2019 PA Super 114

SHARON CARLINO AND CHARLES CARLINO, v. ETHICON, INC. AND JOHNSON & JOHNSON; GYNECARE; SECANT MEDICAL; SECANT MEDICAL, INC.; PRODESCO, INC.; AND SECANT MEDICAL, LLC APPEAL OF ETHICON, INC. AND JOHNSON & JOHNSON	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1129 EDA 2016

Appeal from the Judgment Entered April 1, 2016
In the Court of Common Pleas of Philadelphia County
Civil Division at No: June Term, 2013, No. 3470

SHARON CARLINO AND CHARLES CARLINO, v. ETHICON, INC. AND JOHNSON & JOHNSON; GYNECARE; SECANT MEDICAL; SECANT MEDICAL, INC.; PRODESCO, INC.; AND SECANT MEDICAL, LLC APPEAL OF SHARON CARLINO AND CHARLES CARLINO	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1294 EDA 2016

Appeal from the Judgment Entered April 1, 2016
In the Court of Common Pleas of Philadelphia County
Civil Division at No: June Term, 2013, No. 3470

BEFORE: STABILE, J., STEVENS*, P.J.E. and STRASSBURGER**, J.

OPINION BY STABILE, J.: **FILED APRIL 11, 2019**

In this product liability action, Appellants, Ethicon, Inc. and Johnson & Johnson, Ethicon's parent company (collectively "Ethicon"), and Appellees, Sharon and Charles Carlino, appeal and cross-appeal,[1] respectively, from a judgment of $13,500,000.00 entered in favor of the Carlinos in the Philadelphia Court of Common Pleas. The jury determined that Ms. Carlino suffered injuries from Ethicon's defective design of, and failure to provide adequate warnings about, the TVT device ("TVT"), a medical product used to treat stress urinary incontinence ("SUI"). The jury also determined that Ethicon was liable for punitive damages due to its willful and wanton disregard of Ms. Carlino's rights. For the reasons articulated below, we affirm.

FACTUAL AND PROCEDURAL HISTORY

Johnson & Johnson has its worldwide headquarters in New Jersey. Ethicon is a wholly owned subsidiary of Johnson & Johnson with a principal

---

* Former Justice specially assigned to the Superior Court.

** Retired Senior Judge assigned to the Superior Court.

[1] We consolidated these appeals *sua sponte* on January 25, 2018.

place of business in New Jersey. Ethicon worked closely with other entities and individuals in Pennsylvania to design, test and manufacture the TVT.

SUI is a chronic condition that causes urine to leak involuntarily during everyday activities such as laughing, coughing, sneezing and exercise. Transcript ("Tr."), 1/27 (AM), at 130-31.[2] The TVT is a medical device designed to cure or reduce SUI by supporting the mid-urethra with a tape-like sling of polypropylene surgical mesh. The mesh is knitted from filaments of Ethicon's Prolene polypropylene, a material long used to make surgical sutures, that is cut into strips to comply with the TVT's specific shape and design.[3] Plaintiff's Exhibit ("PTX") 16 (Instructions for Use) at 26. The mesh tape works like a hammock, supporting the urethra to stop urinary leakage. To place the tape, the surgeon makes a small incision in the vagina and then passes the tape through the incision using two trocars (hollow surgical needles) to position the tape. ***Id.*** at 27. Once placed, only the tape remains in the body. The tape is not tied to the pelvic structure but instead is held in place by natural ingrowth of surrounding tissue into the mesh. ***Id.***

---

[2] Since the entire trial took place in 2016, all subsequent citations to the trial transcript will only state the month, date and time of day ("AM" or "PM").

[3] It appears that the TVT differs from the Prolift device at issue in ***Hammons v. Ethicon, Inc.***, 190 A.3d 1248 (Pa. Super. 2018). The Carlinos indicate that the TVT and Prolift device use the same Prolene mesh but are cut to different specifications. Appellees' Brief at 23 n.3; ***see also Kaiser v. Johnson & Johnson***, 334 F. Supp. 2d 923, 941 (N.D. In. 2018) (TVT and Prolift are "separate but similar" devices).

The Carlinos reside in New Jersey. In 2005, Ms. Carlino experienced back pain caused by uterine fibroids and stress urinary incontinence ("SUI"). Her gynecologist referred her to Dr. Andrew Blechman, a surgeon, who recommended that she undergo a laparoscopic hysterectomy and bladder sling procedure to alleviate her pain and SUI. On a consent form signed by Ms. Carlino and certified by Dr. Blechman, Dr. Blechman informed Ms. Carlino that the risks of **surgery** involved "the risk of bleeding, infection, anesthesia and . . . injury to adjacent organs." In a separate report, Dr. Blechman stated that he and Ms. Carlino "discussed the fact that the surgery is no guarantee that she will be pain-free after the surgery." On August 18, 2005, Dr. Blechman implanted a TVT during the bladder sling procedure. The hysterectomy was effective in alleviating Ms. Carlino's back pain, and initially it seemed that the TVT implantation was successful. One year later, on November 14, 2006, Dr. Blechman reported that Ms. Carlino was "in no acute distress." PTX 61 (Carlino medical records), at 12.

In 2007, however, Ms. Carlino felt "something sharp in [her] vagina." Tr., 1/27 (PM), at 26-27. Dr. Blechman advised that part of her TVT was exposed and recommended surgery to revise the mesh and treat her pain. ***Id.*** at 39-40, 45. Ms. Carlino testified that at that point, she understood that "[the exposure] was a risk of the implantation surgery," Tr., 1/27 (AM), at 100-01, and that "the mesh was not intended to be exposed in the vagina." Tr., 1/27 (PM), at 39-40; ***see also id.*** at 45, 72. She called the exposure "unexpected and concerning," ***id.*** at 44, and believed it was "caus[ing] her

harm." ***Id.*** at 39-40. She underwent corrective surgery on November 26, 2007.

There was conflicting evidence as to whether Dr. Blechman advised Ms. Carlino at the time of her corrective surgery that any post-operative complication was a risk of **corrective surgery** or a risk posed by the **TVT**. Prior to this surgery, he advised Ms. Carlino that surgery involved risks such as "bleeding, infection, anesthesia and also the possibility of urinary incontinence in the future." PTX 61, at 24. After surgery, he appeared to reach a different conclusion. During a post-surgical appointment with Ms. Carlino on December 10, 2007, he noted that she "feels okay other than she has some right lower quadrant pain . . . that she thought may have been related to the mesh. I do not believe it is so." PTX 61, at 31. Years later, during his trial deposition, he appeared to change his views once again. He testified that "the mesh [he] w[as] leaving behind could still in the future erode," indicating that the TVT itself could cause post-operative complications. Defense Exhibit ("DTX") 129 (Blechman testimony) at 212:2-6.

In 2010, Ms. Carlino again suffered sharp pain in her vagina. Tr., 1/27 (PM), at 56-59, 76-77. She testified that she "immediately attributed" her pain to the TVT and knew that this was "not what's supposed to happen with bladder slings." Tr., 1/27 (PM), at 69, 75-77. She reported that her "[b]ladder sling [was] coming out" and was "uncomfortable during sex." ***Id.*** at 75-77, 78-79; ***see also*** DTX-7 (medical form and Ms. Carlino's handwritten complaints). Dr. Blechman referred Ms. Carlino to Ellen Conner, a

urogynecologist, who diagnosed another TVT exposure. DTX-10 (treatment note).

As was the case with Dr. Blechman in 2007, there was conflicting evidence as to whether Dr. Conner advised Ms. Carlino in 2010 that her pain was attributable to the TVT or was simply a risk of surgery. On one hand, Dr. Conner testified that she explained to Ms. Carlino that "the mesh was causing her discomfort, that was the most likely cause." DTX-130 (Conner testimony) at 30-32. Ms. Carlino testified that she knew this "was not the expected course," that the device "wasn't supposed to have a small part eroding in the vagina," that "it needed to be repaired," and that "[she] had been harmed by the erosion." Tr. (1/27 PM), at 72-73, 75-79, 81; Tr., 1/28 (PM), at 104-08. On the other hand, Dr. Conner's notes state that she explained that

> the **risks of surgery** were discussed [with Ms. Carlino] and included . . . hemorrhage, infection, damage to surrounding organs, **erosion of mesh**, pain, failure, incontinence . . . I specifically restated that with implantation of mesh, complications such as erosion, pain and infection can occur, may require further surgery, and even then may be difficult to address.

DTX-10035.10. Ms. Carlino signed a consent form that included "erosion of mesh" as one of multiple risks of surgery. PTX 61, at 42.

On December 17, 2010, Dr. Conner performed corrective surgery to remove part of the TVT. Tr., 1/27 (AM), at 102-03.

In March 2011, Ms. Carlino declined Dr. Conner's recommendation to implant a second mesh sling "[b]ecause [she] had so much trouble with the first one." Tr., 1/29 (PM), at 43; ***see also*** Tr., 1/29 (AM), at 5-7, 12-14, 21.

Ms. Carlino's pain returned in late 2012. In April 2013, Ms. Carlino viewed a television advertisement describing her symptoms and relating them to mesh products. Tr., 1/28 (AM), at 112-14. On June 26, 2013, she filed suit against Ethicon alleging that (1) she suffered injuries from a design defect in the TVT, and (2) Ethicon failed to adequately warn of the TVT's medical risks.

Ethicon raised the statute of limitations as an affirmative defense. In response, the Carlinos argued that they were not seeking compensation for pain and suffering suffered in 2007 and 2010 but only for injuries suffered within two years before June 2013.

In 2014 and 2015, Dr. Blechman examined Ms. Carlino and determined that her pain and discomfort were chronic conditions, not temporary byproducts of healing or surgery. Blechman dep., 1/30/16, at 8-16, 34-40. In 2016, Dr. Michael Margolis, an expert witness for the Carlinos, performed another examination and found that the mesh remaining on Ms. Carlino's left side was roped, contracted, banded, and could be felt through the vaginal wall. Tr., 1/28 (AM), at 62-72, 85-87. By examining Ms. Carlino, Dr. Margolis confirmed that the remaining sling material shrunk up and rolled on the left side, and the right side had palpable scar tissue, where the sling used to be. Dr. Margolis identified Ms. Carlino's treatment options as (1) a very invasive surgical procedure aimed at removing as much remaining material as possible (though he cautioned that such a surgery would not be successful in removing

all material), (2) treatment that would destroy the nerves of the vagina, or (3) pain medication. ***Id.*** at 85-88. Dr. Margolis concluded to a reasonable degree of medical certainty that Ms. Carlino's symptoms were caused by the TVT. ***Id.*** at 94-98.

As discussed in further detail in our discussion of punitive damages below, the evidence at trial demonstrated that Ethicon knew that the TVT poses a high risk of injury but nevertheless continued to market the product, ignored calls for improvement, and failed to warn physicians of its known and serious risks.

Ethicon requested a directed verdict on the ground that the action was time-barred, but the court denied the motion. The court submitted a special interrogatory to the jury: "Did [Ms.] Carlino know, or should she have known through the exercise of reasonable diligence, before June 26, 2011, that she was injured and that it was caused by the conduct of another person?" Tr., 2/9 (AM), at 87. The jury answered "no."

On February 10, 2016, the jury returned a verdict for the Carlinos on their design defect and failure to warn claims, awarding $3,500,000.00 in compensatory damages (including $250,000.00 for Mr. Carlino's loss of consortium) and $10,000,000.00 in punitive damages. Ethicon filed timely post-trial motions seeking, *inter alia*, judgment n.o.v. on the basis of the statute of limitations. The trial court denied Ethicon's motions and entered judgment for the Carlinos in the amount of $13,738,119.48, including

$238,119.48 in delay damages. All parties filed timely notices of appeal, and all parties and the trial court complied with Pa.R.A.P. 1925. In this Court, Ethicon raises the following issues:

> 1. Did the trial court commit legal error by exercising personal jurisdiction over [Ethicon], even though [Ethicon is neither] incorporated in nor maintain[s] [its] principal places of business in Pennsylvania, and even though [the Carlinos'] claims do not arise from or relate to any of [Ethicon]'s contacts with Pennsylvania?
>
> 2. Did the trial court commit legal error when it denied [Ethicon]'s directed-verdict and JNOV motions, where [the Carlinos'] claims were barred by the statute of limitations and [the Carlinos] did not present legally sufficient evidence that the discovery rule extended the limitations period?
>
> 3. Did the trial court commit reversible error by barring all evidence from the federal Food and Drug Administration (FDA) regarding TVT, an FDA-regulated medical device?
>
> 4. Did the trial court commit reversible error by striking [Ethicon]'s examination of Dr. Andrew Blechman, who performed Mrs. Carlino's surgery, as a sanction for allegedly violating a pretrial evidentiary ruling?
>
> 5. Did the trial court commit reversible error by refusing to instruct the jury that [the Carlinos'] design-defect claim required them to show a safer alternative design to TVT?
>
> 6. Did the trial court err when it refused to remit the compensatory damages award?
>
> 7. Did the trial court err when it denied [Ethicon]'s directed-verdict and JNOV motions as to punitive damages?

Ethicon's Brief at 3-5. The Carlinos raise one issue in their appeal: "Did the trial court improperly mold the jury's verdict to add delay damages based only on the compensatory portion of the verdict?" Carlinos' Brief at 4.

PERSONAL JURISDICTION

Ethicon asserts that the trial court erroneously denied its preliminary objections to the Carlinos' Short Form Complaint, in which Ethicon argued that personal jurisdiction did not exist over Ethicon in Pennsylvania. The Carlinos respond that Ethicon waived this argument, and in any event, the trial court properly exercised specific jurisdiction over Ethicon. Based on our reasoning in ***Hammons v. Ethicon, Inc.***, 190 A.3d 1248, 1259-63 (Pa. Super. 2018), we hold that Ethicon preserved this issue for appeal, and that the trial court properly exercised specific jurisdiction over Ethicon.

One difference between ***Hammons*** and this appeal deserves brief discussion. The appellee in ***Hammons*** argued that Ethicon's retention of Vincent Lucente, M.D., a Pennsylvania gynecologist, was a basis for exercising jurisdiction over Ethicon. ***Id.***, 190 A.3d at 1263-64. The Carlinos did not advance this argument. Nevertheless, the trial court properly exercised jurisdiction over Ethicon based on other facts also discussed in ***Hammons***, *viz.*, Ethicon's substantial role in the production of mesh for the TVT at the Pennsylvania plant of Secant Medical, Inc. ***Id.*** at 1263.

STATUTE OF LIMITATIONS

Ethicon contends that the trial court erred in denying judgment n.o.v. based on the statute of limitations. We disagree. There was conflicting evidence on this subject that we must construe in the light most favorable to the Carlinos. Viewed in this light, the evidence demonstrates that Ms. Carlino

neither knew nor should have known that the TVT caused her injuries until 2013, less than two years before she filed suit.

There are two bases on which the court can grant judgment n.o.v.:

> [O]ne, the movant is entitled to judgment as a matter of law and/or two, the evidence is such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant. With the first, the court reviews the record and concludes that even with all factual inferences decided adverse to the movant[,] the law nonetheless requires a verdict in his favor, whereas the second, the court reviews the evidentiary record and concludes that the evidence was such that a verdict for the movant was beyond peradventure.

Hammons, 190 A.3d at 1265. In an appeal from the trial court's decision to deny judgment n.o.v.,

> we must consider the evidence, together with all favorable inferences drawn therefrom, in a light most favorable to the verdict winner. Our standard of review when considering motions for a directed verdict and judgment notwithstanding the verdict are identical. We will reverse a trial court's grant or denial of a judgment notwithstanding the verdict only when we find an abuse of discretion or an error of law that controlled the outcome of the case. Further, the standard of review for an appellate court is the same as that for a trial court.

Id.

Since Ms. Carlino's treatment and injuries occurred in New Jersey, we first examine whether New Jersey's or Pennsylvania's statute of limitations applies to this case. Pennsylvania law generally governs the time in which the plaintiff must commence an action. ***Unisys Finance Corp. v. U.S. Vision, Inc.***, 630 A.2d 55, 58 (Pa. Super. 1993); ***Gwaltney v. Stone***, 564 A.2d 498, 502 (Pa. Super. 1989). When an action accrues in another state, however,

Pennsylvania applies the other state's limitation period if it is shorter than Pennsylvania's. 42 Pa.C.S.A. § 5521(b).

Ms. Carlino's action accrued in New Jersey, the site of her treatment with the TVT device and her injuries, but New Jersey and Pennsylvania provide the same limitation period (two years) for personal injury actions. N.J.S.A. § 2A:14 -2(a); 42 Pa.C.S.A. § 5524. Moreover, both jurisdictions employ parallel discovery rules that toll the statute of limitations until the plaintiff knows or reasonably should know that she suffered injury due to the fault of another. ***Kendall v. Hoffman-La Roche, Inc.***, 36 A.3d 541, 552 (N.J. 2012); ***Wilson v. El-Daief***, 964 A.2d 354, 356 (Pa. 2009). Since both jurisdictions have the same law, we apply the law of the forum state, Pennsylvania. ***Unisys Finance Corp.***, 630 A.2d at 58.

The Judicial Code provides that limitations periods run from the time the cause of action accrued. 42 Pa.C.S. § 5502(a). Generally, "a cause of action accrues, and thus the applicable limitations period begins to run, when an injury is inflicted." ***Wilson***, 964 A.2d at 361. "Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action." ***Fine v. Checcio***, 870 A.2d 850, 857 (Pa. 2005). The discovery rule is an exception to this rule that tolls the statute of limitations when the plaintiff is reasonably unaware that she has been injured and that her injury has been caused by another party's conduct. ***Fine***, 870 A.2d at 859. A cause of action accrues upon "actual or constructive knowledge

of at least some form of significant harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause." ***Wilson***, 964 A.2d at 364; ***see also id.*** at n.10.

The discovery rule requires the plaintiff to exercise reasonable diligence in investigating the cause of her injuries. ***Id.*** at 363 & n.6. The reasonable diligence standard

> is objective, as the question is not what the plaintiff actually knew of the injury or its cause, but what he might have known by exercising the diligence required by law. That being said, the objective reasonable diligence standard is sufficiently flexible to take into account the differences between persons and their capacity to meet certain situations and the circumstances confronting them at the time in question, and, as such, is to be applied with reference to individual characteristics.
>
> Under this reasonable diligence standard, a plaintiff's actions are examined to determine whether the plaintiff demonstrated those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interest and the interest of others. It is the party that asserts application of the discovery rule that bears the burden of proving that reasonable diligence was exercised. Finally, as noted, because the reasonable diligence determination is fact intensive, the inquiry is ordinarily a question for the jury.

Nicolaou v. Martin, 195 A.3d 880, 893-94 (Pa. 2018) (citations, quotation marks and ellipses omitted).

To satisfy her burden under the discovery rule, Ms. Carlino had to demonstrate that she neither knew nor should have known prior to June 26, 2011 (two years before she filed this action) that the TVT caused her injuries. Viewing the evidence in the light most favorable to Ms. Carlino, as we must

do in our review of an order denying judgment n.o.v., we conclude that Ms. Carlino satisfied her burden.

The evidence demonstrates that on July 19, 2005, Ms. Carlino met with Dr. Blechman and agreed, after discussing the risks and benefits, to undergo surgery for fibroids and pelvic pain with implantation of a TVT for stress incontinence. PTX-61, at 4 (Ms. Carlino's medical records). Dr. Blechman informed Ms. Carlino that **her surgery** involved risks of, *inter alia*, bleeding, infection and possible injuries to adjacent organs. ***Id.*** He also told her that there was no guarantee she would be pain-free after surgery. ***Id.*** On August 18, 2005, Ms. Carlino underwent surgery, and Dr. Blechman inserted the TVT.

One year later, on November 14, 2006, Dr. Blechman conducted a routine checkup and concluded that Ms. Carlino had a normal post-surgical GYN examination and was in no acute distress. ***Id.*** at 21.

After another year passed, on November 12, 2007, Ms. Carlino reported to Dr. Blechman that she felt something sharp in her vagina. ***Id.*** at 24. Dr. Blechman examined Ms. Carlino and found an area of exposed mesh from the TVT. ***Id.*** Dr. Blechman recommended surgical excision of the exposed mesh and discussed the risks of surgery with Ms. Carlino, including, *inter alia*, bleeding, infection and urinary incontinence. ***Id.*** On November 26, 2007, Dr. Blechman performed the surgery.

In a post-surgical examination on December 10, 2007, Dr. Blechman reported that Ms. Carlino was doing "well" and felt "okay other than . . . some

right lower quadrant pain that has been there for several weeks or possibly months that she thought may have been related to the mesh. **I do not believe that it is so**." ***Id.*** at 31 (emphasis added).

On July 20, 2010, Ms. Carlino reported to Dr. Blechman that she felt something sharp in her vagina. ***Id.*** at 34. Dr. Blechman examined Ms. Carlino and referred her to Dr. Conner for further consultation. ***Id.*** On October 26, 2010, Dr. Conner detected an area of mesh exposure and pain in the area of exposure, and she recommended excision and removal. ***Id.*** at 39. On November 23, 2010, Ms. Carlino met with Dr. Conner again and reviewed the risks of **surgery**, including but not limited to erosion of mesh and pain. ***Id.*** Dr. Conner specifically advised that with mesh implantation, complications such as erosion, pain, and infection can occur, may require further surgery and even then may be difficult to address. ***Id.***

On December 17, 2010, Dr. Conner performed a partial removal and revision of the vaginal sling. ***Id.*** at 49. In post-surgical visits on January 11, 2011 and March 30, 2011, Ms. Carlino told Dr. Conner that she was doing well, and that her pelvic pain and dyspareunia (pain during sexual intercourse) had resolved completely. ***Id.*** at 37, 39. On April 26, 2011, however, Ms. Carlino reported to Dr. Conner that she was experiencing pelvic pain and incontinence. ***Id.*** at 50. Due to her previous experience with a synthetic sling, she did not want to undergo another sling procedure. Nearly one year later, on March 19, 2012, Ms. Carlino visited Dr. Blechman and informed him

that she was doing well. ***Id.*** at 54. Dr. Blechman performed an examination and reported that it was normal.

Ms. Carlino's pain returned in late 2012. In April 2013, Ms. Carlino viewed a television advertisement describing her symptoms and relating them to mesh products. She filed suit later that year.

Ethicon makes a spirited argument that the statute of limitations bars Ms. Carlino's action as a matter of law. Specifically, Ethicon asserts that in view of Ms. Carlino's history of pain in 2007 and 2010, the advice her physicians gave her on both occasions that the TVT was causing her pain due to erosion, her decision to have corrective surgery on both occasions, and the recurrence of her discomfort in March 2011, Ms. Carlino knew or should have known before June 26, 2011 that the TVT caused her injuries. These are indeed strong points, but the other evidence described above supports a different conclusion: she reasonably believed her pain was a risk of surgery. Because there was conflicting evidence on this subject, the trial court properly denied Ethicon's motion for judgment n.o.v.

Nicolaou and ***Hammons*** support the conclusion that the statute of limitations issue fell to the jury. In ***Nicolaou***, the plaintiff suffered a tick bite in 2001 and underwent four Lyme disease tests over the next several years. The test results for Lyme disease were negative; instead, she was diagnosed with multiple sclerosis. In 2009, another health practitioner, Nurse Rhoads, suggested that the plaintiff's Lyme disease tests yielded false negatives and

recommended that the plaintiff undergo a different test. At first, the plaintiff declined because she lacked health insurance and could not pay for it out of pocket, but she later agreed to take the test. On February 13, 2010, the test came back positive for Lyme disease. On February 10, 2012, she filed a complaint against various medical providers alleging that they were negligent for failing to diagnose Lyme disease. The trial court granted summary judgment to the providers. Our Supreme Court summarized the trial court's ruling as follows:

> The trial court reasoned that prior to [the plaintiff]'s last visit with Nurse Rhoads on February 1, 2010, [the plaintiff] was aware that her symptoms arose after a tick bite; that a 2006 MRI indicated that she had either MS or Lyme disease; that treatment for MS had been unsuccessful; that Nurse Rhoads believed she probably had Lyme disease based on her clinical symptoms and prior MRI; that Nurse Rhoads treated her for Lyme disease by administering antibiotics, after which [the plaintiff] saw an improvement in her symptoms; and that Nurse Rhoads had urged [the plaintiff] to confirm the diagnosis with a different type of Lyme disease test.
>
> The trial court reasoned that not only would a reasonable person have suspected that [the plaintiff]'s injuries could have been caused by [the providers'] failure to diagnose and treat her Lyme disease, but that [the plaintiff] actually suspected such connection, as demonstrated by her Facebook post, stating that she suspected she had Lyme disease before she received the positive test results. Finally, the trial court rejected the contention that [the plaintiff]'s inability to pay for a fifth Lyme disease test tolled the statute of limitations, finding that [the plaintiff] "could have confirmed her suspicion regarding the Lyme disease diagnosis on or about the December 7, 2009 visit, but she opted not to."

Id., 195 A.3d at 886-87.

Our Supreme Court reversed and remanded for further proceedings, reasoning that genuine issues of material fact prevented the providers from obtaining summary judgment under the statute of limitations:

> [W]e conclude that it is within the province of a jury to determine whether an untrained lay person who had been repeatedly and definitively diagnosed with MS by several previous physicians, had four prior negative Lyme disease tests, and lacked health insurance to cover the costs of further diagnostic testing reasonably should have known that she suffered from Lyme disease after Nurse Rhoads informed her of a "probable" diagnosis of that disease based on her clinical symptoms, and when some of her symptoms improved after taking antibiotics prescribed for that condition. . . . Moreover, it is for the jury, and not a court, to determine whether a person in [the plaintiff's] circumstances acted reasonably in delaying the administration of a fifth Lyme disease test to confirm Nurse Rhoads' probable diagnosis. We reach this conclusion keeping in mind that the appropriate formulation of discovery rule jurisprudence applies a reasonable-diligence requirement, as opposed to an all-vigilance one.

Id. at 895 (quotations and citations omitted).

In a nutshell, despite the evidence pointing to Lyme disease in ***Nicolau***, other evidence precluded judgment as a matter of law by creating a genuine issue of material fact as to whether the plaintiff reasonably should have known that she suffered from Lyme disease more than two years before she filed suit. ***Id.*** Similarly, in the present case, Ms. Carlino's medical records create a genuine issue of material fact as to whether she knew or should have known before June 26, 2011 that the TVT, rather than her surgeries, was the cause of her pain and incontinence.

In ***Hammons***, we affirmed a judgment against Ethicon in a products liability action involving the Prolift device. Ethicon argued that the appellee's

action was time-barred under Indiana's two-year statute of limitations. ***Id.***, 190 A.3d at 1268-69. We rejected this argument because the statute of limitations issue was a "fact-sensitive question" involving the discovery rule that "was proper for the jury to resolve." ***Id.*** at 1269. Prior to the limitations period, we reasoned, "two experienced gynecologists failed to diagnose Prolift as the cause of [Hammons'] injuries. Since they failed to draw a nexus between Prolift and Hammons' injuries, the jury could conclude that it was reasonable for Hammons not to have drawn any connection [herself]." ***Id.*** Analogously, in the case at bar, certain trial testimony indicates that Ms. Carlino's physicians identified the TVT as the cause of Ms. Carlino's problems in 2007 and 2010, but other medical records suggest that these physicians told her that her problems were risks of surgery. Therefore, as in ***Hammons***, the statute of limitations issue was a fact-sensitive question for the jury to decide.

EXCLUSION OF FDA EVIDENCE

Ethicon argues that it is entitled to a new trial because the trial court erroneously excluded (1) evidence that the FDA cleared the TVT in 2008 through its section 510(k) clearance process and (2) an FDA publication in 2013 relating to the safety and efficacy of TVT's. We hold that the trial court properly excluded this evidence.

Evidence of 510(k) clearance. We review challenges to the trial court's evidentiary rulings for an abuse of discretion. ***U.S. Bank, N.A. v.***

Pautenis, 118 A.3d 386, 391–92 (Pa. Super. 2015). "[D]ecisions on admissibility are within the sound discretion of the trial court and will not be overturned absent an abuse of discretion or misapplication of law. In addition, for a ruling on evidence to constitute reversible error, it must have been harmful or prejudicial to the complaining party." ***Id.*** Since there is unanimous agreement among the parties and trial court that New Jersey substantive law governs this case, we will examine whether evidence of 510(k) clearance is admissible under New Jersey law.

In 1987, New Jersey passed the Products Liability Act, L. 1987, c. 197, codified at N.J.S.A. 2A:58C-1 to -11. The purpose of this act was to codify existing common law and provide "some sense of order and clarity to products liability cases within New Jersey." Governor's Statement to S. 2805; accord N.J.S.A. 2A:58C-1; ***see also In re Reglan Litig.***, 226 N.J. 315, 335, 142 A.3d 725 (2016) ("The PLA is a codification of tort-law principles, where the state has traditionally exercised its historic police powers").

Section 4 of this Act, entitled "Adequate product warning or instruction; rebuttable presumption of adequacy after approval," prescribes:

> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. 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, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive **has been approved or prescribed 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., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

N.J.S.A. 2A:58C-4 [emphasis added]. By attaching a presumption of adequacy to FDA-approved warnings, the legislature "recognized the preeminent role of federal regulation of drugs and medical devices." ***Cornett v. Johnson & Johnson***, 211 N.J. 362, 387, 48 A.3d 1041 (2012). The question before us is whether the 510(k) clearance of TVT is admissible under N.J.S.A. 2A:58C-4 as the FDA's "approval" or "prescription" of TVT's warnings.

Some background on the 510(k) process is necessary. The 510(k) review process originates from the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act. The MDA's purpose was to "impose[] a regime of detailed federal oversight" of medical devices. ***Riegel v. Medtronic, Inc.***, 552 U.S. 312, 316 (2008). Under the MDA, certain devices must complete a thorough premarket approval ("PMA") process with the FDA before marketing, including all devices that cannot "provide reasonable assurance of [their] safety and effectiveness" under less stringent scrutiny, and that are "purported or represented to be for a use in

supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[] a potential unreasonable risk of illness or injury." ***Id.*** at 317; 21 U.S.C. § 360c(a)(1)(C). The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." ***Buckman Co. v. Plaintiffs' Legal Comm.***, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360e(d)(2)(A), (B)).

An exception to the PMA requirement exists for medical devices that were already on the market prior to the MDA's enactment in 1976. These devices are allowed to remain on the market until the FDA initiates and completes PMA review for them. ***See*** 21 U.S.C. § 360e(b)(1)(A); ***Buckman***, 531 U.S. at 345. In addition, to neutralize any monopolistic power that this exception might give manufacturers of pre-1976 devices, the MDA allows other manufacturers to market devices that are "substantially equivalent" to exempt pre–1976 devices. ***Id.***; 21 U.S.C. § 360e(b)(1)(B). The 510(k) process is the method by which a manufacturer demonstrates substantial equivalence. ***Id.***

The Safe Medical Devices Act of 1990 ("SMDA") further clarified the 510(k) process by codifying the definition of substantial equivalence that the FDA developed administratively following the MDA's enactment. 21 U.S.C. § 360c(i). In addition, the SMDA ended the legal necessity to cite a pre-MDA

predicate device. Thus, devices cleared after the MDA's enactment could be used as predicates without construction of a clearance chain back to a pre-MDA predicate device. 21 U.S.C. § 360c(f).

"The § 510(k) process is focused on equivalence, not safety." ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 492 (1996). The design of the device does not undergo review during the 510(k) process for safety or efficacy. ***Id.*** at 493. "Substantial equivalence determinations provide little protection to the public," because they "simply compare a post–1976 device to a pre–1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective." ***Id.***

The 510(k) process is cursory when compared to strenuous PMA review. "In contrast to the 1,200 hours necessary to complete a PMA review," 510(k) review "is completed in an average of only 20 hours." ***Id.*** at 497. "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." ***Id.*** at 479; ***see also Riegel v. Medtronic, Inc.***, 552 U.S. 312, 323 (2008) ("[w]hile § 510(k) is focused on equivalence, not safety, premarket approval is focused on safety, not equivalence").

Because 510(k) does not focus on safety, many courts have refused to admit evidence of 510(k) clearance in product liability cases. For example, in

Kaiser v. Johnson & Johnson, 2018 WL 1358407 (N.D. In. 2018), an action brought against Ethicon under Indiana law, Ethicon attempted to introduce evidence of 510(k) proceedings for the Prolift device. The Indiana Product Liability Act ("ILPA") provides that "in a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective . . . when [the product] complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States . . . or by an agency of the United States." Indiana Code § 34-20-5-1(2). The court held that "[b]ecause § 510(k) is focused on equivalency and not safety, it is not relevant to the application of the presumption in this case and does not mandate its application." ***Id.*** at *3. This decision was consistent with rulings by multiple other courts, including courts in states with rebuttable presumptions similar to Indiana's. ***Id.*** (citing ***Eghnayem v. Boston Scientific Corp.***, 873 F.3d 1304, 1317-19 (11th Cir. 2017) (applying Florida law); ***Tingey v. Radionics***, 193 Fed. Appx. 747, 755 (10th Cir. 2006) (applying Utah law); ***Adams v. Boston Scientific Corp.***, 177 F. Supp. 3d 959 (S.D. W. Va. 2016) (applying Texas law); ***Williams v. Boston Scientific Corp.***, 2016 WL 1448860, at *3 (S.D. W. Va. 2016) (applying Wisconsin law); ***Lewis v. Johnson & Johnson***, 991 F. Supp. 2d 748, 761 (S.D. W. Va. 2014) (applying Texas law)).

The Fourth Circuit's analysis of the 510(k) process in two recent decisions—***Cisson v. C.R. Bard, Inc. (In re C.R. Bard, Inc.)***, 810 F.3d 913

(4th Cir. 2016), and ***Huskey v. Ethicon, Inc.***, 848 F.3d 151 (4th Cir. 2017)—deserves our attention as well. In ***Bard***, the Fourth Circuit held that the district court properly permitted the plaintiff to attack the product's safety while precluding the defendant from presenting evidence that it complied with the 510(k) process. The court reasoned that evidence of the 510(k) process had limited probative value, because while safety considerations might have some tangential bearing on the 510(k) process, by far its main thrust is to determine only whether the product is substantially equivalent to pre-1976 products. ***Id.***, 810 F.3d at 921. The court also observed that this evidence was substantially more prejudicial than probative:

> [T]he court stated that bringing in such evidence would result in a "mini-trial" about (1) the strengths and weaknesses of the process and (2) whether [the defendant] had in fact made all of the disclosures it should have made during the process. [The defendant's] evidence would have initiated a battle of experts: [the defendant] was prepared to characterize the review process as "thorough" and "robust" and the FDA's clearance of the Avaulta Plus as "an affirmative safety . . . decision" based on "specific safety and efficacy findings." [The plaintiff] was prepared to argue, as she has done before this Court, that these characterizations wildly inflate the significance of the process, and that in any event [the defendant] failed to make necessary disclosures to the FDA.
>
> All of this, the district court reasoned, presented "the very substantial dangers of misleading the jury and confusing the issues." The court expressed concern that subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a "mini-trial" could easily inflate the perceived importance of compliance and distract the jury from the central question before it—whether [the defendant's] design was unreasonable based on any dangers it posed versus the costs required to avoid

> them. While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several *amici*, we say so again today.

Id. at 921-22.

In ***Huskey***, another case against Ethicon, Ethicon argued that the district court abused its discretion in excluding evidence of the TVT's compliance with the 510(k) process. The Fourth Circuit held that the district court's ruling was within its discretion, explaining:

> [w]e see no reason to distinguish [***Bard***] here. The information Ethicon sought to introduce would, at best, have had "tangential[]" relevance to the case. This relative lack of probative value, especially given a possible battle of experts over the 510(k) process, underscores the risks of confusion and wasted time that would follow the introduction of this evidence. Ethicon's effort to distinguish [***Bard***] on the ground that the [TVT's] 510(k) compliance process actually did focus heavily on safety would only amplify the risk, as the trial would then likely face a substantial diversion into just how rigorous those safety considerations were, how forthcoming Ethicon was to the FDA, and how robust the 510(k) process is.

Id., 848 F.3d at 160-61.

Returning to the present case, the FDA groups medical devices into three classes (I, II, and III), and exercises the most strenuous regulatory oversight over Class III devices. The FDA originally classified Prolene suture in Class III but reclassified it into Class II in 1990. The FDA also classified polymeric meshes, the umbrella category for the TVT, within Class II. In 1997, Ethicon submitted a 510(k) application asserting that the TVT consisted of the same polypropylene strands that are used to fabricate Prolene's sutures. In

1998, the FDA cleared the TVT as a Class II device under 510(k). Ethicon moved for admission of the TVT's 510(k) clearance into evidence, but the trial court denied the motion.

This decision was a proper exercise of the trial court's discretion. N.J.S.A. 2A:58C-4 provides that a rebuttable presumption arises that a product's warning or instruction is adequate if the FDA has "approved or prescribed" it. The Products Liability Act does not define these terms, but when, as here, "the average person would understand the words used in a statute . . . the terms used in the provision will carry their ordinary, well-understood meanings . . . To ascertain the ordinary meaning of words used in a statute, courts typically look to a dictionary." ***State v. N.G.***, 886 A.2d 186, 191 (N.J. Super. A.D. 2005). The definition of "approve" is "to accept as satisfactory" or "to give formal or official sanction: ratify." Merriam-Webster Dictionary (2009). The definition of "prescribe" is "to lay down as a guide, direction, or rule of action." ***Id.*** During the 510(k) clearance process, the FDA does not "accept" a warning "as satisfactory" or "lay down" a warning as a "guide, direction or course of action." ***Id.*** The FDA merely determines whether the warning is substantially equivalent to other warnings. ***Huskey***, 848 F.3d at 160-61; ***Bard***, 810 F.3d at 921; ***Kaiser***, 2018 WL 1358407, at *3. Such clearance does not constitute the FDA's "approval" or "prescription" of a warning or instruction. Moreover, the foregoing decisions persuade us that the 510(k) process is, at most, marginally relevant to whether the TVT is

safe, and any excursion into this subject would have needlessly prolonged an already lengthy trial and posed considerable risk of confusing the jury.

FDA's 2013 publication. The trial court denied Ethicon's motion to introduce Dr. Denise Elser, an expert witness on urogynecology, to testify about a 2013 FDA publication entitled "Considerations about Surgical Mesh for SUI."[4] Court Exhibit 3. In pertinent part, the publication stated:

> Mesh sling procedures are currently the most common type of surgery performed to correct SUI. Based on industry estimates, there were approximately 250,000 of these procedures performed in 2010.
>
> While all surgeries for SUI carry some risks, it is important for you to understand the unique risks and benefits for surgical mesh slings used in SUI repair.
>
> In order to better understand the use of surgical mesh slings for SUI and evaluate their safety and effectiveness, the FDA held a panel meeting of scientific experts (Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee) in September 2011 and conducted a systematic review of the published scientific literature from 1996 to 2011. For surgical mesh slings used for SUI, both the panel and the FDA's review found that:
>
> - The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one year. **Longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up.**
>
> . . .

[4] The trial court also excluded other FDA publications issued in 2011 and 2012, but because Ethicon does not object in this Court to the exclusion of these publications, we have no need to address them.

- Mesh sling surgeries for SUI have been reported to be successful in approximately 70 to 80 percent of women at one year, based on women's reports and physical exams. Similar effectiveness outcomes are reported following non-mesh SUI surgeries.

- The use of mesh slings in transvaginal SUI repair introduces a risk not present in traditional non-mesh surgery for SUI repair, which is mesh erosion, also known as extrusion.

- Erosion of mesh slings through the vagina is the most commonly reported mesh-specific complication from SUI surgeries with mesh. The average reported rate of mesh erosion at one year following SUI surgery with mesh is approximately 2 percent. Mesh erosion is sometimes treated successfully with vaginal cream or an office procedure where the exposed piece of mesh is cut. In some cases of mesh erosion, it may be necessary to return to the operating room to remove part or all of the mesh.

- **The long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA.**

- The complications associated with the use of surgical mesh slings currently on the market for SUI repair are not linked to a single brand of mesh.

The FDA conducted a review of Medical Device Reports (MDRs) received from Jan. 1, 2008 through Sept. 30, 2011. During this time frame the FDA received 1,876 reports of complications associated with surgical mesh devices used to repair SUI.

The most common complications reported through MDRs for surgical mesh slings for SUI repair, in descending order of frequency, include: pain, mesh erosion through the vagina (also called exposure, extrusion or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-muscular problems and vaginal scarring. Many of these complications require additional medical intervention, and sometimes require surgical treatment and/or hospitalization. With the exception of

> mesh erosion, the above complications can occur following a non-mesh surgical repair for SUI.

Id. (emphasis added). We conclude that the trial court properly excluded this publication from evidence, albeit for reasons different from those expressed by the trial court. ***See Zehner v. Zehner***, 195 A.3d 574, 581 n.12 (Pa. Super. 2018) (appellate court can affirm trial court's ruling on any basis).

Ethicon highlights the publication's statement that the FDA considered multi-incision slings, including TVT's, safe for seventy to eighty percent of patients within one year after SUI surgery. This was not relevant to Ms. Carlino's action. Her problems began close to two years after her initial surgery, and the essence of her case was that the TVT was defective due to its long-term effects, particularly long-term mesh erosion.

Two sentences in the publication touched upon long-term performance, but both were too vague to have probative value. The first sentence stated that "longer follow-up data is available in the literature, but there are fewer of these long-term studies compared to studies with one-year follow-up." Court Exhibit 13. What made up this "literature" and "data," and what these items concluded about the TVT's long-term performance, was anyone's guess. The second sentence stated, "The long-term complications of surgical mesh sling repair for SUI that are reported in the literature are consistent with the adverse events reported to the FDA," ***id.***, such as pain, mesh erosion, urinary problems, incontinence and other symptoms. The publication did not, however, identify the pertinent "literature" or the percentage of cases in which

long-term complications occur. Even assuming these passages had marginal relevance, their probative value was vastly outweighed by the risks of jury confusion and time consumed by experts skirmishing over what the FDA meant by the terms "literature" and "data" and whether the investigation underlying the publication was sufficiently robust. ***See also Bard***, 810 F.3d at 921-22 (subjecting jury to hours or days of complex testimony about regulatory investigation could lead jurors to erroneously infer the product was safe).

DR. BLECHMAN'S TESTIMONY

The next issue involves the effect that the court's order precluding the FDA evidence discussed above had on Dr. Blechman's second deposition in this case.

To elaborate, the parties initially took Dr. Blechman's deposition on June 30, 2015, seven months before trial. DTX-129 (excerpts from June 30, 2015 deposition). In January 2016, shortly before trial, the trial court entered an order precluding Ethicon from entering the aforementioned FDA evidence. On January 30, 2016, in the middle of trial, the parties took Dr. Blechman's second deposition via videotape, intending to play it for the jury.

On February 2, 2016, the Carlinos moved for sanctions on the ground that Ethicon's counsel (1) asked questions during the January 30, 2016 deposition that violated the order precluding FDA evidence and (2) used these questions to dupe Dr. Blechman into changing his testimony. On February 5,

2016, the trial court granted the Carlinos' motion and precluded Ethicon "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 [c]ourt's [o]rder [excluding FDA evidence]." The trial court also precluded the Carlinos from introducing Dr. Blechman's re-direct examination.

Ethicon contends that the trial court abused its discretion not only because the sanction imposed precluded testimony on the FDA evidence, but also because the sanction precluded it from introducing three other portions of Dr. Blechman's testimony unrelated to the FDA evidence. Ethicon argues preclusion of this testimony entitles it to a new trial. We conclude no relief is due.

During the January 30, 2016 deposition, Dr. Blechman testified on direct examination that had he known in 2005 what he now knows about the TVT's potential adverse effects, he would not have recommended it for Ms. Carlino or any other patient. PTX-60, Blechman dep., at 54, 59.

On cross-examination, the following took place:

> [COUNSEL FOR ETHICON]: Okay. Do you know that the FDA cleared the TVT device to be put on the market in 1998?
>
> [COUNSEL FOR THE CARLINOS]: Object. We have a motion *in limine* that was granted excluding . . . what the FDA did or didn't do.
>
> [COUNSEL FOR ETHICON]: I'm just trying to put things in perspective . . . [Y]our objection is preserved and it can be continued for these questions.

> [COUNSEL FOR THE CARLINOS]: It also misstates the facts.
>
> BY [COUNSEL FOR ETHICON]:
>
> Q. Do you know that the TVT was cleared by the FDA? Do you understand that, Dr. Blechman?
>
> A. I understand that it was cleared by the FDA.
>
> Q. Do you know that the FDA has continuously studied it ever since?
>
> [COUNSEL FOR THE CARLINOS]: No . . . that's a false statement. You know, it's not admissible because the [c]ourt has ruled it's not admissible. So these questions are only designed to educate the witness, to get him to change his mind about his prior testimony. It's just flagrantly abusive and I'm sure when the judge sees this, he'll be very unhappy.
>
> BY [COUNSEL FOR ETHICON]:
>
> Q. Dr. Blechman, you can just answer questions unless your lawyer tells you not to –
>
> A. Okay.
>
> Q. -- and ignore attorney talk. All right?
>
> A. Okay.
>
> Q. Do you know that the TVT has been evaluated by the FDA on an ongoing basis?
>
> [COUNSEL FOR THE CARLINOS]: Okay. Now I'm going to give counsel notice that we're going to seek sanctions for this conduct. And with each time this question is asked, the sanctions request is going to be ratcheted upward.

Id. at 65-67. Subsequently, Ethicon's counsel asked, "[B]ased on all the information that you have received today, including the documents I provided, looking back in time, if you had all of that information in 2005, would you have

recommended the use of TVT for your patients?" ***Id.*** at 169-70. Dr. Blechman answered, "Yes." ***Id.*** at 170. Counsel then asked, "Putting yourself back in 2005, but based on the knowledge that you have today, do you still agree that TVT was a safe and effective treatment for stress urinary incontinence in women?" ***Id.*** at 171. Dr. Blechman answered, "Yes." ***Id.***

The trial court determined that Ethicon's counsel violated its order precluding FDA evidence, and that the appropriate sanction was to preclude Ethicon from introducing its entire cross-examination and recross-examination of Dr. Blechman. Trial Ct. Op., 1/3/17, at 34-35. The court explained:

> The effect, and the seeming purpose, of [Ethicon's] counsel's question was to confuse Dr. Blechman and cause him to pivot his testimony so that it would be less favorable to the [Carlinos]. [Counsel] 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?" . . . .
>
> [Ethicon's counsel] 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 Carlinos]. That is why the metaphor of poison is appropriate here: [Ethicon's counsel] 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 [c]ourt had to take action.

Id.

As a result of Ethicon interjecting the FDA evidence into its questioning of Dr. Blechman in direct violation of the trial court's pre-trial order, Dr. Blechman changed his testimony from what he said on direct examination earlier that day. On direct examination, he testified that based on what he now knew, he would not have recommended the TVT to Ms. Carlino or other patients. PTX-60 at 54, 59. On cross-examination, after Ethicon's counsel's improper questions suggesting that the FDA "cleared" the TVT, Dr. Blechman changed his testimony to state that had he known all of the information, "including the documents [Ethicon's counsel] provided today," he would have recommended the TVT to his patients. ***Id.*** at 169-70. Further, he now testified that the TVT was a safe and effective treatment for SUI. ***Id.*** at 171. We agree with the trial court that Ethicon's counsel caused this "pivot" in Dr. Blechman's position by misleading him to believe that the FDA had approved the TVT. Trial Ct. Op. at 34-35. The trial court properly excluded this cross-examination testimony.

Ethicon argues next that the second and third excerpts excluded by the sanction precluding Ethicon from introducing any portion of the cross-examination and recross-examination of Dr. Blechman, were necessary to refute the Carlinos' claim that Ethicon failed to warn Dr. Blechman about the severity of the TVT's risks. In reality, Ethicon contends, Dr. Blechman testified on cross-examination that he knew by 2005 that "the risk of dyspareunia . . . could be permanent" and "severe," and he "did not need a company like Ethicon to tell [him] that dyspareunia and pelvic pain were recognized complications" of a TVT, or that "there would be a chronic foreign body response" to a TVT. PTX-60 at 91:2-92:3, 126:3-127:15. This argument has some appeal. The court's decision to exclude **all** of Dr. Blechman's cross- and recross examination testimony was overbroad. A more appropriate sanction for Ethicon's violation of the order excluding FDA evidence would have been to surgically excise testimony that was attributable to Ethicon's violation while admitting the rest into evidence. The testimony in question should have been admitted because it did not relate to, and was not induced by, Ethicon's improper questions about FDA "clearance" of the TVT. Nevertheless, the exclusion of this testimony was harmless error, because Ethicon was able to present other testimony on the same subject. Specifically, Dr. Blechman gave similar testimony during his first deposition on July 30, 2015 that Ethicon played to the jury on February 3, 2016. DTX-129, at 188-90 (Dr. Blechman knew in 2005 that the TVT's risks included dyspareunia and inflammation, and

that there were no time limits on when these complications could develop). Thus, Ethicon cannot obtain a new trial due to its inability to demonstrate prejudice. ***Rittenhouse v. Hanks***, 777 A.2d 1113, 1118-19 (Pa. Super. 2001) (in medical malpractice action by patient's estate against physician and hospital, after patient died from liver injury allegedly caused by Eulexin, a medication used to treat prostate cancer, physician and hospital were not prejudiced by exclusion of reading of listing in Physician's Desk Reference (PDR) for medication and rarity of side effect of liver damage from Eulexin, because entire PDR listing for Eulexin had been admitted into evidence and estate's witnesses had already discussed information contained therein); ***Peled v. Meridian Bank***, 710 A.2d 620, 626 (Pa. Super. 1998) (exclusion of records of bank that issued irrevocable letter of credit, in breach of contract action against advising bank, was harmless error, since similar documents were admitted that conveyed essentially the same information).

Finally, Ethicon claims that the trial court erred by precluding a fourth excerpt, Dr. Blechman's cross-examination testimony that vaginal atrophy was the cause of Ms. Carlino's dyspareunia in 2015 instead of the TVT. Once again, assuming the court committed error, it was harmless in nature because Ethicon was able to present evidence of vaginal atrophy at other points during trial. ***Rittenhouse***, ***Peled***, ***supra***. For example, Dr. Elser, Ethicon's expert, provided testimony that Ms. Carlino's medical records from her 2015 examination and previous years demonstrated vaginal atrophy. Tr., 2/5 (AM),

at 99-100, 109-11. This testimony enabled Ethicon to argue in its closing that vaginal atrophy caused Ms. Carlino's dyspareunia in 2015 instead of the TVT. Tr., 2/9 (PM), at 51-53. Thus, Ethicon cannot obtain relief due to lack of prejudice. ***Rittenhouse***, ***Peled***, ***supra***.

For these reasons, the trial court's order precluding Dr. Blechman's cross- and recross-examination testimony does not warrant a new trial.

JURY INSTRUCTION ON DESIGN DEFECT

Ethicon posits that the Carlinos' design defect claim required them to prove that a safer, feasible alternative design existed for the TVT. The trial court, Ethicon maintains, erred by instructing the jury that proof of a reasonable safer alternative design was optional instead of mandatory. We conclude that the court's instruction was correct. As we did above, we apply New Jersey law to this question of substantive law.

"[W]hen a court instructs the jury, the objective is to explain to the jury how it should approach its task and the factors it should consider in reaching its verdict." ***Tincher v. Omega Flex, Inc.***, 104 A.3d 328, 351 (Pa. 2014). The court has broad discretion in its choice of language provided that the instruction fully and adequately conveys the applicable law. ***Id.*** A new trial is warranted only "if an erroneous jury instruction amounted to a fundamental error or the record is insufficient to determine whether the error affected the verdict." ***Id.***

Under New Jersey law, a plaintiff in a design defect action generally must provide evidence of a safe and reasonable feasible alternative design. ***Smith v. Keller Ladder Co.***, 645 A.2d 1269, 1271 (N.J. App. Div. 1994) (risk-utility analysis "ordinarily involves the consideration of available alternatives"). ***Smith*** teaches:

> The determination whether a product has been defectively designed ordinarily involves a "risk-utility analysis," under which a manufacturer is held liable only "if the danger posed by the product outweighs the benefits of the way the product was designed and marketed." There are seven factors which the Court has identified as being relevant to a risk-utility analysis:
>
> 1. The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> 2. The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
>
> 3. The availability of a substitute product [that] would meet the need and not be as unsafe.
>
> 4. The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> 5. The user's ability to avoid danger by the exercise of care in the use of the product.
>
> 6. The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product or of the existence of suitable warnings or instructions.
>
> 7. The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Id. at 1270-71. ***Smith*** goes on to state that "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." ***Id.*** at 1271 (citing N.J.S.A. 2A:58C-3(a)(1) ("A manufacturer may not be held liable in a design-defect product liability action "if ... [a]t the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product")). Further, citing the Restatement (Third) of Torts, § 2(b), ***Smith*** instructs: "A product is defective in design when the foreseeable risks of harm posed by the product could have been reduced by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe . . ." ***Id.***

Here, the trial court instructed the jury:

> The plaintiff is also required to prove the existence in August 2005 of a reasonably feasible alternate design unless the risk[s] involved in the TVT's use outweigh its utility even though there is no reasonably feasible . . . alternative design. A design defect exists if the foreseeable risk of harm posed by the TVT could have been reduced or avoided by the adoption of a reasonable safer design and the omission of the alternate design renders the product not reasonably safe.
>
> You are to decide whether the safety benefits from altering the design as proposed by plaintiff were greater than the resulting cost or disadvantage caused by the proposed design, including

> any diminished usefulness or diminished safety. If the failure to incorporate a practical and technically feasible safer alternate design made the TVT not reasonably safe, then the TVT was designed in a defective . . . manner . . . If, on the other hand, plaintiff has not proven there existed a practical and technically feasible safer alternative or if you find that the TVT as designed was reasonably safe, then the product was not designed in a defective manner.

Tr., 2/9 (AM), at 55-56. The first paragraph of these instructions is substantively identical to the test articulated in ***Smith***. ***See id.*** at 1271. The second paragraph of instructions is entirely consistent with the risk-utility analysis defined in ***Smith***. ***Id.*** at 1270-71. The jury instruction correctly described the operative standards under New Jersey law.

We note that the Carlinos introduced evidence that reasonably feasible alternatives to the TVT design were available in 2005. Dr. Klinge testified that Ethicon could have used either (1) macroporous Ultrapro or Vypro as the mesh in the TVT; (2) a different polymer; or (3) the different technique of laser-cutting mesh. The Carlinos' counsel fairly argued this evidence to the jury in closing argument. Tr., 2/9 (AM), at 107-12; Tr., 2/9 (PM), at 59-69.

Accordingly, Ethicon's objection to the jury instruction on design defect is devoid of merit.

AMOUNT OF COMPENSATORY DAMAGES

Ethicon argues that the trial court abused its discretion by denying Ethicon's post-trial motion for remittitur of the compensatory damage verdict of $3.5 million. The trial court upheld the verdict based on Ms. Carlino's chronic pain, inability to have sex and emotional harm from the physical pain,

and the effect her injury has had on her marriage. Trial Ct. Op. at 50-51. We conclude that the trial court acted within its discretion.

While New Jersey law prescribes what items of compensatory damage are available, Pennsylvania law governs the procedural issue of remittitur. Remittitur is the "procedural [process] by which an excessive verdict of the jury is reduced." ***Hammons***, 190 A.3d at 1285. Pennsylvania applies its own procedural laws when it is serving as the forum state. ***Id.***

As we observed in ***Hammons***,

> [u]nder Pennsylvania law, the decision to grant a remittitur depends on whether the award of compensatory damages lies beyond "the uncertain limits of fair and reasonable compensation" or whether the verdict "so shocks the conscience as to suggest that the jury was influenced by partiality, prejudice, mistake, or corruption." ***Potochnick v. Perry***, 861 A.2d 277, 285 (Pa. Super. 2004). This standard is highly deferential, because the trial judge serves not as finder of fact but as impartial courtroom authority with obligation to give great respect to the jury's function. ***Ferrer v. Trustees of Univ. of Pennsylvania***, [] 825 A.2d 591, 611 ([Pa.] 2002). If the compensatory award is excessive, any remittitur must fix "the highest amount any jury could properly award." ***Neal v. Bavarian Motors***, 882 A.2d 1022, 1028 (Pa. Super. 2005). That amount "must necessarily be as high—and may well be higher—than the level the court would have deemed appropriate if working on a clean slate." ***Id.*** This Court is not free to substitute its judgment for that of the fact finder. "Rather, it is our task to determine whether the lower court committed a 'clear' or 'gross' abuse of discretion when conducting its initial evaluation of a defendant's request for remittitur." ***Dubose v. Quinlan***, 125 A.3d 1231, 1244 (Pa. Super. 2015) (citation omitted).

Id. at 1285-86. Moreover,

> [e]ach personal injury case "is unique and dependent on its own special circumstances." ***Kemp v. Philadelphia Transportation Co.***, [] 361 A.2d 362, 364 ([Pa. Super.] 1976). Thus, noneconomic loss must be measured by experience rather than

> any mathematical formula. ***Martin v. Soblotney***, [] 466 A.2d 1022, 1025 ([Pa.] 1983) ("it is immediately apparent that there is no logical or experiential correlation between the monetary value of medical services required to treat a given injury and the quantum of pain and suffering endured as a result of that injury"). For this reason, the law entrusts jurors, as the impartial acting voice of the community, to quantify noneconomic loss and compensation. ***Nelson v. Airco Welders Supply***, 107 A.3d 146, 161 (Pa. Super. 2014).

Id. at 1286.

The trial court instructed the jury in detail that Ms. Carlino sought compensation for past and future pain, suffering, disability, impairment, and loss of enjoyment of life, and Mr. Carlino sought compensation for loss of consortium. Tr., 2/9 (AM), at 66-70, 73. The court also stated that if the jury determined that Ms. Carlino was entitled to damages for future pain and suffering, her life expectancy today was 27 years. ***Id.*** at 70. Ethicon did not object to these instructions.

The evidence permitted the jury to conclude that Ms. Carlino has suffered severe pain in her pelvic region since late 2012. Tr., 1/29 (PM), at 20-21; Tr., 1/27 (AM), at 106. She still has more than 80% of the mesh inside her and suffers significant pain at the site of the implant. Dr. Blechman, Dr. Margolis, and Ethicon's expert Dr. Elser confirmed her symptoms through examination. They testified that she has a recurring throbbing sensation where mesh was excised. She also has developed "pulling" across her right leg and pain, and her incontinence has worsened. Tr., 1/28 (AM), at 26-29, 60-87; Blechman dep., 1/30, at 8-16, 34-40. Her pain is irreversible and will

last the rest of her life, which is expected to be 27 more years, and she will never again be able to have normal sexual relations with her husband. She avoids intercourse with her husband because of her dyspareunia, and when they have sex, it only lasts seconds, causing embarrassment and humiliation. Her pain and sexual dysfunction have become a recurring topic of conversation between her and her husband. Tr., 1/27 (AM), at 103-12, 118-19; Tr., 1/28 (AM), at 64-72; Tr., 1/29 (PM), at 20-21. Her condition carries a lifelong risk of future surgeries if the TVT becomes exposed in the vagina again. Tr., 1/28 (AM), at 36-44. Collectively, this evidence demonstrates Ms. Carlino suffered considerable physical disfigurement, pain, suffering, embarrassment, and loss of life's pleasures, and she will continue to suffer these injuries for the remainder of her life. The court acted within its discretion under these circumstances by determining that the verdict did not shock its conscience.

As it did in ***Hammons***, Ethicon asks us to remit the verdict by comparing Ms. Carlino's damages with the plaintiffs' injuries in ***Smalls v. Pittsburgh–Corning Corp.***, 843 A.2d 410 (Pa. Super. 2004), and ***Hartner v. Home Depot USA, Inc.***, 836 A.2d 924 (Pa. Super. 2003). In ***Smalls***, an action against a manufacturer for asbestos exposure, we remitted a $2 million verdict for pain and suffering because the evidence demonstrated only that a sedentary, seventy-four-year-old man with a twenty-year smoking habit and additional diseases unrelated to asbestos exposure (cirrhosis, chronic obstruction pulmonary disease, anemia, abdominal and colon conditions, and

previously contracted pneumonia) became winded after moderate exercise and no longer was as active around the house as he once was. ***Id.***, 843 A.2d at 417. In ***Hartner***, we remitted a $1 million verdict where the plaintiff sustained a knee injury and undertook physical therapy but had no stiffness or swelling during examination and used the gym three or four days a week. She did not seek employer accommodations nor was there indication of necessity for ongoing treatment. ***Id.***, 836 A.2d at 930. The evidence demonstrates that Ms. Carlino has suffered, and will continue to suffer for another 27 years, considerably more physical and emotional trauma from the TVT than the plaintiff in ***Smalls*** suffered from asbestos exposure or the plaintiff in ***Hartner*** suffered from her knee injury.

Ethicon complains that the Carlinos "made no effort to quantify the severity or duration of damage[s] through evidence that she had been diagnosed with or treated for any emotional condition." Ethicon's Brief at 53. The evidence permitted the jury to conclude that Ms. Carlino suffers from a life-long condition accompanied by severe pain, suffering, loss of life's pleasures and embarrassment. Moreover, the law does not allow her to "quantify" her injuries. To the contrary, the law specifically prohibits counsel from "estimating or suggesting to a jury the amount of damages to be awarded, especially for pain and suffering in a personal injury case." ***Clark v. Philadelphia College of Osteopathic Medicine***, 693 A.2d 202, 206 (Pa. Super. 1997). "The verdict in an action of tort should be a deduction drawn

by the jury from the evidence." ***Nelson v. Airco Welders Supply***, 107 A.3d 146, 162 (Pa. Super. 2014) (granting new trial on damages because counsel suggested formula for calculating noneconomic damages).

PUNITIVE DAMAGES

Ethicon seeks judgment n.o.v. on the punitive damage verdict on several grounds. We hold that the trial court properly denied judgment n.o.v.

There are two bases on which the court can grant judgment n.o.v.:

> [O]ne, the movant is entitled to judgment as a matter of law and/or two, the evidence is such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant. With the first, the court reviews the record and concludes that even with all factual inferences decided adverse to the movant[,] the law nonetheless requires a verdict in his favor, whereas the second, the court reviews the evidentiary record and concludes that the evidence was such that a verdict for the movant was beyond peradventure.

Hammons, 190 A.3d at 1265. In an appeal from the trial court's decision to deny judgment n.o.v.,

> we must consider the evidence, together with all favorable inferences drawn therefrom, in a light most favorable to the verdict winner. Our standard of review when considering motions for a directed verdict and judgment notwithstanding the verdict are identical. We will reverse a trial court's grant or denial of a judgment notwithstanding the verdict only when we find an abuse of discretion or an error of law that controlled the outcome of the case. Further, the standard of review for an appellate court is the same as that for a trial court.

Id. (citation omitted).

New Jersey allows punitive damages if the plaintiff demonstrates that the defendant acted with "wanton and willful disregard" of her rights and that

these acts caused her injuries. N.J. Stat. § 2A:15–5.12(a). Wanton and willful disregard is "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. Stat. § 2A:15–5.10. The standard of proof is "clear and convincing evidence." N.J. Stat. § 2A:15–5.12(a). The jury may consider all evidence relevant to the defendant's misconduct and the plaintiff's injuries, such as:

> (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. Stat. § 2A:15–5.12(b).

When a plaintiff contends that a defectively designed medical device caused her injuries, the question of punitive damages "may turn on whether the manufacturer wantonly disregarded a high probability that injury would occur once the defect manifested itself in the situation that the plaintiff encountered." ***Zakrocki v. Ford Motor Co.***, 2009 WL 2243986 (N.J. Super. App. Div. July 29, 2009). When a plaintiff asserts that a failure to warn caused her injuries, punitive damages are appropriate "where the manufacturer knew of the dangers created by its product and failed to warn users of serious health

hazards." ***Gross v. Gynecare***, 2016 WL 1192556, at *26 (N.J. Super. App. Div. 2016), certification denied, 228 N.J. 430, 157 A.3d 847 (2016).

The Carlinos presented the testimony of experts Bruce Rosenzweig, M.D. and Uwe Klinge, M.D. to establish that the TVT is defective because it poses a high risk of catastrophic injury to patients and that Ethicon sold the TVT without adequate warnings. The testimony of Ethicon's medical director, Piet Hinoul, M.D., corroborated the same points. These witnesses testified that using mesh in transvaginal implantation created a high risk of injury. One piece of mesh is constructed from 80 feet of suture material knitted together so that it is heavy and thick. At the same time, the mesh has pores that are too small to allow the body to heal properly around and through mesh. The TVT mesh frays and sheds plastic particles because Ethicon used a machine to cut the mesh into the TVT's precise shape. The implantation procedure and subsequent normal activities put tension on the mesh and collapsed its pore structure. Transvaginal implantation increases the rates of TVT degradation and of infection relative to other locations in the body, in light of the higher amount of bacteria and the oxidation processes that occur in the vagina. Hinoul admitted that Ethicon knew about these risks at the time it launched the TVT. PTX-19, Hinoul dep. (1/13/14), at 551-55, 773-79, 807, 917-20, 1045-50, 1106-26; PTX-19, Hinoul dep. (1/15/14), at 1717-31; PTX-30, Klinge dep. (11/4/15), at 16-114, 263-64; PTX-1, Rosenzweig dep. (12/22/15), at 72-204; PTX-42, Weisberg dep. (5/31/13), at 460-74.

Dr. Rosenzweig acknowledged that temporary inflammatory reaction and scar tissue formation is normal with any surgery. But as he explained, the weight, thickness, and degradation of the TVT trigger a harmful permanent cycle of severe inflammatory reaction and scar tissue formation. Because the pores of the mesh are small, tissue does not grow normally but forms firm scarring known as scar plating or fibriotic bridging. As fibriotic bridging occurs, the mesh contracts and bunches, and the vagina becomes scarred and shortened. Firm scar tissue causes friction, irritation, pain from nerve constriction, and otherwise impedes the proper functioning of the vagina. Dr. Rosenzweig added that these processes can irritate nerves, causing vaginal and muscular pain and dyspareunia, which can lead to sexual dysfunction. If the mesh obstructs the urethra, the patient can develop new urinary symptoms, such as frequency, urgency, pain with urination and voiding dysfunction. The mesh can also cause fistulas and erode layers of tissue in the vagina and neighboring organs, as occurred in Ms. Carlino's case. PTX-30, Klinge dep. at 16-114; PTX-1, Rosenzweig dep. at 72-204, 721-26.

Research in the International Urogynecology Journal demonstrates that mesh exposure in the vagina occurred in 19% of cases. Injuries from the TVT required additional "very difficult" surgeries, and "about 30 percent of women will require more than one surgery to treat mesh complications," but there is no way to excise mesh completely. Tr., 2/8 (AM), at 112-22; PTX-19 Hinoul dep. (3/28/14), at 115-21; PTX-1, Rosenzweig dep. at 787-91.

The TVT has a high rate of failure. Ethicon's medical director, Hinoul, admitted that the rate of the TVT's long-term success as a treatment for incontinence was around 66% to 68%. Ethicon, however, officially reported the success rate as over 90%. Tr., 2/8 (AM), at 101; PTX-19, Hinoul dep. (1/13/14), at 114-18.

The Instructions For Use ("IFU") in use at the time of Ms. Carlino's initial surgery in 2005 listed transitory local irritation and transitory foreign body response among its potential adverse reactions. Ethicon's IFU provided no warning about the risks of foreign body reaction, fibriotic bridging, mesh shrinkage, vaginal scarring, vaginal perforation, nerve damage, chronic pain, dyspareunia, or complications requiring mesh removal. Dr. Rosenzweig testified that Ethicon should have warned that the TVT is cytotoxic, and that it causes a severe inflammatory reaction because of the amount of foreign material introduced in the body. He testified that Ethicon should have warned about the TVT's substantial degradation, small pore size, and pore collapse. He also testified that Ethicon should have warned about the risks of serious injuries, and about the severity, frequency, or permanency of those injuries. PTX-1, Rosenzweig dep., at 205-46. Dr. Rosenzweig also testified that Ethicon knew about alternatives to the TVT that were both available and safer for implantation in humans, and Ethicon's failure to utilize available alternative designs rendered the TVT unreasonably unsafe. ***Id.*** at 99-101, 200-01, 940-41.

The evidence demonstrates that Ethicon knowingly understated the risks of the TVT in all six versions of the IFU published between 2000 and 2015. The IFU's adverse reactions section did not change during that time, and it failed to acknowledge new information Ethicon was obtaining from treaters and its own researchers on adverse effects associated with the TVT. ***Id.*** In addition, Ethicon consistently and misleadingly informed physicians that the TVT produced few adverse results and was intentionally evasive about common complications. PTX-19, Hinoul dep. (1/14/14), at 1157-1208; PTX-1, Rosenzweig dep., at 210-46; PTX-42 Weisberg dep. (5/31/13) at 398-410, 968-69; PTX-42, Weisberg dep. (11/12/15), at 207-49, 311-26; PTX-42, Weisberg dep. (11/13/15), at 587-92.

Ms. Carlino testified that Dr. Blechman did not explain crucial risks of the TVT before she consented to surgery but only warned her about the risks of surgery and anesthesia. Tr., 1/27 (AM), at 63-72, 95-97. In turn, Dr. Blechman testified that he expected Ethicon's IFU to list the adverse reactions of which Ethicon was aware, but Ethicon did not warn about the TVT's risk for causing severe and permanent injury. Further, Dr. Margolis testified that Ethicon's failure to warn about these risks of common and severe complications also caused Ms. Carlino's permanent injuries. Tr., 1/27 (AM), at 118-19; Tr., 1/28 (AM), at 34-36, 79-98; Tr., 2/2 (PM), at 4-20. In reaching these conclusions, Dr. Margolis excluded all other causes of Ms. Carlino's injuries. Tr., 1/28 (AM), at 91-96.

Taken as a whole, and viewed in the light most favorable to the verdict winner, this evidence permitted the jury to find Ethicon acted with wanton and willful disregard of Ms. Carlino's rights and that this conduct caused her injuries. The evidence showed that Ethicon knew that the TVT could cause permanent vaginal and muscular pain and sexual dysfunction, because of its mesh weight, pore size, pore collapse, and particle loss. Despite this knowledge, Ethicon promoted the TVT for patients who sought to fix SUI, knowingly understated the risks of the TVT in its IFU, and consistently misled physicians that the TVT produced few adverse results. PTX-1, Rosenzweig dep., at 210-46; PTX-42, Weisberg dep. (5/31/2013) at 398-410; PTX-42, Weisberg dep. (11/12/15-11/13/15) at 207-49, 311-26; PTX-42, Weisberg dep. (11/15/15) at 587-92; PTX-19, Hinoul dep. (1/14/14) at 1157-1208.

Ethicon insists that punitive damages are unavailable because (1) the FDA granted 510(k) clearance of the TVT device, and (2) the FDA issued a publication in 2013 that "the safety and effectiveness of multi-incision slings is well-established." We held above that the trial court properly excluded this evidence. Since it was inadmissible, it cannot protect Ethicon from an award of punitive damages.

DELAY DAMAGES

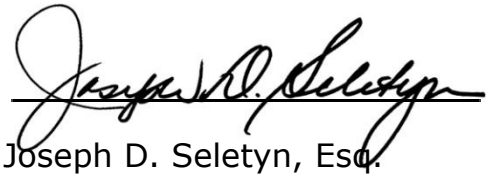
In their cross-appeal, the Carlinos argue that the trial court should have awarded delay damages on the punitive damage portion of the verdict instead of on the compensatory portion only. We rejected this argument in

Hammons, and we reject it here for the same reasons. ***Id.***, 190 A.3d at 1289-91.

Judgment affirmed. Ethicon's Application To Strike Supplemental Trial Court Record denied.

Judge Strassburger did not participate in the consideration or decision of this case.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 4/11/19