2019 PA Super 287

MARGARET ENGLEMAN	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
ETHICON, INC., AND JOHNSON AND JOHNSON,	:	
Appellants.	:	No. 3320 EDA 2017

Appeal from the Judgment Entered, September 12, 2017, in the Court of Common Pleas of Philadelphia County, Civil Division at No(s): March Term, 2014 - No. 05384.

MARGARET ENGLEMAN,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
ETHICON, INC. AND JOHNSON & JOHNSON	:	No. 3400 EDA 2017

Appeal from the Judgment Entered, September 12, 2017, in the Court of Common Pleas of Philadelphia County, Civil Division at No(s): 05384.

BEFORE: PANELLA, J., DUBOW, J., and KUNSELMAN, J.

OPINION BY KUNSELMAN, J.: **FILED SEPTEMBER 20, 2019**

Ethicon, Inc. and Johnson & Johnson ("the manufacturers") designed, produced, marketed, and sold transvaginal-mesh, named "TVT-Secur," from 2006 through 2012. Unaware of the mesh's health risks, in 2007, Margaret

Engleman's physicians implanted the product in her to treat stress urinary incontinence ("SUI"). This surgery occurred in Philadelphia.

In 2013, Ms. Engleman sued the manufacturers in the Court of Common Pleas of Philadelphia. She claims their vaginal mesh permanently damaged her internal organs, continues to cause her pain and suffering, and will negatively impact her standard of life indefinitely. Because Ms. Engleman and the manufacturers are New Jersey residents, the parties agreed New Jersey's substantive law governs this case.

The manufacturers argued at trial that the statute of limitations time-barred Ms. Engleman's lawsuit. The jury disagreed, found them liable, and awarded her $20,000,000 in damages. Both sides appealed.

The manufacturers continue to argue Ms. Engleman's case is time-barred. Additionally, they argue the punitive damages must be reduced. We agree that, under New Jersey's punitive-damages cap, this Court must reduce the punitive damages to $12,500,000 – *i.e.*, to five times the compensatory damages of $2,500,000. This lowers the jury's total verdict to $15,000,000. In all other respect, we affirm the judgment below.

Factual Background

Ms. Engleman filed this lawsuit against the manufacturers on October 8, 2014. Among many defenses raised at trial, the manufacturers asserted the two-year statute of limitations for personal-injury causes of action.

The facts set forth in the trial court's 1925(a) Opinion are as follows:

> Beginning in 2003, Dr. Gregory Bolton, a Philadelphia gynecologist, began treating [Ms. Engleman] for mild stress urinary incontinence ("SUI"). In June 2007, Dr. Bolton recommended surgery.
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> On June 14, 2007, Dr. Bolton performed surgery to correct [Ms. Engleman's] incontinence and implanted [the manufacturers'] Tension Free Vaginal Tape Secur ("TVT-Secur"). A month after surgery, [Ms. Engleman] experienced pain in her vagina and a return of urinary incontinence. In September 2007, Dr. Bolton surgically removed [part of the] TVT-Secur mesh which was exposed in [Ms. Engleman's] vagina.
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> [Ms. Engleman's] vaginal pain continued and her incontinence increased. Dr. Bolton referred [Ms. Engleman] to Dr. Joseph Montella, a urogynecologist at Thomas Jefferson University Hospital in Philadelphia. In February 2008, Dr. Montella performed a third surgery and removed all but approximately three centimeters of the TVT-Secur. In 2012 and 2013, [Ms. Engleman] pelvic pain returned. [Ms. Engleman's] new gynecologist, Dr. Geoffrey Bowers, identified additional TVT-Secur erosion in [Ms. Engleman's] vaginal wall. In December 2013, Dr. Montella performed yet another procedure to remove the remaining mesh. [Ms. Engleman] continued to experience dyspareunia, vaginal spasms, and sexual dysfunction following the surgery.
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> [Ms. Engleman] continued to treat with Dr. Bowers for chronic vaginal pain, urgency, and frequent urination. Physical therapy, oral medications, creams and vaginal suppositories failed to alleviate [Ms. Engleman's] symptoms. [Ms. Engleman] testified that her pain has changed her life "drastically."

Trial Court Opinion, 1/23/18, at 2-3.

The case proceeded to a jury trial in April 2017. The jurors found the manufacturers' vaginal mesh defective under New Jersey's Product-Liability

Act[1] and awarded Ms. Engleman compensatory and punitive damages. The trial court denied all post-trial motions, including the manufacturers' request for a new trial. The manufacturers timely appealed. [2]

They bring eleven appellate issues before this Court, which we have reordered for ease of disposition as follows:

1. Did the trial court err in not awarding defendants judgment as a matter of law under the two-year statute of limitations?

2. Did the trial court err in excluding evidence of public-health notices issued in 2008 and 2011 that linked Ms. Engleman's symptoms with the type of mesh device she was implanted with?

3. Did the trial court commit reversible error by barring all evidence from the federal Food and Drug Administration (FDA) regarding TVT-Secur, an FDA-regulated medical device?

4. Did the trial court commit reversible error by admitting evidence regarding Australian complaints about TVT-Secur that Ethicon received months after Ms. Engleman's implantation surgery?

5. Did the trial court err when it refused to remit the compensatory-damages award?

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[1] N.J.S.A. 2A:58C-1 *et seq*.

[2] Ms. Engleman also filed a timely cross-appeal, docketed at 3400 EDA 2017. She claims the trial court erred by refusing to calculate delay-damages based on both compensatory and punitive damages, instead of just compensatory damages. While this appeal was pending, this Court rejected Ms. Engleman's reading of the Pennsylvania Rules of Civil Procedure in ***Hammons v. Ethicon, Inc***., 190 A.3d 1248, 1289-1290 (Pa. Super. 2018), *allowance of appeal granted in part*, 206 A.3d 495 (Pa. 2019). At oral argument, Ms. Engleman's counsel agreed that ***Hammons*** controls her cross-appeal. We thus dismiss her cross-appeal as meritless.

6. Should the punitive-damages award be eliminated, because New Jersey law prohibits any award?

7. Should the punitive-damages award be eliminated or reduced, because the award violates New Jersey law and is constitutionally excessive?

8. Did the trial court err in instructing the jury to consider whether fraudulent concealment tolled the statute?

9. Did the trial court commit legal error in not awarding defendants judgment as a matter of law on the design-defect claim, when Ms. Engleman failed to present legally sufficient evidence of a safer, effective, feasible, and available alternative design to TVT-Secur?

10. Did the trial court commit legal error in excluding evidence demonstrating that Ms. Engleman's theoretical "alternative" was neither available in 2007 nor safer than TVT-Secur?

11. Did the trial court commit legal error in refusing to instruct the jury that Ms. Engleman was required to prove a safer, effective, feasible, and available alternative design?

See Manufacturers' Brief at 3-4.

Manufacturers' Request for Judgment N.O.V. under Pennsylvania's and New Jersey's Statute of Limitations

As their first appellate issue, the manufacturers assert that the trial court erred by not granting them judgment notwithstanding the verdict ("n.o.v.") on their statute-of-limitations defense. They argue Ms. Engleman brought this case well after the two-year statute of limitations had expired, under both New Jersey and Pennsylvania law. Thus, they believe they are

entitled to a judgment as a matter of law, regardless of which state's statute applies.

The trial court ruled that Pennsylvania's statute of limitations applied and instructed the jury accordingly. The jury found that Ms. Engleman had timely filed her lawsuit, and the trial court denied the manufacturers' post-trial motion for judgment n.o.v. on this issue. As we will explain below, Pennsylvania's statute of limitations and corresponding discovery rule apply.

When reviewing a trial court's ruling on a post-trial motion for judgment n.o.v., our scope of review:

> is plenary, as with any review of questions of law. Our standard of review when examining the lower court's refusal to grant a judgment n.o.v. is whether, when reading the record in the light most favorable to the verdict winner and granting that party every favorable inference therefrom, there was sufficient, competent evidence to sustain the verdict. Although we accord deference to a trial court with regard to its factual findings, our review of its legal conclusions is *de novo.*

Bailets v. Pennsylvania Tpk. Comm'n, 181 A.3d 324, 332 (Pa. 2018). To the extent that the manufacturers challenge the trial court's interpretations of various statutes, they "present this Court with questions of law for which our standard of review is *de novo*, and our scope of review is plenary." ***Id.***

To support their assertion for judgment n.o.v., the manufacturers begin by claiming that we should apply New Jersey's statute of limitations, because they think that Ms. Engleman's claim accrued there. ***See*** Manufacturers' Brief at 21 n. 2. Under New Jersey law, the trial court, and not the jury, decides

whether the discovery rule tolls a plaintiffs' claims. *Compare* ***Burd v. New Jersey Telephone Co.***, 386 A.2d 1310, 1312 (N.J. 1978) (accepting, for New Jersey statute-of-limitations purposes, "findings of fact made by the trial judge") *with* ***Nicolaou v. Martin***, 195 A.3d 880, 894-895 (Pa. 2018) (reinforcing Pennsylvania's long history of submitting all statute-of-limitations factual disputes to a jury).

The manufacturers contend that:

> Plaintiff's claims accrued in New Jersey, where she resides and experienced complications. Thus, Pennsylvania's borrowing statute compels the Court to apply New Jersey limitations law if it first bars Plaintiff's claims. 42 Pa.C.S.A. § 5521(b).

Manufacturers' Brief at 21 n. 2.

We disagree. Pennsylvania's Uniform Statute of Limitations on Foreign Claims Act only applies to claims "accruing outside this Commonwealth . . . ." 42 Pa.C.S.A. § 5521. Thus, we must establish when and where Ms. Engleman first suffered harm from the manufacturers' product.

The manufacturers suggest that their mesh only harmed Ms. Engleman *after* she returned home from Pennsylvania to New Jersey. In support of their contention, the manufacturers cite to ***Gwaltney v. Stone***, 564 A.2d 498 (Pa. Super. 1989). That case cuts against them.

Gwaltney involved a car accident in Tennessee, but the plaintiffs filed suit in Pennsylvania. This Court held that Tennessee's one-year statute of limitations applied, because "a claim *accrues* when and where the injury is

sustained." ***Id.*** at 501 (emphasis in original). Because the wreck happened in Tennessee, the Gwaltneys sustained their injuries in Tennessee.

Here, Ms. Engleman's doctors implanted the manufacturers' defective vaginal mesh in Philadelphia. ***See*** Complaint at 6. Additionally, the manufacturers failed to warn Ms. Engleman and her doctors that their product could harm her in the manufacturer's product literature in Pennsylvania. When Ms. Engleman's surgeons implanted the vaginal mesh inside her body, the manufacturers' tort of product liability was completed and accrued. Thus, as in ***Gwaltney***, we conclude that Ms. Engleman's cause of action accrued in the state where the wrongful conduct occurred – *i.e.*, in Pennsylvania.

The manufacturers' suggestion that Ms. Engleman's tort accrued in New Jersey, because that is where she first felt pain from their vaginal mesh, has no basis in the law. Were we to accept their theory that the *situs* of pain dictates where and when a cause of action accrues, then a person in a Tennessee car accident, who did not feel its effects until returning to Pennsylvania, would be able to circumvent ***Gwaltney*** simply because his injury did not manifest itself immediately. But the event that caused the underlying harm – *i.e.*, the ***tort*** – would have still occurred in Tennessee. The same is true of Ms. Engleman. The harmful event occurred in Pennsylvania, even though the resultant pain manifested after she returned to New Jersey.

Thus, the Uniform Statute of Limitations on Foreign Claims Act does not apply in the instant case, because Ms. Engleman's cause of action did not accrue in a foreign jurisdiction. It accrued here. As a matter of law, the trial

court properly applied Pennsylvania's statute of limitations to Ms. Engleman's lawsuit.

Under Pennsylvania's two-year statute of limitations for personal injuries and corresponding discovery rule, whether a plaintiff exercised reasonable diligence in investigating the cause of her injuries generally raises a question of fact for the jury. ***See*** 42 Pa.C.S.A. § 5524; ***see also Nicolaou***, ***supra***. As the trial court explained:

> 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). The discovery rule is invoked in cases "involving latent injury, and/or instances in which the causal connection between an injury and another's conduct is not apparent." ***Wilson v. El-Daief****,* 964 A.2d 354, 361-62 (Pa. 2009). "Application of the discovery rule involves a factual determination as to whether a party was able, in the exercise of reasonable diligence, to know of his injury and its cause. ***Therefore, application of the rule ordinarily must be decided by a jury." Mariner Chestnut Partners v. Lenfest****,* 152 A.2d 265, 279 (Pa. Super. 2016) . . .
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> During trial, [Ms. Engleman] introduced sufficient evidence to permit the jury to decide whether her claims were timely filed. [Ms. Engleman] testified that she believed that her body was rejecting the pelvic mesh for an unknown reason and that this was the cause of her symptoms. She further testified that, in December 2013, she saw advertisements on television describing the symptoms she was experiencing, and that the advertisements connected the symptoms to TVT-Secur. For the first time, [Ms. Engleman] testified, she was made aware of the connection. On April 2, 2014, within two years of learning of the potential defect, [Ms. Engleman] filed suit.

> It is undisputed that none of Plaintiff's physicians advised [Ms. Engleman] of a possible defect in the TVT-Secur. Dr. Bolton testified that he was unaware of any possible defects. Dr. Montella testified that he did not suspect the TVT-Secur caused [Ms. Engleman's] symptoms.
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> It was proper as a matter of law for the trial court to apply Pennsylvania law with regard to the statute of limitations and the discovery rule. Under Pennsylvania law, the trier of fact determines whether the statute of limitations is tolled by the discovery rule. Viewed in the light most favorable to the [Ms. Engleman], as the verdict winner, the evidence presented at trial was sufficient to permit the jury to determine that [Ms. Engleman] filed suit within two years of learning the cause of her injuries.

Trial Court Opinion, 9/5/17, at 12-13 (emphasis added; citations to the record omitted). The trial court properly submitted the question of whether the discovery rule tolled the Pennsylvania statute of limitations to the jury.

Because the jury believed Ms. Engleman's version of events, we must defer to its finding of fact that the discovery rule tolled the statute of limitations on her claims. As such, the manufacturer's claim for judgment n.o.v. warrants no relief. ***See Nicolaou***, 195 A.3d at 894-895 (Pa. 2018) (holding "courts may not view facts in a vacuum when determining whether a plaintiff has exercised the requisite diligence as a matter of law, but must consider what a reasonable person would have known had he or she been confronted with the same circumstances that [plaintiff] faced at the time").

Admissibility of FDA's Website Notifications on Vaginal Mesh

For their second claim of error, the manufactures assert the "trial court erred by excluding evidence showing that [Ms. Engleman's] claim was time-

barred." Manufacture's Brief at 31. Specifically, the manufactures disagree with the trial court's decision to exclude from evidence public-health notices from the Food and Drug Administration (FDA) website.[3] ***See id.*** In support

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[3] For example, the FDA published the following notice about a year after Ms. Engleman began to experience complications from the mesh:

> ## Medical Devices
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> ## FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
>
> **For updated information about Surgical Mesh for Pelvic Organ Prolapse, see: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ**
>
> Prolapse, released July 13, 2011.
>
> Issued: October 20, 2008
>
> Dear Healthcare Practitioner:
>
> This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.
>
> **Nature of the Problem**
>
> Over the past three years, FDA has received over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices

of their theory that the trial court erred, the manufacturers offer a case from the United States Court of Appeals for the Fourth Circuit, ***Timothy v. Bos. Sci. Corp.***, 665 F.App'x 295 (4th Cir. 2016).

The manufacturers challenge both the trial court's finding that the FDA website notices were irrelevant and hearsay. They argue that, under the

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> are usually placed transvaginally utilizing tools for minimally invasive placement.
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> The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia . . .
>
> Sincerely,
>
> Daniel G. Schultz, MD
> Director
> Center for Devices and Radiological Health
> Food and Drug Administration
>
> If you have questions about this Notification, please contact FDA's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by e-mail at dsmica@fda.hhs.gov or by phone at 1-800-638-2041 or 301-796-7100
>
> Page Last Updated: 03/21/2013

Manufacturers' Exhibit 5 to CTX-C; U.S. Food and Drug Administration, FDA Public Health Notification: "Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence" (Oct. 20, 2008), http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm.

discovery rule, Ms. Engleman should have "the knowledge that a reasonable investigation would have uncovered . . . ." Manufacturers' Brief at 32. Not only do they view the notices as relevant as to when the statute of limitations began to run, the manufactures say the notices are "dispositive." ***Id.***

Our standard of review for a challenge to an evidentiary ruling is the deferential abuse-of-discretion standard, and, even if an abuse of discretion occurred, we will not disturb the result below without some harm or prejudice befalling the appellant. As we have said:

> Admission of evidence is within the sound discretion of the trial court and we review the trial court's determinations regarding the admissibility of evidence for an abuse of discretion. To constitute reversible error, an evidentiary ruling must not only be erroneous, but also harmful or prejudicial to the complaining party. For evidence to be admissible, it must be competent and relevant. Evidence is competent if it is material to the issue to be determined at trial. Evidence is relevant if it tends to prove or disprove a material fact. Relevant evidence is admissible if its probative value outweighs its prejudicial impact. The trial court's rulings regarding the relevancy of evidence will not be overturned absent an abuse of discretion.

Czimmer v. Janssen Pharm., Inc., 122 A.3d 1043, 1058 (Pa. Super. 2015) (quoting ***Conroy v. Rosenwald***, 940 A.2d 409, 417 (Pa. Super. 2007)).

An "abuse of discretion" is not merely an error of judgment. ***Paden v. Baker Concrete Construction, Inc.***, 658 A.2d 341, 343 (Pa. 1995). It only occurs when a trial court renders a judgment that is manifestly unreasonable, arbitrary, or capricious, or if it fails to apply the law or was motivated by partiality, prejudice, bias, or ill will. ***Harman v. Borah***, 756 A.2d 1116, 1123

(Pa. 2000). If the record adequately supports the trial court's reasons and factual basis, the court did not abuse its discretion. ***Id.***

Although it is not entirely clear from their brief, the manufactures appear to claim the ruling was manifestly unreasonable and that exclusion of the FDA notices was reversible error. ***See*** Manufacturers' Brief at 31. They point out that the "trial court's primary rationale" for disallowing the notifications into evidence "— that the notices 'referred specifically to mesh used for pelvic organ prolapse and not stress urinary incontinence,' is incorrect." ***Id.*** at 32 (quoting Trial Court Opinion, 1/23/18, at 42). They also attack the trial court's secondary grounds for exclusion – namely, that the notifications constituted hearsay – as legally untenable. Thus, they also attack the ruling as legally erroneous.[4]

The manufacturers' argument attempts to reframe the issue of the notices' relevance on appeal in a manner that they did not present to the trial court. While they may well be relevant under the Fourth Circuit's application of Utah law in ***Timothy***, ***supra***, they are obviously irrelevant under the case law of this Commonwealth, because Ms. Engleman is not expected to self-diagnose. She is "only charged with the knowledge communicated to . . . her by the medical professionals who provided treatment and diagnosis." ***Nicolau***, 195 A.3d at 893. As such, under Pennsylvania law, we only "impose

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[4] Because we find the FDA notices irrelevant, we dismiss the issue of whether they were also hearsay as moot.

a relatively limited notice requirement upon the plaintiff [and] submit factual questions regarding that notice to the jury as factfinder." ***Id.***

Given this limited notice requirement, Ms. Engleman did not need to scour the Internet in the hopes of possibly uncovering the FDA notices and then use them to determine whether the vaginal mesh was harming her, as a matter of law. Thus, in Pennsylvania, these notices have no "tendency to make a fact more or less probable than it would be without the evidence . . ." Pennsylvania Rule of Evidence 401. They are irrelevant to Ms. Engleman's discovery-rule theory under ***Nicolau***; the FDA is not one of her "medical professionals who provided treatment and diagnosis." ***Id.***

Additionally, according to defense counsel, the manufacturers were not willing to say the FDA notices provided "notice of a defect in the product." N.T., 4/24/17, at 62. Thus, we do not see how the manufacturers can argue the FDA notices to the public at large informed Ms. Engleman that their vaginal mesh was defective and causing her injuries. This argument is duplicitous. In other words, the manufacturers wished to introduce the FDA notices to show Ms. Engleman should have known about the defect in their product, even though they themselves did not think the FDA notices were accurate. The manufacturers cannot have it both ways. Either the FDA notices ***were*** notice of the defect in the product, or they ***were not***.

As previously mentioned, the two relevant issues for the discovery rule were when Ms. Engleman learned of 1) her injury, and 2) who caused that injury. ***See Nicolau***, ***supra***. The exclusion of the notices that they believe

were inaccurate did not harm or prejudice the manufactures. The notices were clearly irrelevant to Ms. Engleman's knowledge that she was suffering an injury – she already knew that. And, as to whether the notices informed her that the manufacturers were the cause of that injury, the manufacturers themselves denied, at the time of proffer, that the notices did any such thing. Thus, the manufacturers attempted to admit the notices solely to ask Ms. Engleman whether she saw them, not for proving the FDA's conclusion therein – *i.e.*, the mesh was harmful.

Now, on appeal, they switch positions. The manufacturers advance the accuracy of the FDA notices as dispositive of Ms. Engleman's case, because they now contend that any reasonable person reading the FDA notices should have known their product was defective. Both theories cannot be true, and the manufactures did not advance the latter in the trial court.

Finally, we note the manufacturers disregarded the FDA notices. They kept marketing their product for years after the 2008 notice, and for some time after the 2011 one. They did not alter their behavior when the FDA published these notices; yet, they hypocritically contend that Ms. Engleman and any reasonable person in her position should have altered theirs. We disagree. Under these circumstances, the manufacturers fall woefully short of meeting their burden to show harm or prejudice due to the exclusion of the FDA notices from evidence.

We dismiss their second appellate issue as meritless.

Admissibility of the FDA 510(k) Clearances

For their next issue, the manufacturers claim that the trial judge's exclusion of FDA-created evidence, in the form of 510(k) clearances,[5] was "wrong." Manufacturers' Brief at 46. They disagree with the trial judge's conclusions on this issue. To underscore that disagreement, they reargue this point to us *de novo*, and rely on an opinion from the United States District Court for the District of Arizona, reaching the opposite conclusion. ***See In re Bard IVC Filters Prods. Liab. Litig.***, 289 F. Supp. 3d 1045 (D. Ariz. 2018).

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[5] According to the FDA:

> Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification – also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

United States Food & Drug Administration, "510(k) Clearances," available at https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/ (last visited 11/29/18).

However, as mentioned above and as the manufacturers acknowledge in the opening of their brief, when an evidentiary ruling is on appeal, this "Court determines whether the trial court abused its discretion or misapplied the law." Manufacturers' Brief at 2 (citing ***Hutchinson v. Penske Truck Leasing Co.***, 876 A.2d 978 (Pa. Super. 2005)). The manufactures overlook what constitutes an abuse of discretion. "Abuse of discretion occurs if the trial court renders a judgment that is manifestly unreasonable, arbitrary or capricious; that fails to apply the law; or that is motivated by partiality, prejudice, bias or ill-will." ***Hutchinson***, 876 A.2d at 984. In other words, a judgment call by the trial court – even a judgment call this Court thinks is "wrong" – does not create an abuse of discretion, without something more.

Here, by re-litigating their argument on the FDA clearances from the beginning, without something more, the manufacturers have not shown an abuse of discretion. They do not contend that the trial court's decision was arbitrary or capricious; based on partiality, prejudice, bias, or ill-will; or manifestly unreasonable. Nor do they reference any Pennsylvania Rule of Evidence that they believe the trial judge misapplied. And their citation to the Arizona trial court's ***Bard IVC*** case, at most, indicates that reasonable minds can differ regarding this FDA evidence. The Arizona judge reached one reasoned conclusion by admitting the evidence; the Pennsylvania judge reached the other by excluding it.

Thus, we are unpersuaded that the Pennsylvania trial court abused its discretion, when it reached the opposite, equally reasonable conclusion. As the trial court explained in its 1925(a) Opinion:

> Prior to trial, [Ms. Engleman] submitted a motion *in limine* to preclude all evidence of the FDA 510(k) clearance of any Ethicon products . . . During trial, [Ms. Engleman] moved to preclude evidence regarding the regulatory history of the [defective product], arguing that the evidence was irrelevant and thus precluded under Pa.R.E. 403. The court, in its discretion, granted these motions. The court excluded FDA-related evidence under Pa.R.E. 403 as irrelevant to the trial at hand. Under Rule 403, the court may exclude relevant evidence if its probative value is outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence. Pa.R.E. 403.
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> In its discretion, the trial court chose not to hold a "trial within a trial" over the FDA approval process. FDA 510(k) approval . . . is not a review for the safety and efficacy of a product and is instead only a review of substantial similarity between two devices. Including FDA evidence on the approval process for other TVT devices would involve a history of the TVT line of products and devices, which would not be relevant to TVT-Secur safety, design, or warnings. Such evidence would serve only to confuse the issues and mislead the jury regarding the role of the 510(k) approval process.

Trial Court Opinion, 1/23/18, at 41-42.

This opinion is well-reasoned and based upon a proper construction of Rule of Evidence 403. Simply because the trial court reached conclusions that the manufacturers consider "wrong" does not mean that the court abused its discretion. We may not second guess its logical determination that the FDA

clearances risked confusing the jurors and creating undue delay by leading to a trial within the trial. Nor may we second guess its conclusion that such a risk outweighed the probative value of the FDA clearances.

Hence, this issue warrants no relief.

Admissibility of the Australian Physicians' Complaints

The manufacturers also allege that the trial court should not have admitted complaints from Australian physicians about the safety of the vaginal mesh. They argue that these complaints were irrelevant and inadmissible hearsay. The trial judge decided otherwise.

Addressing this issue, the trial court explained in great detail why this evidence was relevant:

> In September 2007, [the manufacturers] began receiving complaints from Australian doctors who were having difficulty implanting the [defective mesh]. In response, [the manufacturers] performed a quality investigation and root cause analysis with Australia's Therapeutic Goods Administration. Dr. Aran Maree placed a "quality block" on [vaginal mesh] devices, meaning they could not be used until the investigation was completed.
>
> The trial court properly admitted evidence of the Australian doctors' concerns and the "quality block." Evidence of complaints is relevant to [Ms. Engleman's] failure-to-warn and design-defect claims under the NJPLA. ***See*** N.J.S.A. § 2A:58C-1. Under New Jersey law, a product is unreasonably dangerous if not accompanied by adequate warnings. ***See*** N.J.S.A. § 2A:58C-2. To succeed in an action under the NJPLA, a Plaintiff must prove that the product was not reasonably fit, suitable, or safe for its intended purpose, because it either contained a manufacturing defect, failed to contain adequate warnings

> or instructions, or was designed in a defective manner. ***Id.*** A manufacturer is required to warn of risks known during the time in which the plaintiff was using the product. 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 Laboratories Inc.***, 734 A.2d 1245, 1261 (N.J. 1999).
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> The evidence is also relevant to [Ms. Engleman's] design-defect claim. To prevail on a design-defect claim, a plaintiff "must prove either that the product's risk outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." ***Lewis v. Am. Cyanamid Co.***, 715 A.2d 967 (N.J. 1998). A plaintiff must provide sufficient evidence, so a reasonable juror could find "either that the product's risks outweighed its utility or that the product could have been designed in an alternate manner so as to minimize or eliminate the risk of harm." ***Id.*** at 571.
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> Here, evidence of the complaints in Australia is relevant to show that [the manufacturers] were aware of the risks associated with the [defective vaginal mesh] but failed to take action and adequately warn [Ms. Engleman's] physicians of these issues. Alternatively, [the manufacturers] assert that the complaints were inadmissible hearsay. However, this evidence was not offered to prove the truth of the matter asserted. Rather, the evidence of complaints from Australian doctors and subsequent quality block was offered to establish notice, which is not hearsay. ***See Castellani v. Scranton Times, L.P.***, 124 A.3d 1229 (Pa. 2015) (holding that out-of-court statements offered to put a defendant on notice is not hearsay).
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> For the reasons set forth, [Ms. Engleman's] evidence of Australian doctors' complaints was admissible and relevant to her case. The trial court did not abuse its discretion in permitting this evidence, and, thus, the ruling of the trial court should be affirmed.

Trial Court Opinion, 1/23/18, at 44-47 (citations to record omitted).

Much like their attack against the trial court's refusal to admit the FDA clearances above, the manufacturers again failed to explain how the trial court's judgment was manifestly unreasonable, biased, prejudiced, based on ill-will, clearly erroneous, or misapplied the Pennsylvania Rules of Evidence. In fact, the manufacturers only mention Pennsylvania Rule of Evidence 403 as an afterthought in the last paragraph of their argument on this issue. ***See*** Manufacturers' Brief at 53.

They baldly claim that the evidence of complaints from the Australian physicians violated that Rule 403, "because the jury likely viewed the evidence as proof of Ethicon's knowledge, which it logically could not be." ***Id.*** Additionally, the manufacturers speculate that the "jury very well may have based its $17,500,000 verdict on this evidence, even though post-implant knowledge cannot support a punitive award." ***Id.***

Whatever the jury *may have* based its verdict and damages award is an unproductive guessing game, played in hindsight, well after the trial court ruled this evidence admissible. And, more to the point, it does not speak to the test established in Rule 403. Under that Rule:

> The court may exclude relevant evidence if its probative value is outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

Pa.R.E. 403 (emphasis added).

The test focuses on "outweighed." This requires trial judges to balance the relevant evidence's truth-proving value against the Rule's six competing factors. For the manufacturers to show that the trial court has misapplied this Rule, they need to prove that the danger of prejudice, confusion, delay, etc. exceeded the evidence's probative value. But the manufacturers attempt no such weighing analysis in their brief, much less craft a persuasive argument showing how the trial judge exceeded the scope of her discretion in applying Rule 403.

As this Court previously told these same manufacturers in another vaginal-mesh case:

> all relevant evidence is meant to prejudice a defendant, so exclusion is limited to evidence so prejudicial that it would inflame the jury to make a decision based upon something other than the legal propositions relevant to the case. A trial court is not required to sanitize the trial to eliminate all unpleasant facts from the jury's consideration, where those facts form part of the history and natural development of the events.
>
> In other words . . . a party may strike hard blows, so long as it does not strike foul blows. The evidence . . . in this case was highly relevant . . . its probative value outweighed any prejudice to Ethicon. Indeed, we do not consider Ethicon to have suffered "unfair prejudice [or delay]," Rule 403's operative term[s].

Hammons v. Ethicon, Inc., 190 A.3d 1248, 1283 (Pa. Super. 2018), *allowance of appeal granted in part*, 206 A.3d 495 (Pa. 2019) (citations and some punctuation omitted).[6]

Thus, we find the trial court acted within its discretion when it made the reasonable decision to admit evidence of the Australian doctors' complaints, and we dismiss this issue as it affords the manufacturers no relief.

Remittitur of Compensatory Damages

Next, the manufacturers challenge the trial judges' refusal to remit the jury's award of $2,500,000 in compensatory damages. However, their argument not only repeats, but magnifies, the error they committed when arguing the evidentiary rulings above. The manufacturers totally ignore our deferential standard of review. They incorrectly state, as our standard of review, that remittitur "is proper if the verdict is 'excessive, exorbitant, and beyond what the evidence warrants, or where the verdict resulted from partiality, prejudice, mistake, or corruption.'" Manufacturers' Brief at 2 (quoting ***Smalls v. Pittsburgh-Corning Corp.***, 843 A.2d 410, 414 (Pa. Super. 2004)).

To be clear, that is ***NOT*** our standard of review; it is the legal test for the trial court. As the trial court clearly and correctly informed them in the

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[6] The parties had already filed their briefs when this Court issued its Opinion in ***Hammons***, ***supra***. They therefore did not have the benefit of that decision in preparing their written arguments.

1925(a) Opinion, a "grant of remittitur is a matter within the sound discretion of the trial court and will not be disturbed absent a ***gross abuse*** of discretion." Trial Court Opinion, 1/23/18, at 40 (citing ***Botek v. Mine Safety Appliance Corp.***, 611 A.2d 1174, 1177 (Pa. 1992) (emphasis added).

Despite the trial court's admonition, the manufacturers look the other way. Citing two cases from New Jersey and one from Pennsylvania, they reargue their cause for remittitur *de novo*. Because the manufacturers do not explain how the trial court abused its discretion, we dismiss this issue as affording them no relief.

Availability of Punitive Damages

Next, the manufacturers claim that, under New Jersey law, punitive damages are unviable, because they are barred when a medical device "is generally recognized as safe and effective pursuant to conditions established by the federal [FDA] and applicable regulations, including packaging and labelling regulations." Manufacturers' Brief at 56-57 (quoting N.J.S.A. § 2A:58C-5). They argue that the "FDA cleared TVT-Secur for marketing through its 510(k) process," and the FDA's 510(k) process "*is* a safety and efficacy review . . . ." ***Id.*** at 57 (emphasis in original).

This issue involves the interpretation of the New Jersey statute and the Pennsylvania Rules of Appellate Procedure, which are both questions of law. As such, our scope of review is plenary, and our standard of review is *de novo*. ***See Snead***, ***supra.***

The manufacturers' statement that the FDA's 510(k)-clearance process "is a safety and efficacy review" is untenable. The Supreme Court of the United States has said "the 510(k) process is focused on equivalence, not safety." ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 323 (2008). Indeed, the trial court included that very quote in its 1925(a) Opinion. ***See*** Trial Court Opinion, 1/23/18, at 32-33. As if that quote alone did not render this issue meritless, the trial court also provided another decisive quote from the United States Court of Appeals for the Third Circuit:

> 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 [premarket approval ("PMA")]. ***A premarket 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. See [Medtronic, Inc. v.] Lohr***, 518 U.S. at 478–79 (1996) ("The § 510(k) notification process is by no means comparable to the PMA process.").

Horn v. Thoratec Corp., 376 F.3d 163, 167 (3rd. Cir. 2004) (quoting an *FDA* amicus brief) (emphasis in original). Based on this language, neither the FDA nor the Supreme Court of the United States views the 510(k) process as a safety or efficacy review on the level of PMA review.

Finally, the trial court recognized this Court's holding that 510(k) review does not equate to a safety or efficacy declaration from the FDA. "***See also Burgstahler v. AcroMed Corp.***, 670 A.2d 658 (Pa. Super. 1995) ('At least two federal courts have expressly found that the 510(k) approval under the [Medical Device Amendments of 1979, 21 U.S.C. §§ 360c-360k (Supp. 1995)],

standing alone, is not a finding of safety and effectiveness . . .')." Trial Court Opinion, 1/23/18, at 33. Furthermore, this Court has said, "The FDA's own regulations provide that its acceptance of a claim that a device is 'substantially equivalent to a device in commercial distribution before May 28, 1976, . . . ***does not in any way denote official approval of the device*** . . . .' 21 C.F.R. 807.97 (emphasis supplied)." ***Burgstahler***, 670 A.2d at 663.

Accordingly, we dismiss this appellate issue as affording no relief to the manufactures.

New Jersey's Punitive Damages Limit

The manufacturers also assert that the jury improperly imposed $17,500,000 punitive-damages award against them, because "the award violates New Jersey law and is constitutionally excessive." Manufacturers' Brief at 4. The manufacturers advance two appellate theories here.

First, they argue "New Jersey law caps punitive damages at five times the compensatory award." ***Id.*** at 56 (citing N.J.S.A. § 2A:15-5.14(b)). The jury awarded compensatory damages of $2,500,000. The manufacturers therefore claim the jury could not lawfully award any more than $12,500,000 in punitive damages – $5,000,000 less than its original award.

Second, after the award is reduced under the cap, the manufacturers believe that this Court should either (a) totally eliminate or (b) reduce the remaining $12,500,000 punitive award to $2,500,000 or less. They claim that a $12,500,000 punitive-damages award violates the New Jersey statute

and/or the Constitution of the United States. By way of support, the manufacturers cite N.J.S.A § 2A:15-5.14(a) and the Due Process Clause of the Fourteenth Amendment via a quote from ***State Farm Mutual Auto. Insurance Co. v. Campbell***, 538 U.S. 408 (2003).

Ms. Engleman agrees that N.J.S.A. § 2A:15-5.14(b) limits punitive damages to five times the compensatory damages.[7] However, she disagrees that we should reduce punitive damages below $12,500,000. Instead, she says New Jersey substantive law does not control, because, under Pennsylvania law, "remittitur is a 'procedural mechanism by which an excessive verdict of the jury is reduced.'" Engleman's Brief at 62 (quoting ***Refuse Management Sys. v. Consol. Recycling & Transfer Sys.***, 671 A.2d 1140 (Pa. Super. 1996)). And, she asserts, even if reduction is substantive, there is no conflict between New Jersey and Pennsylvania law, because, under both laws, the standard of review is an abuse of discretion. She claims no such abuse occurred, as the record supports punitive-damages award.

In resolving these issues, the trial court applied New Jersey law and the

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[7] In the trial court and her appellee brief, Ms. Engleman originally asked the courts of Pennsylvania to strike-down N.J.S.A. § 2A:15-5.14(b), because it violated her right to a jury trial under Article I, § 9 of the Constitution of New Jersey. When we questioned her counsel on this Court's power to declare a Sister State's law unconstitutional under *its* constitution, counsel was unaware of any case where that had occurred. He also said that we may not certify this issue to the Supreme Court of New Jersey, as the United States Court of Appeals for the Third Circuit might do under New Jersey Rule of Appellate Procedure 2:12A. Essentially, counsel withdrew this constitutional attack on the New Jersey statute at oral argument, and, therefore, we do not reach its merits.

federal constitution. The court recognized the jury award must be reduced; it opined:

> States have discretion over the imposition of punitive damages. However, 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 gives three guideposts for reviewing a punitive damages award for reasonableness: (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 indicium of 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, 576 (1996). Considerations are the nature of the victim's harm, the degree of defendant's culpability, the victim's vulnerability to the harm, and whether the conduct involved repeated actions. ***Id.*** at 576-77.
>
> Trial evidence supported the jury's determination that [the manufacturers] acted reprehensibly. [Ms. Engleman] established that [they] misrepresented the safety concerns of [their vaginal mesh] to patients and physicians in an effort to gain a foothold in a quickly growing market and subsequently marketed the device for six years, despite knowledge of the risks.
>
> Regarding proportionality, the Supreme Court has stated "we have been reluctant to identify concrete constitutional limits on the ratio between harm or potential harm to the plaintiff and the punitive damages award." ***State Farm Mutual Automobile Insurance Co. v. Campbell***, 538 U.S. 408, 425 (2003). The Supreme Court has "consistently rejected the notion that the constitutional line is marked by a single mathematical formula, even one that compares actual and potential damages to the punitive award" though "single-digit multipliers are more likely to comport with due

> process." ***Id.*** Here, the jury's punitive damage award used a multiplier of seven.[8] Although there is no bright-line test to determine when a ratio is excessive, the damage award is within the Supreme Court's suggested proportionality test.
>
> Alternatively, [the manufacturers] claim that the punitive damages should be reduced to $12,500,000 (the maximum amount permitted under the New Jersey Punitive Damages Act). N.J.S.A. § 2A:15-5.14(b). . . . The Trial Court acknowledges that this section of the New Jersey Punitive Damages Act applies and, under New Jersey law, [Ms. Engleman's] punitive damage award should be reduced from $17,500,000 to $12,500,000.

Trial Court Opinion, 1/23/18, at 38-39.

We agree with the trial judge's well-reasoned opinion above and adopt it as our own on the issue of punitive damages. Accordingly, we modify Ms. Engleman's punitive-damages award, under N.J.S.A. § 2A:15-5.14(b), to $12,500,000.

Wavier of Jury-Instructions Issue

Next, the manufacturers assert that the trial court erroneously charged the jury on fraudulent-concealment. ***See*** Manufacturers' Brief at 33. Without reference to or quoting from any authority whatsoever, the manufacturers offer only one paragraph of conclusory statements in their appellants' brief to allege that the trial court was "triply wrong." ***Id.***

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[8] Moreover, after New Jersey's punitive-damages cap is applied, the multiplier is reduced to five times the compensatory damages.

It is incumbent upon the party claiming error in this Court to develop all issues raised in its brief fully. ***See*** Pennsylvania Rules of Appellate Procedure 2111 and 2119. Those Rules require that arguments include, among other things, "citation of authorities . . . ." Pa.R.A.P. 2119. As the manufacturers have failed to cite or quote any rule, case law, or statutory basis for their claim that the trial court's charge was erroneous, we dismiss this claim of error as waived.

Mootness of Design-Defect Issues

Finally, the manufacturers argue that they were entitled to judgment n.o.v. on Ms. Engleman's design-defect claim, because she "failed to prove that a safer, alternative design to TVT-Secur was feasible and available." Manufacturers' Brief at 35.

Ms. Engleman argues that we "should not even reach this argument." Engleman's Brief at 20. She points out that she:

> [b]rought one product-liability action under the New Jersey Product Liability Act and submitted that claim to the jury on two factual theories: design-defect and failure-to-warn. The jury found in [her] favor on *both* theories, as it was entitled to do. On appeal, [the manufacturers] made no argument concerning the failure-to-warn theory. This amounts to a concession that there was sufficient evidence to sustain the jury's verdict on failure-to-warn grounds.

Id. at 20-21 (citations omitted) (emphasis in original). We agree.

In fact, the manufacturers' failure to appeal both theories renders the jury's verdict against it, on the failure-to-warn theory, conclusive. Thus, as a

matter of law, this vaginal mesh is defective due to the manufacturers' failure to warn, regardless of whether a design defect was present. Hence, no ruling from this Court regarding Ms. Engleman's design-defect theory will change that. We therefore dismiss this claim of error as moot.

Additionally, the manufacturers argue that a new trial is warranted, because the trial court should have (1) admitted FDA evidence regarding the unavailability of a safer, alternative design and (2) instructed the jury regarding Ms. Engleman's obligation to prove the existence of "a safer, practical, and feasible alternative design." Manufacturers' Brief at 40.

We have concluded that, as a matter of law, the jury verdict may be upheld solely on Ms. Engleman's failure-to-warn theory. Thus, no new trial on the design-defect issue is warranted as to either of these alleged errors. Hence, we also dismiss these two issues as moot.

Conclusion

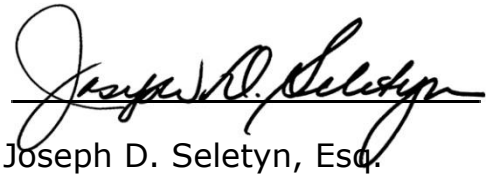
In sum, the manufacturers raised many appellate issues. Some they forfeited on procedural grounds, and on others, they ignored the correct standard of review. Their only surviving issue of merit is the trial court's failure to apply New Jersey's punitive-damages cap. Accordingly, we modify the judgment in favor of Ms. Engleman to $12,500,000 for punitive damages. We find no basis to alter the jury's award of $2,500,000 for compensatory damages or the trial court's award for delay damages, based solely upon those compensatory damages.

Judgment, as modified, affirmed.

Judge Panella joins this Opinion.

Judge Dubow files a Dissenting Statement.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 9/20/19