneously permitted Plaintiffs to encourage the jury to nullify or disregard the statute of limitations by neither (1) instructing the jury that it must consider the earliest injury that Ms. Carlino could reasonably have discovered, without regard to whether Plaintiffs were seeking damages for that injury nor (2) correcting Plaintiffs' mischaracterization of the statute of limitations during closing. Defendants were prejudiced by the Court's rulings and a new trial is necessary. *See* Post-Trial Mot. 84–85, 91–92

4.

A. The Court erred by giving an inadequate and inaccurate instruction on Plaintiffs' burden to prove an alternative design that is safer, available, practical, and feasible and would have prevented or lessened their alleged injuries. Specifically, the Court erred by refusing to give Defendants' proposed instruction No. 31 and instead instructing the jury that Plaintiffs were required to prove a safer alternative design "unless the risk involved in the TVT's use outweigh its utility even though there is no reasonably feasible . . . alternative design." These errors prejudiced Defendants and require a new trial. *See* Post-Trial Mot. 89–91.

B. The Court erred in denying Defendants' motions for directed verdict and jnov because Plaintiffs failed to present evidence sufficient to carry their burden of proving the existence of an alternative design to TVT that was safer, available, practical, and feasible and that would have prevented or lessened their alleged injuries. *See* Post-Trial Mot. 19–27

5.

A. The Court erred in providing proximate causation instructions and a verdict form that (1) failed to convey New Jersey law on the learned intermediary doctrine because they improperly asked the jury what the patient would have done if the warnings had been provided rather than limiting the alleged failure to warn to the prescribing physician and (2) did not instruct the jury that it could not find proximate causation when Dr. Blechman already knew the risks of the mesh at the time he prescribed it and testified that he did. Defendants were prejudiced by the Court's rulings and a new trial is necessary. *See* Post-Trial Mot. 31–34, 86–88, 93–96.

B. The Court erred in finding that Plaintiffs had presented legally sufficient evidence that an inadequacy in Ethicon's warnings caused their alleged injuries. Under New Jersey law, there is no duty to warn of the frequency, severity, or incidence of complications, but the Court permitted Plaintiffs to argue that that information was necessary to an adequate label. For this reason, the Court also erred in permitting Plaintiff to argue that Defendants were liable for failing to include that information in TVT's warnings. In addition, New Jersey law requires that Plaintiffs prove that the prescribing physician would have changed his prescribing decision if the product had had an adequate warning. Plaintiffs did not show that Dr. Blechman was unaware of the complications Ms. Carlino complained of. Because Plaintiffs failed to present sufficient evidence that an inadequacy in Ethicon's warnings caused their alleged injuries, the Court erred in denying Defendants' motions for directed verdict and post-trial relief, including jnov, on this issue. *See* Post-Trial Mot. 31–38, 74–76.

C. The Court erred in permitting the jury to be misled about whether Dr. Blechman's decision to prescribe in general would have changed had he known of Ms. Carlino's complications. This error, described further at ¶ 6, infra, arose because the Court admitted testimony from Dr. Blechman without permitting other testimony in which he clarified that the admitted testimony was based on his misunderstanding of the question. This and the other stricken portions of the testimony from Dr. Blechman would have negated the notion that an inadequacy in Ethicon's warnings caused Dr. Blechman to use TVT. *See* Post-Trial Mot. 36–38.

6. The Court erred in striking Defendants' cross-examination of Dr. Blechman from his mid-trial deposition as a sanction, for two reasons. First, the Court erred in holding that Defendants violated the Court's ruling on a motion *in limine* regarding FDA evidence (which by its terms governed only the admissibility of evidence at trial) at all, because the deposition was taken subject to the Pennsylvania Rules of Civil Procedure governing discovery, including, inter alia, Pa.R.C.P. No. 4017.1(h) (providing for the transcribing of the portions of video depositions admitted and those excluded on objection) and the Pennsylvania Rules of Evidence, and the case law construing them. All parties and the Court understood that only portions of the deposition would be designated for trial and that the Court would review objections before testimony was admitted. Second, the Court further erred in imposing an excessive and prejudicial sanction for what (a) did not violate the terms of the Pennsylvania Rules of Civil Procedure or the Court's ruling on the motion *in limine*; and (b) did not take into account and was contrary to (i) the nature and severity of the supposed violation; (ii) the willfulness or bad faith of the supposed violation; (iii) prejudice; (iv) the ability to cure the prejudice; and (v) the importance of the evidence in light of the supposed failure to comply. Defendants were prejudiced by the Court's ruling, *see supra* at ¶ 5.C., and the motion for mistrial should have been granted and a new trial is necessary. *See* Post-Trial Mot. 49–54.

7. The Court erred in denying Defendants' motions for directed verdict and post-trial relief, including jnov, and thereby permitting punitive damages to be awarded, for three reasons.

First, the Court lacked constitutional authority to impose punitive damages because a Pennsylvania jury may not award punitive damages for conduct that had no nexus to Pennsylvania. Punitive damages here were unconstitutional because it is entirely arbitrary to have a Pennsylvania jury determine whether and how to "punish" a New Jersey defendant for New Jersey conduct regulated by New Jersey law (to the extent that it was not preempted). *See* Post-Trial Mot. 6, 40–42. Second, the New Jersey Punitive Damages Act bars punitive damages when, as here, the FDA has recognized a medical device as safe and effective pursuant to the conditions and requirements the FDA imposes. *See* Post-Trial Mot. 42–44 (quoting N.J.S.A. § 2A:58C-5). Third, under New Jersey's general punitive damages statute, N.J.S.A. § 2A:15-5.12, the Court erred by permitting punitive damages to be awarded, because Plaintiffs failed to present evidence sufficient to prove by clear and convincing evidence that the acts or omissions causing the Plaintiffs' alleged harm "were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." *See* Post-Trial Mot. 42, 44–47. In the alternative, the Court should have remitted the punitive damages award. The punitive damages award was excessive and inconsistent with other New Jersey awards, and it should have been remitted, because the compensatory damages were largely non-economic, thus already containing a punitive element, and because the punitive damages award was unsupported by the evidence. *See* Post-Trial Mot. 99–103.

8. The Court erred in failing to remit the compensatory damages award. It was excessive and unsupported by the evidence because (a) there was no testimony of past or future medical costs, and (b) the award was clearly excessive for the alleged injuries (i.e., intermittent post-2012 pain and its consequences), particularly in light of the testimony that Ms. Carlino's symptoms could be mitigated, but she refused to do so. *See* Post-Trial Mot. 96–99.

9. The Court erred in excluding all evidence of and argument regarding FDA's clearance of TVT as well as related regulatory processes; FDA's advisory committee process and statements regarding mesh midurethral slings; FDA's approval, regulation, and study of Prolene suture; and FDA's regulation and study of surgical mesh. This evidence was admissible to counter Plaintiffs' assertions that Ethicon's warnings were inadequate and that TVT is defectively designed. Exclusion of this evidence also deprived Defendants of defenses guaranteed by New Jersey law, because (a) manufacturers who comply with FDA requirements, as Ethicon did here, are rebuttably presumed to have adequate labels; and (b) punitive damages are not permitted where, as here, a medical device has been approved or is generally recognized as safe and effective. Defendants were prejudiced by the exclusion of this evidence, and a new trial is necessary. *See* Post-Trial Mot. 55–65.

10. The Court erred in admitting evidence that did not relate to TVT. First, the Court erred by admitting evidence of an October 13, 2002 email from Axel Arnaud to Martin Weisberg regarding the Prolene Soft material (Pls.' Trial Ex. 46), which is not used in TVT. That material was not at issue in this case, and impugning Defendants with it requires a new trial. *See* Post-Trial Mot. 70–71. Second, the Court erred by admitting evidence of an irrelevant material safety data sheet issued by Chevron Phillips (Pls.' Trial Ex. 54) regarding a product that Defendants neither manufactured nor used in making TVT and thus was both irrelevant and prejudicial, warranting a new trial. *See* Post-Trial Mot. 71–73.

11. The Court erred by holding that any admission of otherwise admissible evidence that TVT remains on the market and is the current gold-standard surgical treatment for stress urinary incontinence or present-tense references to TVT would open the door to Plaintiffs introducing evidence of changes to TVT's Instructions for Use, which is inadmissible as a subsequent remedial measure. These errors prejudiced Defendants by effectively precluding the admission of this critical evidence and require a new trial. *See* Post-Trial Mot. 65–68.

IV. Discussion

a. This Court's Decision to Calculate Delay Damages Only on the Compensatory Damages Portion of the Jury's Award Was Proper.

Plaintiff-Appellant argues that this court erred when it calculated delay damages only on the compensatory damages portion of the jury's award. Pa. R.C.P No. 238 permits a plaintiff to recover prejudgment interest on awards in tort cases under Pennsylvania Law. The Rule states in relevant part:

> At the request of the plaintiff in a civil action seeking monetary relief for bodily injury, death or property damage, damages for delay shall be added to the amount of compensatory damages awarded against each defendant or additional defendant found to be liable to the plaintiff in the verdict of a jury, in the decision of the court in a nonjury trial or in the award of arbitrators." Pa.R.C.P. No. 238(a)(1). Damages for delay shall be calculated at the rate equal to the prime rate as listed in the first edition of the Wall Street Journal published for each calendar year for which the damages are awarded, plus one percent, not compounded.

Pa.R.C.P. No. 238(a)(3). Rule 238 has been applied narrowly by Pennsylvania Courts. *See Touloumes v. E.S.C. Inc.*, 899 A.2d 343, 348 (Pa. 2006) (*citing Colodonato v Consolidated Rail Corp.*, 470 A.2d 475 (Pa. 1983) ("Virtually all cases emphasize the narrow breadth of the Rule"); *see also Hodges v. Rodriguez*, 645 A.2d 1340, 1349 (Pa. Super. 1994) ("Rule 238 applies only to certain actions and does not encompass every action."). The Pennsylvania Supreme Court expressly excluded punitive damages from the calculation of delay damages following an analysis of the "clear and unambiguous language of Rule 238." *Colodonato*, 470 A.2d at 478.

The Court determined that "inclusion of punitive damages would be offensive to the fairness that the rule seeks to ensure" because Rule 238 "serves to compensate the plaintiff for the inability to utilize funds rightfully due him. *Id.* Since punitive damages are "intended to punish and not to compensate, they are irrelevant to the concern underlying Rule 238 that tort victims be fully compensated for their losses." *Id.*

The Supreme Court adopted Rule 238 in 1978. In *Craig v. Magee Mem'l Rehab. Ctr.*, 515 A.2d 1350, 1353 (1986), the Supreme Court determined that amendments to Rule 238 were needed and made recommendations to the Civil Procedural Rules Committee. In 1988, The Supreme Court adopted the Rules Committee's amendments to Rule 238. Our Supreme Court's decision in *Colodonato v. Consol. Rail Corp.*, 470 A.2d 475, 479 (1983), interpreting the 1978 version of Rule 238, is definitive as to the issue Plaintiff-Appellant raises on appeal.

Plaintiff-Appellant opines that calculating delay damages on punitive damages is appropriate since the Supreme Court's ruling in *Colodonato* was based solely on an interpretation of the 1978 version of Rule 238 and not on the amended 1988 version. However, one of the oldest canons of statutory interpretation is the implied repeal doctrine. American courts have a longstanding history of advising against repeal by implication. *Wood v. United States*, 41 U.S. 342, 343, 10 L. Ed. 987 (1842). Pennsylvania's Supreme Court has not deviated from this longstanding practice. *See Kelly v. City of Philadelphia*, 115 A.2d 238, 244 (1955) (Repeals by implication "are not favored and will not be implied unless there be an irreconcilable conflict between statutes embracing the same subject matter."); *see also HSP Gaming, L.P. v. City of Philadelphia*, 954 A.2d 1156, 1175 (2008) ("The reason for such a restriction is obvious: absent irreconcilability, a judicial finding of implied repeal would essentially rewrite the legislation").

A review of the 1978 and 1988 versions of Rule 238 uncovers no irreconcilable conflict authorizing this Court to abrogate our Supreme Court's decision in *Colodonato*. The 1988 amendments revised practice and procedure under Rule 238 in several respects. *See Pa.R.C.P. No. 238 Explanatory Comment -1988*. However, the amended rule contains no language that explicitly overturns *Colodonato* or permits a court to include punitive damages in the calculation of delay damages. The Supreme Court approves amendments to the Pennsylvania Rules of Civil Procedure with the assistance of the Civil Procedural Rules Committee. Just as this Court is bound by legislative intent and admonitions against implied repeals of statutes, it is also bound by the Supreme Court's intent with respect to rules it has promulgated and its interpretations of those rules. In the absence of a new interpretation of Rule 238 and relying on *Colodonato*, this Court committed no error when it calculated delay damages only on the compensatory damages portion of the jury's verdict. This allegation of error, the sole allegation raised by the Plaintiff-Appellant, is meritless.

b. <u>This Court Did Not Lack Personal Jurisdiction.</u>

Initially, this Court notes that the Appellants did not make an appropriate, timely preliminary objection to the master long-form complaint that initiated this and related actions. A case management order entered on March 31, 2014 directed defendants to file preliminary objections within twenty days of filing of the master long-form complaint. Any alleged defect in personal jurisdiction should have been apparent to the Appellants at that time, and Pa.R.C.P. 1028(a)(1) indicates that preliminary objections are the proper vehicle to challenge "lack of jurisdiction over the subject matter of the action or the person of the defendant, improper venue or improper form or service of a writ of summons or a complaint." The master long-form complaint was filed on May 14, 2014, and the preliminary objections timely filed on June 10,

2014 did not include any challenge to jurisdiction. The appellants' post-verdict motion lists September 29, 2014 as the first instance in which they raised this issue.

As the plaintiffs pointed out in their reply to the defendants' Motion to Dismiss for Lack of Personal Jurisdiction, filed September 29, 2014, the defendants had argued earlier that personal jurisdiction was properly treated as a global issue, and as such should be decided at the outset of this and all related litigation. This Court is inclined to agree. Pennsylvania law provides that preliminary objections are the exclusive manner in which one challenges the jurisdiction of a tribunal. *See* Pa.R.C.P. 1028(a)(1); *Monaco v. Montgomery Cab. Co.*, 208 A.2d 252, 255 (Pa. 1965); *Ball v. Barber*, 621 A.2d 156, 158 (Pa. Super. 1993) ("A party who fails to raise a question of the court's *in personam* jurisdiction by timely preliminary objections waives that claim."); *Bergere v. Bergere*, 527 A.2d 171, 173 (Pa. Super. 1987) ("preliminary objections are the exclusive means by which to raise the question of *in personam* jurisdiction and the failure to so raise the question of personal jurisdiction constitutes a waiver of that defense"). Here, the defendants filed preliminary objections to the Master Long Form Complaint but failed to object to jurisdiction. This was the proper moment in which to raise such a foundational issue, but the defendants' failure to do so results in waiver.

This claim is also meritless. Pennsylvania law authorizes jurisdiction over a foreign corporation that carries on a "continuous and systematic part of its general business within this Commonwealth." 42 Pa.C.S. § 5301(a)(2)(iii). When jurisdiction over a defendant is based on Section 5301(a), any cause of action may be asserted against the defendant, whether or not it arises from the defendant's conduct in Pennsylvania.

The Due Process Clause of the Fourteenth Amendment to the United States Constitution governs the authority of a state to exercise *in personam* jurisdiction over non-resident defendants. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471–72, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985). The extent to which jurisdiction is proscribed by the Due Process Clause depends on the nature and quality of the defendant's contacts with the forum state. *See id.* at 474–76, 105 S.Ct. 2174; *Kubik v. Letteri*, 532 Pa. 10, 614 A.2d 1110, 1114 (1992); *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014) (exercise of general jurisdiction appropriate where a defendant's "affiliations with the [forum] state are so 'continuous and systematic' as to render [it] essentially at home"). Where a defendant "has established no meaningful contacts, ties or relations" with the forum, the Due Process Clause prohibits the exercise of personal jurisdiction. *Burger King*, *supra* at 472, 105 S.Ct. 2174. However, where a defendant has "purposefully directed" his activities at the residents of the forum, he is presumed to have "fair warning" that he may be called to suit there. *Id.*

General jurisdiction involves "circumstances, or a course of conduct, from which it is proper to infer an intention to benefit from[,] and thus an intention to submit to[,] the laws of the forum State [.]" *J. McIntyre Machinery, Ltd. v. Nicastro,* 564 U.S. 873, 131 S.Ct. 2780, 2787, 180 L.Ed.2d 765 (2011). "For an individual, the paradigm forum for the exercise of general jurisdiction is the individual's domicile; for a corporation, it is an equivalent place, one in which the corporation is fairly regarded as at home." *Goodyear, supra* at 2853–54. Thus, general jurisdiction may be exercised against foreign corporations "when their affiliations with the [forum] State are so 'continuous and systematic' as to render them essentially at home [there]." *Goodyear, supra* at 2851 (quoting *International Shoe Co. v. Washington,* 326 U.S. 310, 317, 66 S.Ct. 154, 90 L.Ed. 95 (1945)). In contrast to specific jurisdiction, a state that has general

jurisdiction may adjudicate "both matters that originate within the State and those based on activities and events elsewhere." *J. McIntyre, supra* at 2787.

Ample facts demonstrate the appellants' significant and continuing contact with Pennsylvania:

- While Johnson & Johnson is a public corporation incorporated in the State of New Jersey, it controls and operates seventy-eight subsidiaries in the United States. Of these seventy-eight subsidiaries, fully sixteen of them are incorporated in or have their principle place of business in Pennsylvania. *See* Johnson & Johnson's "10-K" filed with the U.S. Securities and Exchange Commission, filed Feb. 21, 2014 (attached to the plaintiff's response to the defendant's jurisdiction motion as Exhibit "E").

- These Pennsylvania subsidiaries include McNeil Consumer Healthcare, headquartered in Fort Washington, PA. McNeil Consumer Healthcare is responsible for manufacturing and selling many of the brands consumers associate with Johnson & Johnson, including Tylenol, Motrin, Imodium, Lactaid, Listerine, Plax, Visine, Benadryl, Caladryl, Zyrtec, Mylanta, Pepcid, Splenda and Benecol.

- Another Pennsylvania subsidiary is Janssen Pharmaceuticals, Inc., also headquartered in Fort Washington, PA. Janssen manufactures and sells prescription drugs including Concerta, Levaquin, Ortho Evra, Ortho Tri-Cyclen Lo, Risperadal, and Topamax. In 2013, one of its products – Remicade - accounted for 9.4% of the company's total revenues. *See id.* at 2. Remicade, Simponi and Stelara are manufactured by Janssen Biotech, which is headquartered in Horsham, PA. These three drugs accounted for 12.8% of the company's total revenue in 2013. *See id.* at 21.

c. **These Claims Are Not Preempted.**

Defendant-Appellants argue that Plaintiffs' claims are preempted insofar as they are based on (a) a state-law duty to sell an alternative design that required, but had not received, FDA's permission by the time of Ms. Carlino's TVT surgery; (b) a challenge to the information on which the FDA based its decision to permit the marketing of the product and the scope and content of the product's warnings; or (c) Plaintiffs' suggestion that Defendants had a duty not to sell TVT or to stop selling TVT altogether.

Initially, this Court would find that this claim is waived for failure to state it with sufficient specificity in the 1925(b) statement. Nowhere in the statement do the Defendant-Appellants cite *what federal law* they believe preempts state law in this case. Even if the Defendant-Appellants have argued this claim with sufficient specificity elsewhere, incorporating issues into a Rule 1925(b) statement by reference to another document constitutes a failure to comply with letter and spirit of Rule 1925(b). *Commonwealth v. Osteen*, 552 A.2d 1124, 1126 (Pa. Super. 1989).

"[F]ederal preemption of state law can occur in three types of situations: where Congress expressly preempts state law, where preemption is implied because Congress has occupied an entire field, and where preemption is implied because there is an actual conflict between federal and state law." *Cellucci v. Gen. Motors Corp.*, 676 A.2d 253, 258 (Pa. Super. 1996), *aff'd*, 706 A.2d 806 (Pa. 1998) (citations omitted). Conflict preemption "may arise in two contexts. First, there may be conflict preemption where compliance with state and federal law is an impossibility... Furthermore, conflict preemption may also be found when state law stands as an obstacle to the accomplishments and execution of the full purposes and objectives of Congress."

Dooner v. DiDonato, 971 A.2d 1187, 1194 (Pa. 2009) (citations omitted). Preemption analysis begins with the assumption that 'the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth v. Levine*, 555 U.S. 555, 565, 129 S. Ct. 1187, 1194–95 (2009) (*quoting Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 2250 (1996). Proper preemption analysis depends upon a comparison of the federal statute or regulation and the particular state law applicable. *See Foster v. Love*, 522 U.S. 67, 71, 118 S.Ct. 464 (1997) (preemption determination must turn on whether state law conflicts with the text of the relevant federal statute or regulation).

It appears that Defendant-Appellants argue impossibility preemption.[1] This claim applies to the design defect judgment, and not to the failure to warn judgment, though it purports to apply to "claims" in the plural. *See, e.g.*, Defendant-Appellants' Motion for Summary Judgment, Control No. 15103170, filed Oct. 23, 2015, pp. 3, 29-35 (claiming preemption solely as to design defect claim); Defendant-Appellants' Post-Trial Motion, Control No. 16023260, filed Feb. 22, 2016, p. 17-18 (same). To the extent that the Defendant-Appellants are arguing that the Plaintiffs "suggested" that they had a duty not to sell TVT, this is inapt as it misrepresents the Plaintiffs' position. The Plaintiffs argue, in their response to the Defendant-Appellants' Motion for Summary Judgment, "defendants could have altered its design before marketing and/or obtaining 510(k) clearance when defendants were well aware of the serious risks and complications it

[1] This Court finds that the Statement of Errors' claim that the Plaintiffs argued at trial that the Defendant-Appellants had "a state-law duty to sell an alternative design that required, but had not received, FDA's permission by the time of Ms. Carlino's TVT surgery" is unsupportable. Pennsylvania law does not impose any duty that the Defendant-Appellants sell any particular thing, and the Plaintiffs never argued that the Defendant-Appellants had any affirmative duty to sell any particular thing. Nor did the Plaintiffs proceed to trial based on a "challenge to the information on which the FDA based its decision to permit the marketing of the product and the scope and content of the product's warnings." The Plaintiffs did not join the FDA for trial or otherwise try to divine the basis for the FDA's decisions regarding the product in question. This is a design defect and failure to warn case, based on Pennsylvania law, not some sort of *qui tam* case involving the federal government's interest in receiving accurate information during the FDA approval process.

posed to women." The 510(k) clearance process is not a review for safety and effectiveness but only a review to verify that a device is "substantially equivalent" to an already-approved device.[2] "That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law." *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014) (510(k) evidence excluded as irrelevant; tort claim against TVT manufacturer not preempted by federal law).

The United States Supreme Court has determined that the Food, Drug, and Cosmetic Act's preemption provision does not apply to products liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501-02, 116 S. Ct. 2240 (1996). In *Lohr*, the Court found that because the 510(k) requirements did not relate to the safety or efficacy of the device, they did not preempt state design defect claims. *Id.* ("the Court of Appeals properly concluded that the 'substantial equivalence' provision did not pre-empt the Lohrs' design claims."); *see also Lewis*, 991 F. Supp. 2d at 756 (Ethicon's preemption argument that because the material used to make TVT underwent premarket approval as a suture material, state tort claims involving TVT are preempted, fails); *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 743-44 (S.D.W. Va. 2014) ("[t]hat a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law."). *Lohr* is dispositive; even if this claim were not waived for failure to plead it with sufficient specificity in the 1925(b) statement, it is meritless.

Defendant-Appellants argue that *Lohr* is not dispositive because they are not arguing express preemption but implied conflict preemption – in other words, it is not that federal law

[2] Federal Food, Drug, and Cosmetic Act, § 510(k), as amended, 21 U.S.C. § 360(k).

explicitly preempts state law, but that it would be impossible for Defendant-Appellants to comply with New Jersey tort law and (some unstated) federal law. Defendant-Appellants cite no cases involving a medical device put to market after 510(k) "substantial equivalence" analysis; instead, they cite pharmaceutical cases. It is clear that Defendant-Appellants have been lofting trial balloons of various iterations of preemption arguments in TVT matters, as in *Lewis*; this case seems exceedingly unlikely to give them what they seek, given that there is no federal law against manufacturing a TVT device that will not cause the harms the Plaintiffs experienced. The strong presumptions against preemption are backed by sound policy, and the Defendant-Appellants have cited no law establishing that implied conflict preemption applies in this context; this claim fails.

d. <u>These Claims Are Not Time-Barred.</u>

The Defendant-Appellants claim that Plaintiffs did not bring suit within two years of the accrual of their claims, and that under both New Jersey and Pennsylvania law, their claims were barred, and the Court erred in permitting them to go forward and in denying Defendant-Appellants' motions for directed verdict and jnov, in permitting improper argument on the issue, and in failing to charge the jury correctly on the issue. They argue that under either states' law, Plaintiffs' claims were time-barred because they failed to establish that the discovery rule rendered their claims timely. Ms. Carlino was prescribed TVT in August 2005, but Plaintiffs did not file suit until June 2013, even though she underwent revision surgeries in 2007 and 2010 to remove portions of the TVT that had become exposed in her vagina. Defendant-Appellants argue that she was obligated to exercise reasonable diligence to determine "any details she was lacking," but she did not establish that she did so. They further argue that this Court erred in not enforcing—despite Defendants' objections—its own ruling on nonsuit that Plaintiffs could not

avoid the statute of limitations by claiming that they were not seeking damages from the 2007 and 2010 manifestations of the claimed injury. By allowing Plaintiffs to argue precisely that in closing, Defendants were prejudiced and a new trial is necessary. In addition, the Court erroneously permitted Plaintiffs to encourage the jury to nullify or disregard the statute of limitations by neither (1) instructing the jury that it must consider the earliest injury that Ms. Carlino could reasonably have discovered, without regard to whether Plaintiffs were seeking damages for that injury nor (2) correcting Plaintiffs' mischaracterization of the statute of limitations during closing.

In Pennsylvania, the borrowing statute, known as the Uniform Statute of Limitations on Foreign Claims Act ("USLFCA"), establishes the time in which an out-of-state action must be commenced. *See* 42 Pa.C.S. § 5521(b), which specifies that "[t]he period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim." A two-year statute of limitations applies to Plaintiff's claims under both Pennsylvania and New Jersey law. *See* 42 Pa.C.S. § 5524(2) & (7); N.J.S.A. 2A:14-2. Both jurisdictions employ an analogous "discovery rule," which tolls the running of the statute of limitations until such time that the plaintiff knew or should have known both that she was injured and that her injuries were caused by the tortious conduct of another. *See Miller v. Ginsberg*, 874 A.2d 93, 97-98 (Pa. Super. 2005) (party invoking discovery rule must establish inability to know of injury by another's act despite exercise of reasonable diligence; generally, this is a jury issue); *Mancuso v. Neckles ex rel. Neckles*, 747 A.2d 255 (N.J. 2000) (discovery rule postpones accrual of cause of action so long as a party is reasonably unaware either that she has been injured or that the injury is due to fault or neglect of identifiable individual or entity; plaintiff may bring claim

based on 1989 negligent misreading of mammogram where she did not know until 1996 of the potential error).

In *Mancuso*, the Supreme Court of New Jersey reiterated that application of the discovery rule in medical malpractice cases "requires special focus on the 'nature of the information' possessed by the claimant," further explaining that "[i]n cases of complex medical causation, it is not at all self-evident that the cause of injury was '(a) the fault of (b), a third party. Not only is the nature of the injury generally unclear, its very existence is frequently masked." *Id.* at 34, *quoting Vispisiano v Ashland Chemical Co.*, 527 A.2d 66, 76 (N.J. 1987).

Under the USLFCA, when both states have an equivalent statute of limitations period and "virtually identical" discovery rules, Pennsylvania law applies. *See Coleman v. Wyeth Pharmaceuticals, Inc.*, 6 A.3d. 502, at fn. 13 (Pa. Super. 2010). However, the statute of limitations analysis under both jurisdictions is substantially similar and requires the same result: Plaintiffs' claims are not time-barred.

Defendants argue that the statute of limitations began to run when Ms. Carlino complained of dyspareunia due to exposed mesh in November 2007 and again in 2010. Plaintiffs timely filed their complaint within the applicable two year statute of limitations. Generally, the limitations period begins to run from the time the cause of action accrues. Here, the discovery rule tolled the running of the statute of limitations until the spring of 2013, when Ms. Carlino saw a television commercial that described transvaginal mesh products as defective. This was the first time Ms. Carlino learned that there was an issue with the TVT itself, and that issue could be the reason for her TVT issues. Defendant-Appellants focus overmuch on the initial appearance of negative symptoms related to the TVT, rather than making a case that Ms. Carlino should have

understood the fuller implications of the nature and extent of her injury when her negative symptoms first arose. Notably, the Defendant-Appellants have made no assertion that *they themselves* made every effort to alert people in Ms. Carlino's position when they first became aware that there might be a systematic issue with their product.

In Pennsylvania, the discovery rule is a judicially created exception that tolls the applicable statute of limitations when an injury or its cause was not known or reasonably knowable. *Fine v. Checcio, D.D.S.*, 870 A.2d 850 (Pa. 2005). It is for the jury to decide the knowability of the harm or its cause. *Crouse v. Cyclops Industries*, 745 A.2d 606 (Pa. 2000).

Under New Jersey law, the discovery rule requires "knowledge not only of the injury but also that another is at fault." *Martinez v. Cooper Hosp. –Univ. Med. Ctr.*, 747 A.2d 266 (N.J. 2000). The time begins to run when "the facts presented would alert a reasonable person, exercising ordinary diligence, that he or she was injured *due to the fault of another*." *Caravaggio v. D'Agostini*, 765 A.2d 182, 187 (N.J. 2001) (emphasis added). Because the jury was justified in finding that Ms. Carlino brought her suit in a timely fashion, within two years of when she became aware of the Defendant-Appellants' culpability, this claim is meritless under the laws of Pennsylvania and New Jersey.

In its claim of error, Defendant-Appellants focus almost single-mindedly on when Ms. Carlino should have been aware that she was *injured*, ignoring entirely the "fault" portion of the discovery rule as it appears in both Pennsylvania and New Jersey law. For instance, the Defendant-Appellants argue that the Court's jury instruction was erroneous because the Court did not "instruct[] the jury that it must consider the earliest injury that Ms. Carlino could reasonably have discovered, without regard to whether Plaintiffs were seeking damages for that

injury" – where is the analysis as to fault? By reading half of the discovery rule out of existence, the Defendant-Appellants have fatally undermined their own argument at the outset.[3] For this Court to charge the jury on half of the discovery rule and not the other half would have been error.

The Defendant-Appellants also claim that the Plaintiffs made improper statements as to the statute of limitations during closing argument. They do not include references to the statements that they find problematic. However, if anything, Plaintiffs' counsel risked reigniting the issue of the statute of limitations by raising it in closing arguments. The jury was instructed that counsels' argument is not evidence. *See* N.T. February 9, 2016, a.m., p. 30. Of course, the Defendant-Appellants were free to address any inaccuracies in the Plaintiffs' argument, and to use such inaccuracies to their advantage in their closing remarks. This claim is meritless.

e. <u>This Court Did Not Err in Refusing Defendant-Appellants' Proposed Instruction on Alternative Design.</u>

Defendant-Appellants argue that this Court "erred by giving an inadequate and inaccurate instruction on Plaintiffs' burden to prove an alternative design that is safer, available, practical, and feasible and would have prevented or lessened their alleged injuries. Specifically, the Court erred by refusing to give Defendants' proposed instruction No. 31 and instead instructing the jury that Plaintiffs were required to prove a safer alternative design 'unless the risk involved in the TVT's use outweigh its utility even though there is no reasonably feasible . . . alternative

[3] Of course, the Defendant-Appellants are in a difficult position as to this argument, as in order to assert that Ms. Carlino should have known of their culpability in her injuries much earlier, they have to acknowledge that culpability. Inconsistent arguments make for barren bedfellows on appeal.

design.'" Because the Defendant-Appellants did not cite the record and again attempted to incorporate arguments made elsewhere (*see Osteen, supra*), this argument is waived.

However, even if it is not waived, it is meritless. A trial court has wide latitude in choosing the precise language of the jury charge, but must fully and adequately convey the applicable law to the jury. *Seewagen v. Vanderkluet*, 488 A.2d 21, 26 (Pa. Super. 1985). Review of the charge must be in its entirety, to determine if it is fair and complete. *Commonwealth v. Cooper*, 941 A.2d 655, 669 (Pa. 2007).

The Court's charge on the plaintiff's burden on design defect, N.T. February 9, 2016, a.m., pp. 50-57, was thorough in every respect and accurately reflected the applicable law. It instructed the jury based on New Jersey's standard charge for design defect, Charge 5.40D-3.[4] Defendant-Appellants offered a custom instruction that was more to their liking than the standard instruction. However, they did not establish that New Jersey's standard design defect instruction was insufficient or inaccurate. The language that the Defendant-Appellants cite, a snippet of a multi-page instruction, reflects the rule as expressed in *Smith v. Keller Ladder Co.*, 645 A.2d 1269 (N.J. Super. 1994) ("Therefore, unless there is some basis for a jury to find that the risks involved in a product's use outweigh its utility even though there is no reasonably feasible alternative design, a plaintiff in a design-defect case is required to show the existence of 'a safe and reasonably feasible alternative to [the] defendant's product.'") (*quoting Macri v. Ames McDonough Co.*, 512 A.2d 548 (N.J. App. Div. 1986); *see also* N.J.S.A. 2A:58C-3(a)(1). Because this Court's charge, when examined as a whole, accurately instructed the jury on the applicable law, this claim is meritless.

[4] Available at https://www.judiciary.state.nj.us/civil/charges/5.40D-3.pdf.

f. The Court Did Not Err in Denying Directed Verdict.

The Defendant-Appellants argue that this Court "erred in denying [their] motions for directed verdict and jnov because Plaintiffs failed to present evidence sufficient to carry their burden of proving the existence of an alternative design to TVT that was safer, available, practical, and feasible and that would have prevented or lessened their alleged injuries."

On the contrary, the Plaintiffs established that the Defendant-Appellants could have used a safer material in the design of their TVT products from the outset, before achieving 510(k) clearance. The Plaintiffs submitted expert testimony from Dr. Rosenzweig and showed the jury an alternative product that, though structurally similar, was significantly lighter and had a significantly larger pore size. The Plaintiffs' evidence tended to show that these preferable features would minimize foreign body reaction in patients receiving implants, and that therefore use of the alternative material was safer. *See, e.g.*, N.T. January 28, 2016, a.m., pp. 44-49. Because this claim is belied by the record, it is meritless.

g. This Court Did Not Err in its Proximate Causation Instructions.

The Defendant-Appellants claim that this Court erred in "providing proximate causation instructions and a verdict form that (1) failed to convey New Jersey law on the learned intermediary doctrine because they improperly asked the jury what the patient would have done if the warnings had been provided rather than limiting the alleged failure to warn to the prescribing physician and (2) did not instruct the jury that it could not find proximate causation

when Dr. Blechman already knew the risks of the mesh at the time he prescribed it and testified that he did."[5]

In New Jersey, a product is unreasonably dangerous if not accompanied by adequate warnings. *See* N.J. Stat. Ann. § 2A:58C-2. A manufacturer is required to warn of risks known during the time in which the plaintiff was using the product. The manufacturer is assumed to have the knowledge of an expert in the field when evaluating the adequacy of the warnings given. In the case of medical devices, the manufacturer's duty is discharged if adequate warning is given to doctors, who act as learned intermediaries between the manufacturer and the ultimate user. *See Perez v. Wyeth Lab., Inc.*, 161 N.J. 1 (1999) (citing *Niemiera v. Schneider*, 114 N.J. 550 (1989)). An adequate product warning or instruction is "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used." N.J.S.A. 2A:58C-4; *see also Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34 (1996); *Feldman v. Lederle Lab.*, 97 N.J. 429 (1984); *Canty v. Ever-Last Supply Co.*, 296 N.J. Super. 68 (Law Div. 1996).

Evidence of either "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" or economically-driven manipulation of the post-market regulatory process will rebut a presumption of adequate warning. *Perez v. Wyeth Lab., Inc.*, 161 N.J. 1 (1999); *McDarby v. Merck*, 401 N.J. Super. 10 (App. Div. 2008). Here, the Plaintiffs established that several decision-makers at Ethicon were aware of the risks of serious and long-term injuries

[5] Again, the Defendant-Appellants attempt in their claim of error to incorporate prior argumentation, a practice that is improper and contrary to the spirit of Pa.R.A.P. 1925. This is true for all of their claims of error.

including painful sexual intercourse, chronic pain, and major erosion amounting to the body's rejection of the implant. During depositions, Medical Director Dr. Martin Weisberg testified that Ethicon did not include warnings that the device presented a risk of permanent, lifelong, worsening, and debilitating pain. He also testified that there were no warnings of the risk of severe or chronic inflammation, or of the possibly lifelong need for surgical repairs. *See* N.T., August 9, 2013 deposition of Martin Weisberg, M.D. at p. 968.

As stated *supra*, the charge must be evaluated in its entirety in order to ensure that it is an accurate recitation of the law. In its instruction, this Court relied on New Jersey's model instructions on design defect, failure to warn, and proximate cause.[6] Further, Defendant-Appellant's claim that the instruction and verdict form "failed to convey New Jersey law on the learned intermediary doctrine because they improperly asked the jury what the patient would have done if the warnings had been provided rather than limiting the alleged failure to warn to the prescribing physician" is simply wrong. The jury verdict form focuses, properly, on the Defendant-Appellants' conduct, in asking whether they "fail[ed] to adequately warn of the TVT's medical risks." The form does not ask what the patient would have done. It asks whether there was a failure to warn, and whether that failure was a proximate cause of Ms. Carlino's injuries. Further, though the Defendant-Appellants' Post-Trial Motion faults the Court for declining to use their proffered instruction, it does not specify where any flaw might be found in the jury instruction; therefore, this claim of error is waived in addition to being meritless.

The Defendant-Appellants also claim that Dr. Blechman was aware of all of the risks of the TVT, and that this Court should have "instruct[ed] the jury that it could not find proximate

[6] These instructions are also available at https://www.judiciary.state.nj.us/civil/civindx.html (Charge 5:40C, Failure to Warn, 5:40D, 1-4, Design Defect, 5:40I, Proximate Cause).

causation when Dr. Blechman already knew the risks of the mesh at the time he prescribed it and testified that he did." This would have been completely improper. The jury is the finder of fact, and it is not for the Court to instruct it as to what findings it should make based on the testimony. Certainly, there was ample evidence from which the jury could conclude that Dr. Blechman was *not* adequately informed as to the risks the TVT posed, and that the deficiencies in the product's warnings were very serious; *see, e.g.*, Expert Report of Dr. Michael Margolis, Sept. 1, 2015 (listing numerous serious risks that were known to the Defendant-Appellants but not included in the TVT Instructions For Use or otherwise disclosed to prescribing physicians). The factfinder may choose to believe all, some, or none of the testimony offered at trial. *See State v. Wesler*, 137 N.J.L. 311, 314 (1948) (the factfinder is "not bound to believe testimony of any witness in whole or in part, but may reject what in their conscientious judgment out to be rejected and accept that which they believe credible."), *aff'd*, 1 N.J. 58 (1948); *Neison v. Hines*, 653 A.2d 634, 637 (Pa. 1995) ("the jury is free to believe all, some, or none of the testimony presented by a witness."). Because it would have been manifestly inappropriate for the Court to include in its jury instructions on the law a conclusory statement of contested fact, and to instruct the jury that it must reach that conclusion and act thereon, this claim is meritless.

h. <u>The Evidence is Sufficient as to Causation.</u>

The Defendant-Appellants also make the following argument as to sufficiency:

> The Court erred in finding that Plaintiffs had presented legally sufficient evidence that an inadequacy in Ethicon's warnings caused their alleged injuries. Under New Jersey law, there is no duty to warn of the frequency, severity, or incidence of complications, but the Court permitted Plaintiffs to argue that that information was necessary to an adequate label. For this reason, the Court also erred in permitting Plaintiff to argue that Defendants were liable for failing to include that information in TVT's warnings. In addition,

> New Jersey law requires that Plaintiffs prove that the prescribing physician would have changed his prescribing decision if the product had had an adequate warning. Plaintiffs did not show that Dr. Blechman was unaware of the complications Ms. Carlino complained of. Because Plaintiffs failed to present sufficient evidence that an inadequacy in Ethicon's warnings caused their alleged injuries, the Court erred in denying Defendants' motions for directed verdict and post-trial relief, including jnov, on this issue. *See* Post-Trial Mot. 31–38, 74–76.

1925(b) Statement, 5B. These claims go to the crux of the dispute between the parties. The Defendant-Appellants claim that "under New Jersey law, there is no duty to warn of the frequency, severity, or incidence of complications" of a medical device. The case cited in the Post-Trial Motion to support this claim is *Calabrese, v. Trenton State College*, 392 A.2d 600 (N.J. App. Div. 1978), *aff'd*, 413 A.2d 315 (N.J. 1980). *Calabrese* is a vaccine case, and the holding is that a drug manufacturer does not need to include in its product warnings "statistical information concerning the incidence of the condition for which the drug can be used." *Id.* at 604. To take this language, which in that case pertained to the statistics concerning risk of contracting rabies, and use it to argue that there is no duty to warn of the frequency, severity, or incidence of complications, is nonsense. *Calabrese* is about cost-benefit analysis – the plaintiffs in that case proposed that the remoteness of the risk of rabies contraction should be part of the product warnings for a rabies vaccine. In the present case, Ms. Carlino definitely had the condition that TVT was designed to treat, so how a case about presenting doctors with the odds of contraction of the underlying condition when given treating product information would apply here is unclear at best. Again, here is how the Defendant-Appellants want to use *Calabrese*: "But under New Jersey law, a manufacturer does not have a duty to include 'statistical information concerning incidence' of potential risks in its warnings. *Calabrese v. Trenton State College*, 392 A.2d 600, 604-05 (N.J. App. Div. 1978) (rabies vaccine manufacturer had no duty to provide 'available statistical data on the remoteness of the danger of rabies' and confirming that 'the duty

to explain the risks involved' belongs to the physician)." Defendant-Appellants' Post-Trial Motion, p. 74. There is a slip between what the Defendant-Appellants want *Calabrese* to say, which is that there is no duty to inform as to statistics *about potential product risks*, and what *Calabrese* says, which is that there is no duty to inform as to the odds that a person might contract the disease that the vaccine is designed to protect against. Note the disjointed use of the pseudo-quote "statistical information concerning incidence" which is then jammed before "of potential risks" in the Post-Trial Motion, and which actually appears nowhere in *Calabrese* itself but is used in a West headnote that says "Drug manufacturer's warnings have to include information concerning undesirable side effects of drug being marketed but do not have to also include statistical information concerning incidence of condition for which drug can be used." That is a very different statement of the law. It has nothing to do with rates of potential complications. It has everything to do with rates of contraction of rabies, on average, in a relevant population.

Calabrese's statement about statistical information is confined to a determination that a vaccine manufacturer does not have a duty to inform about the statistical prevalence of the disease that the vaccine is meant to guard against. It makes sense that this information would be relevant in deciding whether to use a vaccine, but it also makes sense that the information might vary greatly from year to year, or even from season to season, and that it might be difficult for manufacturers to anticipate outbreaks. Thus, placing the duty of providing this particular data on the manufacturer might be unwise, in addition to being beyond the scope of New Jersey's law on duty to warn. What any of this has to do with Sharon Carlino is beyond this Court entirely. No one has accused the Defendant-Appellants of having failed to state the incidence rates of SUI, a condition from which Ms. Carlino definitely suffered at the time the TVT was prescribed for her,

or of having such a burden. There is no dispute as to this point. *Calabrese* is completely inapposite, and the Defendant-Appellants have cited no New Jersey law supporting their specious conclusion that there is no duty to warn about the frequency, severity, or incidence of complications of a given medical device. This claim is meritless.

Further, as demonstrated *supra*, the Plaintiffs did submit ample evidence that Dr. Blechman was unaware of the many risks that the Defendant-Appellants knew of but failed to include *at all* in the IFU. Again, the jury is free to believe all, some, or none of the evidence offered at trial, and their verdict is amply supported by the thorough case presented by the Plaintiffs. This claim is meritless.

i. **This Court Did Not Err in its Admissibility Determinations as to Dr. Blechman's Testimony.**

The Defendant-Appellants also argue, in 5B of the 1925(b) statement, that:

> The Court erred in permitting the jury to be misled about whether Dr. Blechman's decision to prescribe in general would have changed had he known of Ms. Carlino's complications. This error, described further at ¶ 6, *infra*, arose because the Court admitted testimony from Dr. Blechman without permitting other testimony in which he clarified that the admitted testimony was based on his misunderstanding of the question. This and the other stricken portions of the testimony from Dr. Blechman would have negated the notion that an inadequacy in Ethicon's warnings caused Dr. Blechman to use TVT. *See* Post-Trial Mot. 36–38.

Again, the Defendant-Appellants do not make appropriate reference to the trial record itself, instead attempting to incorporate their voluminous Post-Trial Motion. It puts the Court in the position of searching under nested Russian dolls in order to attempt to represent their argument in the fullest light, a situation that helps nobody. This allegation of error will be analyzed with the description at paragraph 6.

Paragraph 6 of the 1925(b) statement claims that

> The Court erred in striking Defendants' cross-examination of Dr. Blechman from his mid-trial deposition as a sanction, for two reasons. First, the Court erred in holding that Defendants violated the Court's ruling on a motion *in limine* regarding FDA evidence (which by its terms governed only the admissibility of evidence at trial) at all, because the deposition was taken subject to the Pennsylvania Rules of Civil Procedure governing discovery, including, *inter alia*, Pa.R.C.P. No. 4017.1(h) (providing for the transcribing of the portions of video depositions admitted and those excluded on objection) and the Pennsylvania Rules of Evidence, and the case law construing them. All parties and the Court understood that only portions of the deposition would be designated for trial and that the Court would review objections before testimony was admitted. Second, the Court further erred in imposing an excessive and prejudicial sanction for what (a) did not violate the terms of the Pennsylvania Rules of Civil Procedure or the Court's ruling on the motion *in limine*; and (b) did not take into account and was contrary to (i) the nature and severity of the supposed violation; (ii) the willfulness or bad faith of the supposed violation; (iii) prejudice; (iv) the ability to cure the prejudice; and (v) the importance of the evidence in light of the supposed failure to comply. Defendants were prejudiced by the Court's ruling, *see supra* at ¶ 5.C., and the motion for mistrial should have been granted and a new trial is necessary. *See* Post-Trial Mot. 49–54.

In 5B, the Defendant-Appellants refer to a portion of Dr. Blechman's deposition when he was asked about whether he would have recommended TVT in 2005, knowing what he knows now about the product, and he said no, "for the reasons just described" and because "[i]t has potential to do a lot of harm." Defendant-Appellant's Post-Trial Motion, p. 37. The Defendant-Appellants make much of the "reasons just described" portion of his answer, which appears to refer back to the specific harms experienced by Ms. Carlino. However, the "potential to do a lot of harm" portion of his answer seems to refer to the potential harms that were known to the Defendant-Appellants but not included in the IFU, as described *supra*. This highly technical argument, when taken in the light most favorable to the Plaintiffs as verdict winner, cannot prevail.

The Defendant-Appellants next complain in Paragraph 6 about this Court's evidentiary decision excluding certain cross-examination of Dr. Blechman in order to enforce its decision *in limine* as to FDA evidence. "[R]eview of the trial court's evidentiary decisions is limited to determining whether the trial court abused its discretion. The trial court abuse[s] its discretion only if the court's ruling reflects manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support to be clearly erroneous." *Commonwealth v. Foley*, 38 A.3d 882, 886 (Pa.Super.2012), *alloc. denied*, 619 Pa. 671, 60 A.3d 535 (2013) (quotations and citations omitted).

The order in question read as follows: "Defendants are precluded from introducing any portion of the cross-examination and recross-examination of Dr. Blechman from his January 30, 2016 deposition as a sanction for questioning during that deposition that violated this Court's Order on Plaintiffs' Motion in Limine No. 1." At the time this order was entered, the Defendant-Appellants had been given ample opportunity to depose Dr. Blechman; thus, their characterization of this sanction as singularly punitive seems misguided.

The Court viewed this violation of its order as notably blatant, given that all parties were on notice at that time that there should be *no questioning* as to the FDA. This was a mid-trial deposition, a stressful and tiring task for all parties, including the Court, and an especially egregious time to make willful transgressions of orders already entered in the case. There is simply no reason that defense counsel should have felt empowered to exceed the boundaries this Court had placed on the testimony to be taken. This Court considered the full panoply of available sanctions, including removal of counsel from the case and referral of the sanction to disciplinary bodies, and instead imposed a relatively limited sanction. *See* N.T. Feb. 2, 2016, pp. 4-5. This Court must have the power to punish blatant violations of its own orders. The

transgressing attorney acknowledged that questions asked in depositions must be reasonably calculated to lead to admissible evidence. *Id.* at 10. Where it is crystal clear that the FDA is out of the case, asking about the FDA is not a reasonable strategy to lead to admissible evidence. Everyone knew that this was a *de bene esse* deposition. Because counsel should have confined her questioning appropriately, her flagrant transgression of this Court's order was worthy of sanction. This Court listened to both sides, considered an array of potential sanctions, and imposed a relatively limited sanction for counsel's disregard of its order.

The effect, and the seeming purpose, of counsel's question was to confuse Dr. Blechman and cause him to pivot his testimony so that it would be less favorable to the Plaintiffs. It stated as fact that "the TVT has been evaluated by the FDA on an ongoing basis." N.T. Dep. Dr. Blechman, June 30, 2016, pp. 64-70. Basically, defense counsel's strategy was to present Dr. Blechman with materials that supported Ethicon's position that the product was safe, and then to ask him at the end, based on all this information, looking back in time, if you had been privy to this information at the time you recommended TVT to Ms. Carlino, would you have recommended it? Of course the doctor said yes. Why would being presented with positive studies and with the idea that the FDA thought that Ethicon's TVT product was just fine have changed what he did at the time he recommended the product in the first place? The salient point is that defense counsel does not present the entire universe of relevant data. There is a systematic presentation of positive data, and a significant overstatement of the FDA's position, and then a shift from "knowing this, would you have recommended it?" to "knowing everything, would you have recommended it?"

This kind of cross-examination tactic is not necessarily abusive when dealing with a sophisticated party and sharp counsel across the aisle. However, in this case, Ms. Smith knew

that she was transgressing when she brought the FDA into the matter, and in fact her transgression went to the heart of why the FDA was to be kept out. She misled the witness into thinking that the FDA had taken an aggressive, positive position on TVT, based on years of ongoing evaluation by the agency. Then she systematically used that misleading stance, incorporated into her pool of positive evidence, to undermine Dr. Blechman's testimony and to try to turn him against the Plaintiff. That is why the metaphor of poison is appropriate here: she tainted every assertion that she coaxed from Dr. Blechman after her FDA questioning. Doctors are very deferential to the FDA; they depend on it for many of the decisions they make in their practice as a matter of routine. To misuse the FDA's authority in this manner goes to the heart of why the pretrial order was in place, and that is why this Court had to take action. Dr. Blechman is not an expert witness, with experience in dealing with lawyerly chicanery. He is a regular doctor who treats patients. Everyone at the deposition knew that they were, mid-trial, developing testimony that was essentially *trial* testimony. This was not a discovery-stage deposition, and Ms. Smith knew that. Mr. Specter, Plaintiffs' counsel, was unprepared to counter her aggressive overstatement of the FDA's position on TVT, because he had relied on this Court's order excluding such materials completely; thus, he could not pull out those materials, mid-deposition, in order to rehabilitate his increasingly confused and frustrated witness.[7] He was ambushed.

Ms. Smith also mischaracterized what she did during argument before this Court. She claimed that Dr. Blechman already knew that the FDA had "cleared" TVT, and that her question

[7] See N.T. February 2, 2016, pp. 36-37 (confirming that Plaintiffs' counsel did not bring FDA materials to the *de bene esse* deposition. Perhaps Ms. Smith, who is not barred in Pennsylvania and appeared *pro hac vice* in this matter, was simply unaware that this type of disregard for a court order would necessarily lead to consequences from this Court in the enforcement of that order. Nevertheless, attorneys who are admitted *pro hac vice* must familiarize themselves with the expectations of practice in the jurisdiction in which they are operating, and where an attorney goes to an unfamiliar jurisdiction and decides to toe the line as aggressively as possible, it should not be surprising to find that they might cross the line and then face consequences.

merely confirmed something that Dr. Blechman already knew.[8] In fact, Ms. Smith asked "Do you know that the TVT was cleared by the FDA? Do you understand that, Dr. Blechman?" The question was designed to develop the impression that the FDA had "cleared" this product, not to make an honest inquiry into what Dr. Blechman *already knew*. Ms. Smith diligently avoided any analysis as to what "clearance" consisted of in this context, and led Dr. Blechman to the impression that the product had been fully "cleared" by the FDA after extensive testing, as an entirely novel medical device would have to be (a process that, as discussed elsewhere, is much more intense and demanding than 510(k) clearance). This strategy was continued and confirmed with her next question: "Do you know that the TVT has been evaluated by the FDA on an ongoing basis?" Ms. Smith did not even seek to have Dr. Blechman answer this question, because of course his answer was *completely beside the point*, which was to mislead him into thinking that Ethicon's product had the FDA's full blessing, after ongoing and complete evaluation. Of course, that's not what happened here, and had Plaintiffs' counsel been aware that he would have to counter this false impression, he could have come prepared to do battle as to the FDA issue. However, because he relied, appropriately, on this Court's order, he had no reason to believe that this preparation would be necessary.

Given that the effect of counsel's transgression was to poison the witness with material that this Court had already determined was more prejudicial than probative, and to put the Plaintiffs in the extremely unpleasant position, mid-trial, of having to accommodate this violation that went against their reasonable witness preparation, made in reliance on this Court's order, exclusion of cross-examination was really the least this Court could do. In preparing their key witness, the Plaintiffs should have been able to assume that material that is excluded would

[8] *See* N.T. February 2, 2016, pp. 21-22.

not be pertinent to witness preparation and should not be a part of that preparation. This form of mid-trial "shock therapy" by violation of this Court's order went beyond appropriate zealous representation, went beyond reasonable disagreement with a trial court ruling and making a record thereof, and instead extended to poisoning the testimony of a key witness in a way that rendered the rest of that witness' testimony unreliable because of the dubious impression conveyed about the FDA's stance on TVT. This is intolerable.

Because the Court acted within its power, considered an appropriate array of sanctions and imposed a lesser sanction than many it had considered, and focused its sanction not on punitive measures but on preservation of the intent of its initial ruling *in limine*, the Court's ruling is not a product of bias or ill will, is not erroneous, and is therefore not an abuse of discretion.

j. This Court Does Not Lack Authority to Impose Punitive Damages.

In their seventh claim of error, Defendant-Appellants argue that this Court lacks the constitutional authority to impose punitive damages because Defendant-Appellants' conduct had no nexus to Pennsylvania, and thus a Pennsylvania jury's determination of punishment of New Jersey conduct is necessarily arbitrary. It is well-settled that punitive damages "may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996). Initially, it is far from clear that the conduct in question was solely New Jersey conduct, given that Ethicon is a large, multinational corporation. The jury was instructed on punitive damages based on New Jersey law. *See* New Jersey Model Instruction 8.62 (Punitive Damages Actions – Products Liability). Defendant-Appellants attempt to rely on *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S.

408, 421-22 (2003), for the principle that there is a sort of hard jurisdictional limit on imposition of punitive damages by a court from a state other than the one where the damaging conduct occurred. But *State Farm* instructs that the proper procedure would be for the state law where the conduct occurred to be applied, which is exactly what happened here. *See Id.* So on its own terms, *State Farm* cannot support the conclusion that the Defendant-Appellants wish to derive from it. The Defendant-Appellants argue that any Pennsylvania jury's determination of punitive damages would necessarily be arbitrary, but how can that be true when the jury was instructed based on New Jersey law? In addition to being unsupported, this argument does not make sense.

k. <u>Punitive Damages Are Not Barred by New Jersey Law.</u>

The Defendant-Appellants then argue that "the New Jersey Punitive Damages Act bars punitive damages when, as here, the FDA has recognized a medical device as safe and effective pursuant to the conditions and requirements the FDA imposes." But the 510(k) clearance method allows a product to be sold without official FDA approval if it is based on another already-approved product. This is a clearance method based on similarity to an existing device, not a recognition that the device is safe and effective, so the "as here" portion of this argument is simply wrong. Another court has already reached the same conclusion. *See In re: Ethicon*, 2014 WL 186869 (S.D.W.V. January 15, 2014) (unreported) ("the FDA has not 'approved or licensed' or 'generally recognized' the TVT as 'safe and effective ... [t]herefore, I find that Ethicon is not immune from punitive damages pursuant to the NJPLA."), *partially rev'd on other grounds*, 2014 WL 457551 (S.D.W.V. February 3, 2014) (unreported); *see also Huskey v. Ethicon*, 29 F. Supp. 3d 736, 745-46 (S.D.W.V. 2014) ("the FDA has not 'approved or licensed' or 'generally recognized' the TVT-O as 'safe and effective' [via the 510(k) process]"); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748 (S.D.W.V. 2014) ("The 510(k) process is not a safety statute or

administrative regulation"); . This argument misconstrues the 510(k) clearance process, an analysis of substantial equivalence, to a degree that is not plausible. It is meritless.

I. The Punitive Damages Award Is Constitutional.

In our federal system, states necessarily have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case. *Id.* Only when an award can fairly be categorized as "grossly excessive in relation to these interests does it enter the zone of arbitrariness that violates the Due Process Clause of the Fourteenth Amendment." *Id.*

States possess discretion over the imposition of punitive damages and "there are procedural and substantive constitutional limitations on these awards." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). The Supreme Court instructs courts reviewing the reasonableness of a punitive damages award to consider three guideposts: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases. *Id.* at 418.

Perhaps the most important factor in evaluating the reasonableness of a punitive damages award is "the degree of reprehensibility of the defendant's conduct." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 (1996) Lawful out-of-state conduct may be probative when it demonstrates the deliberateness and culpability of the defendant's action in the state where it is tortious, but that conduct must have a nexus to the specific harm suffered by the plaintiff. *State Farm.* 538 U.S at 422. A state cannot punish a

defendant for conduct that may have been lawful where it occurred *Id.* at 421. A proper adjudication of out of state conduct would need to apply the laws of their relevant jurisdiction. *Id.*

Defendant-Appellant largely relies on *State Farm* to support their contention that this court lacked constitutional authority to impose punitive damages. *State Farm* involved a Utah jury awarding punitive damages to a Utah plaintiff. At trial the jury was permitted to hear "dissimilar and out-of-state conduct evidence" in addition to evidence about State Farm's conduct in Utah that motivated plaintiff to file their complaint. State Farm filed a *motion in limine* to exclude the evidence of State Farm's nationwide conduct but the trial court denied it. The jury considered the evidence of State Farm's statewide and nationwide conduct, and awarded plaintiff $1 million in compensatory damages and $145 million in punitive damages, a 145-to-1 ratio of punitive to compensatory damages. The Supreme Court found the punitive damages award excessive and in violation of the Due Process Clause of the Fourteenth Amendment. The court was critical of the trial court and defendant's decision "from their opening statements onward" to use the case as a platform "to expose, and punish, the perceived deficiencies of State Farm's operations throughout the country" rather than "for the conduct directed toward the Campbells." *State Farm,* 538 U.S.at 420. *State Farm* reiterated earlier cases in generally approving a four-to-one ratio between compensatory and punitive damages but expressing suspicion of punitive damages awards that exceed that ratio. *Id.* at 425. The award in this case is comfortably short of four-to-one, and thus *State Farm* cannot support this challenge.

Further, the trial forming the genesis of this opinion involved a New Jersey Plaintiff and a New Jersey Defendant. The events giving rise to Plaintiff's injury occurred in New Jersey. The trial took place in Philadelphia's Court of Common Pleas under New Jersey substantive law and

punitive damages were imposed under New Jersey's Punitive Damages Statute. Here, Defendant-Appellant is making a back-door personal jurisdiction argument despite the fact that Defendant-Appellant's motion to dismiss for lack of personal jurisdiction was denied by the Hon. Arnold K. New on November 6, 2014 and the issue is addressed earlier in this opinion *See supra* Section 1. Defendant-Appellant suggests that *State Farm's* holding prohibits a Pennsylvania jury from applying New Jersey Law and awarding punitive damages to a New Jersey Plaintiff against a New Jersey defendant. However, Defendant-Appellant's argument takes the Supreme Courts caveats in *State Farm* out of context. *State Farm* instructs a trial court to ensure that the jury considers appropriate evidence about the conduct that harmed plaintiff for the purposes of calculating punitive damages. The court in *State Farm* provides further explanation for its reversal of a punitive damages award:

> For a more fundamental reason, however, the Utah courts erred in relying upon this and other evidence: The courts awarded punitive damages to punish and deter conduct that bore no relation to the Campbells' harm. A defendant's *dissimilar acts*, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis, but we have no doubt the Utah Supreme Court did that here.

State Farm, 538 U.S.at 422-423 (emphasis added). To date, no Supreme Court decision reviewing unconstitutional punitive damages awards has held that a court is prohibited from properly applying the substantive law of another state and awarding punitive damages to an out of state plaintiff against an out of state defendant for an out of state injury. Further, there is no reason to believe that any portion of the punitive damages award was based on "dissimilar acts"

or evidence that the Defendant-Appellants are a generally unsavory business. Defendant-Appellant does not allege that this court allowed a jury to award punitive damages based on the type of evidence that *State Farm* prohibits a jury from considering, and this Court correctly confined the evidence submitted to the jury to that which was strictly relevant to the case before it.

Pennsylvania's Superior Court has upheld punitive damages awards against out of state Defendants where the events giving rise to a plaintiff's injury occur entirely outside of Pennsylvania and the substantive law of another state is applied. See *Barton v. Wyeth Pharm., Inc.*, No. 694 EDA 2010, 2012 WL 112613 (Pa. Super. 2012) (unpublished; punitive damages award of $75 million remitted to $7,492,689.94 in Philadelphia Court of Common Pleas, applying Illinois substantive law, affirmed by Superior Court); *see also Kendall v. Wyeth, Inc.*, No. 1154 EDA 2010, 2012 WL 112609, at *1 (Pa. Super. 2012) (unpublished; punitive damages award of $28 million in Philadelphia Court of Common Pleas, applying Illinois substantive law, affirmed by Superior Court.)

Therefore, because this Court does not lack the constitutional authority to award punitive damages in this case, the Defendant-Appellant's allegation of error is meritless.

m. <u>New Jersey's Punitive Damages Act Does Not Bar Punitive Damage Awards in Cases Involving 510(k) Approval.</u>

Next, Defendant-Appellant argues that The New Jersey Punitive Damages Act bars punitive damage awards where a medical device is recognized as "safe and effective" pursuant to the conditions and requirements the FDA imposes. FDA cleared the TVT for marketing as a Class II medical device through its 510(k) process, which Defendant-Appellant argues is a "safety and efficacy review." The New Jersey Punitive Damages Act states in relevant part:

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

N.J. Stat. Ann. § 2A:58C-5.

Under New Jersey Law, this defense is unavailable to Defendant-Appellant. Unlike the comprehensive and rigorous premarket approval (herein PMA) process for regulating a product with no known predicate, as a general matter 510(k) clearance does not require clinical trials but requires the product to go through a substantial-equivalence review to compare its product to one already on the market. As part of its application for PMA, a manufacturer must provide the FDA with "reasonable assurance" that the device is both safe and effective. 21 U.S.C.A. § 360e(d)(2). Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Defendant-Appellant argues that the 510(k) process is a safety and efficacy review, but the Supreme Court has stated otherwise, and in contrast to PMA, "the 510(k) process is focused on equivalence, not safety." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). The FDA itself also confirms this distinction:

> A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA). A pre-market notification submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to FDA that the device is safe and effective.

Horn v. Thoratec Corp., 376 F.3d 163, 167 (3d Cir. 2004) (quoting an amicus brief filed by the FDA).

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." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996). The Superior Court of New Jersey recently upheld a $7.76 million dollar punitive damages award against a pelvic mesh manufacturer that used the same 510(k) approval process to get their product into the market, *Gross v. Gynecare*, No. A-0011-14T2, 2016 WL 1192556, at *1 (N.J. Super. Ct. App. Div. 2016) (finding that the New Jersey Products Liability Act did not bar an award of punitive damages after 510(k) approval). Additional courts in pelvic mesh trials have also examined the 510(k) approval process within the context of the NJPLA and awarded punitive damages, finding that the "510(k) process is focused on equivalence, not safety." *Bellew v. Ethicon, Inc.*, 2014 WL 6674433, at *3 (S.D.W. Va. Nov. 24, 2014).

Because the TVT was never deemed "safe and effective" by the FDA under the "substantial equivalence" regulatory pathway allowed by Section 510(k) of the Food, Drug & Cosmetic Act, the New Jersey Punitive Damages Act does not bar this Court's punitive damages award.

n. <u>This Court Properly Denied Remittitur.</u>

Additionally, Defendant-Appellant argues that the Court erred by permitting punitive damages to be awarded because Plaintiffs failed to present evidence sufficient to prove by clear and convincing evidence that the acts or omissions causing the Plaintiffs' alleged harm "were actuated by actual malice or accompanied by a wanton and willful disregard of persons who

foreseeably might be harmed by those acts or omissions." Defendant-Appellant also argues that this court should have remitted the punitive damages award under the New Jersey Punitive Damages Act.

The New Jersey Supreme Court has been "in the vanguard of the development of a responsive and progressive products liability law," *Fischer v. Johns-Manville Corp.*, 472 A.2d 577, 583 (N.J. Super. App. Div. 1984), recognizing that punitive damages "serve as the only deterrent to manufacturers who would purposefully market dangerous products with insufficient warnings." *Ripa v. Owens-Corning Fiberglas Corp.*, 660 A.2d 521, 532 (N.J. Super. App. Div. 1995). The Punitive Damages Act vests in a trial judge the power to reduce or eliminate an award of punitive damages. N.J.S.A. 2A:15-5.14(a). When the trial court is "vested with what is essentially a fact-finding role, we generally defer to the court's findings." *Maudsley v. State,* 816 A.2d 189 (NJ. Super. App. Div.2003).

Punitive damages are awarded to "deter egregious conduct and punish the offender." *Longo v. Pleasure Prods., Inc.*, 71 A.3d 775 (N.J. 2013). The Punitive Damages Act allows such damages where:

> the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence including gross negligence.

N.J.S.A. 2A:15–5.12(a).

Wanton and willful disregard' means a "deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." N.J.S.A. 2A:15–5.10. In determining whether to award punitive damages,

a trier of fact must consider all relevant evidence, including, but not limited to: (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct; (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct; (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and (4) The duration of the conduct or any concealment of it by the defendant. N.J.S.A. 2A:15–5.12(b).

Punitive damages are available in failure-to-warn, strict products liability actions when a manufacturer is (1) aware of or culpably indifferent to an unnecessary risk of injury, and (2) refuses to take steps to reduce that danger to an acceptable level. *Fischer v. Johns-Manville Corp., 512 A.2d 466,* 480 (N.J. 1986).

To obtain punitive damages in the failure-to-warn context, a plaintiff "must show that a reasonable person with defendants' knowledge about the product would consider sales of the product to be a serious risk." *DeGennaro v. Rally Mfg. Inc.*, 2011 WL 5248153, at *4 (D.N.J. Nov. 2, 2011) (*citing Smith v. Whitaker*, 734 A.2d 243, 254 (N.J. 1999)).

The New Jersey Punitive Damages Act also requires a trial court reviewing an award of punitive damages be satisfied that the award is "reasonable in amount" and "justified in the circumstances of the case." N.J.S.A. § 2A:15-5.14a-b. The relevant statutory provision provides:

> Before entering judgment for an award of punitive damages, the trial judge shall ascertain that the award is reasonable in its amount and justified in the circumstances of the case, in light of the purpose to punish the defendant and to deter that defendant from repeating such conduct. If necessary to satisfy the requirements of this section, the judge may reduce the amount of or eliminate the award of punitive damages. No defendant shall be liable for punitive damages in any action in an amount in excess of five times the liability of that defendant for compensatory damages or $350,000, whichever is greater.

Id.

The evidence of Defendant-Appellant's wanton and willful disregard for Plaintiff adequately supported the Jury's award of punitive damages. At trial, Plaintiff's produced evidence from Dr. Piet Hinoul, current Medical Director for Ethicon Energy that Defendant-Appellant was aware of every risk and adverse event associated with TVT since it was first cleared and marketed in 1998. Hinoul video deposition at 550:10-16, 551:7-11, 552:14-21, 554-14-555:11.

Ethicon's Medical Director, Dr. Martin Weisberg, testified that Defendant-Appellant did not warn in the TVT IFU or patient brochures that there was a risk of the following complications even though they knew about them when the TVT was released: multiple surgeries to repair erosions, severe and chronic inflammation, mesh extrusion, exposure extrusion into the vagina or other structures or organs, chronic pain, pain with intercourse, neuromuscular problems including acute and/or chronic pain in the groin, thigh, leg pelvic and/or abdominal area, surgical treatment or revision surgeries, excessive contraction or shrinkage of the tissue surrounding the mesh and urinary frequency. Weisberg video deposition 961:1-17, 969:19-21, 970:17-18, 91:4, 91-12, 228:7-229:14, 19-21, 319:20-321:19, 323:8-11. Dr. Weisberg's deposition also discusses an email exchange between him and an Ethicon employee named Axel Arnaud dated October 13, 2002 suggesting that they conceal information about potential complications arising from the Prolene Mesh comprising the TVT.

> Dear Marty, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning potential complications/Fistula&Erosions [sic]. This is a problem which arises rather commonly in practice even with polypropylene and it might be wise to be more elusive on this. Also, as you said, when this happen [sic], it is much less a problem with polypropylene

> meshes since it usually resolves with a partial excision and local care.

Id. at 401:23 – 407:6 discussing Plaintiff's exhibit T 353.

Additional testimony during cross-examination from Dr. Elser, Defendant-Appellant's expert witness, also confirmed that the IFU lacked a comprehensive listing of these complications. N.T. 2/5/16 (P.M.), 95-100.

The jury also heard testimony from Plaintiff's expert Dr. Bruce Rosenzweig, who testified about the defects in the TVT, discussing a number of characteristics of the mesh that make it unsuitable to implant in humans (including chronic foreign body reaction, fibrotic bridging, mesh contraction, degradation, and particle loss). These characteristics were identified by Dr. Rosenzweig as defects that exist in the TVT. Rosenzweig video deposition 83:08 – 86:01. Rosenzweig also testified about alternatives to the TVT that Ethicon knew were both available and safer for implantation in humans and that Ethicon's failure to utilize available alternative designs rendered the TVT unreasonably unsafe. *Id.* at 99:18 – 101:4; 200:8-201:6, 940:11-941:5. Dr. Rosenzweig also testified that Ethicon's studies on polypropylene degradation prior to the TVT's regulatory approval by the FDA were insufficient. *Id.* at 193:21 – 194:9.

Plaintiff's urogynecology expert, Dr. Michael Margolis, provided testimony about the chronic injuries Plaintiff has suffered from the TVT implant and that Plaintiff's injuries are permanent. N.T. 1/18/16 (A.M.), 36:04-36-20. Dr. Margolis also testified that the remaining mesh in Plaintiff's body puts her at risk for future complications from mesh erosions. *Id.* at 40:11 – 42:06, 44.

The jury was entitled to find from this testimony and other evidence that defendants deceptively withheld important information about the risks of undergoing a TVT implant

procedure, conducted insufficient risk assessments, and were cognizant of alternative designs that were less risky to patients. From this evidence, the jury was free to determine that Ethicon provided warnings so deliberately misleading as to warrant the imposition of punitive damages. Furthermore, the punitive damages award of $13.5 million is not beyond the limits of the guidelines codified in N.J.S.A. § 2A:15-5.14a-b, and is reasonable in relation to the compensatory damages of $ 3.5 million, as well. *See, e.g., Baker v. Nat'l State Bank*, 801 A.2d 1158 (N.J. App. Div. 2002) (ratio of 6:1 of punitive to compensatory damages was not unreasonable or excessive). Defendant-Appellants' request for remittitur is meritless and this court made no error by allowing punitive damages to be awarded.

o. **This Court Did Not Err in Denying Remittitur of the Compensatory Damages Award.**

The Defendant-Appellants also argue that the Court should have remitted the compensatory damages award of $ 3.5 million because there was no testimony as to past or future medical costs and the award was excessive. They further argue that Ms. Carlino's alleged failure to mitigate supports remittitur of the compensatory damages award.

In support of its argument, the Defendant-Appellants state that "Mrs. Carlino sought compensation only for post-2012 pain and suffering, namely, intermittent pelvic pain, dyspareunia, and an unquantified amount of emotional harm." To characterize her testimony in this way is to minimize her real damages to an unreasonable degree, even as defense argument. She feels pain very frequently, and takes gabapentin in order to treat that pain. This is not merely "intermittent" pain – it is chronic pain, pain that will be with her for the rest of her life, with no real prospect of resolution. She has pain during intercourse, which affects her marriage. The

emotional harm that she experiences from her pain and from the impact that her injuries have had on her life and on her marriage are real, despite being "unquantified," as the Defendant-Appellants would have it. The Defendant-Appellants also argue that her refusal to use topical estrogen constitutes a failure to mitigate, rather than a reasonable medical choice about the Plaintiff's own body, the kind of decision that *she* is entitled to make, with complete understanding of the benefits and drawbacks of any particular course of treatment. Given that Ms. Carlino is already taking gabapentin, a seemingly reasonable step to mitigate her pain, this Court will certainly not reduce her compensatory damages because she refuses to submit to the exact medication regime recommended by the party that has been found to have harmed her with its medical product. Such an action would be ironic and perverse. This argument is meritless.

p. <u>This Court Properly Excluded FDA Evidence.</u>

The Defendant-Appellants argue that this Court erred in excluding all evidence of, and argument regarding, FDA's clearance of TVT as well as related regulatory processes; FDA's advisory committee process and statements regarding mesh midurethral slings; FDA's approval, regulation, and study of Prolene suture; and FDA's regulation and study of surgical mesh. They claim that this evidence was admissible to counter Plaintiffs' assertions that Ethicon's warnings were inadequate and that TVT is defectively designed, and that exclusion of this evidence also deprived Defendants of defenses guaranteed by New Jersey law, because (a) manufacturers who comply with FDA requirements, as Ethicon did here, are rebuttably presumed to have adequate labels; and (b) punitive damages are not permitted where, as here, a medical device has been approved or is generally recognized as safe and effective. The argument as to FDA "approval" has been discussed *supra* and need not be rehashed, as the 510(k) process *absolutely does not* insulate parties from punitive damages under New Jersey law.

Here, the Defendant-Appellants hash together a number of arguments about a number of related, but far from identical, products. This confusion of issues supports this Court's ruling that the FDA should not become a part of this case. For instance, Prolene sutures, a product used for wound closure and not for structural implantation as a permanent fixture in the interior of the human body, is related inasmuch as it is materially similar to the base material of which the TVT sling product consists. Structurally, it is much different, both in its size and in its purpose. Its FDA approval is as a suture product, not as a TVT implant. The FDA has great authority, and its approval of a product has the potential to muddy the waters, especially where the relationship between that product and the implant at issue is tangential at best.

The probative value of FDA approval is at its greatest when a product has been thoroughly evaluated for safety in the exact application at issue in the case, and is at its weakest when the product is only somewhat similar, is used for a different purpose, and is fundamentally different, and where the evaluation or "approval" in question is not for safety but for similarity, as under 510(k). The prejudicial effect of bringing FDA approval into a case of this type is always considerable, given the obvious authority of the FDA and the jurors' tendency to want to trust an authority of that type to make reasonable safety decisions based on special expertise. Given the necessarily broad latitude that trial courts have to make evidentiary decisions, as discussed *supra*, and given the smattering of products and processes that the Defendant-Appellants purport to have wanted to bring into the case (despite what nasty doors such evidence would necessarily have opened; *see, e.g.*, "FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence" and "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA

Safety Communication"), this Court should not be found to have erred in restricting this state tort case to state tort law and keeping the vicissitudes of the regulatory state out of the jury's evaluations.[9]

The Defendant-Appellants cite one unreported case supposedly finding that a rebuttable presumption that labeling is adequate applies after the 510(k) process: *Seavey v. Globus Med., Inc.*, 2014 WL 1876957, at *6 (D.N.J. Mar. 11, 2014). The Defendant-Appellants characterize the opinion as holding that the presumption applied where the FDA requires changes during the 510(k) process. In fact, the opinion reports that "Plaintiff does not dispute that the FDA approved the warnings that appeared in the labelling accompanying the ...Device. Rather, Plaintiff argues that the presumption that the warning is adequate can be rebutted in this case." So the question of whether the presumption applied was not before the *Seavey* court, which was dealing with off-label use of a device, a scenario that is inapposite. Because the Defendant-Appellants have cited no law holding that they were entitled to the rebuttable presumption as a result of the 510(k) approval, this claim is meritless.

q. <u>This Court's Evidentiary Rulings Were Proper.</u>

The Defendant-Appellants claim that The Court erred in admitting evidence that allegedly did not relate to TVT. First, they object to admission of evidence of an October 13, 2002 email from Axel Arnaud to Martin Weisberg regarding the Prolene Soft material (Pls.'

[9] The FDA's Public Health Notification is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm, and includes language like "[b]ased on an updated analysis of adverse events reported to the FDA and complications described in the scientific literature, the FDA identified surgical mesh for transvaginal repair of POP as an area of continuing serious concern. The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**." (emphasis in original). The Notification lists significant numbers of complications in POP and SUI repair with surgical mesh. The Update is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm.

Trial Ex. 46). Second, they object to admission of evidence of a material safety data sheet issued by Chevron Phillips (Pls.' Trial Ex. 54).

"Evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Pa.R.E. 401. The first piece of contested evidence, an email from Axel Arnaud to Martin Weisberg in which Dr. Arnaud indicates "it might be wise to be more elusive" about rates of mesh erosions, apparently relates to another product. The Defendant-Appellants' Post-Trial Motion argues "As the email itself makes clear, Dr. Arnaud's comments related to Prolene Soft, a different product than TVT that is used in other pelvic floor devices manufactured by Ethicon, rather than the Prolene mesh used in TVT." If it is true that the email itself makes clear that it relates to another related product, then this would go to weight of the evidence and the Defendant-Appellants were of course free to argue at trial that the email should be given limited weight by the jury for this reason. However, it is reasonable to determine that the email reveals a broader policy decision about how forthcoming Ethicon should be about mesh erosion issues with its pelvic floor mesh implant devices, issues that the two products seem to share. Under Rule 401, the email is clearly relevant, as it tends to make a contested issue more or less probable. Because the Defendant-Appellants' argument goes to the weight the evidence should be afforded rather than its admissibility, and because the Defendant-Appellants were free to make that argument to the jury, this claim is meritless.

The other piece of contested evidence is a Material Safety Data Sheet from Chevron Phillips concerning Marlex® polypropylene mesh. *See* Pls.' Trial Ex. 54, Chevron Phillips MSDS. Marlex, which is used by another mesh manufacturer, C.R. Bard, Inc., but not by Ethicon, apparently has a different chemical composition than Prolene, the polypropylene

material in the TVT. The Chevron Phillips MSDS states: "Do not use this Chevron Phillips Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." *Id.* at 1. This exhibit was used in the questioning of Dr. Martin Weisberg, one of Ethicon's employees, about the advisability of using polypropylene in the human body. Again, the fact that Ethicon does not use Marlex goes to the weight of the evidence, not its admissibility, and the Defendant-Appellants were free to argue that Ethicon did not purchase Marlex, but instead used another brand of polypropylene in its TVT product, and to explain the significance of this distinction to the jury. The reference to Marlex and the Material Data Safety Sheet was relatively fleeting, in the full context of this case, and it is exceedingly doubtful to have made a significant impact on the jury's evaluations of the case. Given the broad discretion the Court has in making evidentiary determinations, as detailed *supra*, and given that the Defendant-Appellants were free to bring up in witness examinations and argue to the jury the weight this evidence should be afforded, these claims are meritless.

r. <u>This Court Did Not Err in Excluding Current Market Evidence.</u>

Finally, the Defendant-Appellants argue that "this Court erred by holding that any admission of otherwise admissible evidence that TVT remains on the market and is the current gold-standard surgical treatment for stress urinary incontinence or present-tense references to TVT would open the door to Plaintiffs introducing evidence of changes to TVT's Instructions for Use, which is inadmissible as a subsequent remedial measure." How could the Defendant-Appellants even imagine that they would be permitted to argue that TVT remains on the market and is some sort of "gold standard" without opening the door to evidence and discussion of the *terms* under which TVT remains on the market? This argument is nonsensical at the outset. It would be impossibly irresponsible to allow the Defendant-Appellants to argue, essentially, that

TVT's continued presence in the market meant that Ms. Carlino's case was some sort of outlier (instead of being exactly the kind of case discussed in the FDA's Public Health Notification, *see supra* n.7), and that the product remained on the market "as is" when in fact the changes to the IFU address many of the concerns raised in this litigation. This line of argumentation would have, as the Defendant-Appellants point out, inevitably opened the door to evidence otherwise excludable as evidence of subsequent remedial measures.

Rule 407, excluding evidence of subsequent remedial measures for public policy reasons ("to encourage remedial measures;" *see* Comment to Rule), embodies a longstanding policy in products liability cases that companies must not be penalized for reacting appropriately when they learn that one of their products may be harmful. It also appropriately focuses the jury's inquiry on the relevant period of time and iteration of the product at hand. The Rule contains an explicit exception when used for impeachment. The Defendant-Appellants' argument would have this Court read that exception out of the Rule, in contravention of its express language and of the law of our Supreme Court. *See, e.g., Duchess v. Langston Corp.*, 769 A.2d 1131, 1146-47 (Pa. 2001) ("Where ... a defendant's evidence and arguments are framed in categorical terms, are presented in the form of superlatives, or, more generally, upset the balance of fairness that Rule 407 seeks to maintain, courts have found the exceptions applicable."); *citing Wood v. Morbark Industries, Inc.*, 70 F.3d 1201, 1208 (11th Cir. 1995) (where the defendant's expert described the product design using superlatives, namely, the "safest [design] you could possibly put on the machine," the plaintiff should have been permitted to impeach the expert by inquiring why the safest design possible was modified following the plaintiff's accident). The *Wood* scenario would seem to apply directly here, given the Defendant-Appellants' acknowledgement that they wished to describe this product as some sort of "gold standard."

Each litigant must decide which doors it is willing to open and which it must avoid, but in this argument the Defendant-Appellants attempt to blame this Court from not freeing them from this dilemma. In effect, they ask, why were we not permitted to show that our product is still on the market and still in use, without showing that it took serious relevant action from the FDA and serious relevant remedial measures from us in order to keep it on the market? These types of difficult choices characterize products liability litigation. This Court did not design this conundrum, which comes up frequently in products liability cases. Nor is it for the Court to attempt to disentangle subsequent product evidence that would be useful for one side in the litigation from subsequent product evidence that would be useful for the other side, but would not exist if it were not for the evidence useful for its adversary. It is not for this Court to untangle the Gordian Knot that subsequent evidence presents in products liability litigation. It affects both sides, and both sides usually have subsequent evidence that helps their case. To ask this Court to look the other way while the Defendant-Appellants open the door to subsequent remedial measures is to ask far too much. Without context, such evidence is misleading, and much more prejudicial than probative. This Court was right to preserve the balance that is naturally presented in cases like these, allowing the parties to decide whether to 'open the door" but making clear what the consequences of that act would be. This claim, too, is meritless.

V. Conclusion

For the foregoing reasons, the Court's verdict should be affirmed.

BY THE COURT,

/s/

KENNETH J. POWELL, JR., J.