190 A.3d 1248
Superior Court of Pennsylvania.

Patricia L. HAMMONS
v.
ETHICON, INC., Johnson & Johnson; Gynecare; Secant Medical; Secant Medical, Inc.; Prodesco, Inc.; and Secant Medical, LLC
Appeal of Patricia L. Hammons
Patricia L. Hammons
v.
Ethicon, Inc., Johnson & Johnson; Gynecare; Secant Medical; Secant Medical, Inc.; Prodesco, Inc.; and Secant Medical, LLC
Appeal of Ethicon, Inc., Johnson & Johnson; Gynecare; Secant Medical; Secant Medical, Inc.; Prodesco, Inc.; and Secant Medical, LLC

No. 1522 EDA 2016
|
No. 1526 EDA 2016
|
Argued October 11, 2017
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Filed June 19, 2018
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Reargument Denied August 29, 2018

Synopsis

Background: Patient brought action under the Indiana Products Liability Act (IPLA) against medical device manufacturer for negligent design of and failure to provide adequate warnings for pelvic mesh, which was surgically implanted in the patient during pelvic floor surgery. The Court of Common Pleas, Philadelphia County, Civil Division at No. 3913 May Term 2013, Idee C. Fox, J., issued a case management order transferring patient's case to a Mass Tort Program action. Jury thereafter rendered a verdict in favor of patient, which included $12,850,945 million in damages. Both parties appealed.

Holdings: The Superior Court, Nos. 1522 EDA 2016 and 1526 EDA 2016, Stabile, J., held that:

[1] trial court had specific personal jurisdiction over manufacturer;

[2] evidence was sufficient to establish that manufacturer failed to provide adequate warnings to treating physicians;

[3] evidence was sufficient to establish the availability of a safer alternative design for device;

[4] evidence was sufficient to establish causation;

[5] jury instructions did not amount to an improper directive;

[6] denial of remittitur by trial court as to the amount of compensatory damages did not constitute abuse of discretion; and

[7] manufacturer was subject to $7 million in punitive damages.

Affirmed.

West Headnotes (45)

[1] Courts
Waiver of Objections

Medical device manufacturer did not waive challenge to personal jurisdiction in a products liability action by failing to contest it in preliminary objections to patient's complaint; case management order restricted preliminary objections to issues that applied to all cases concerning the type of device which allegedly injured patient and the complaint itself lacked any specific allegations of personal jurisdiction, such as the state where the alleged injury occurred, required for manufacturer to assert any objections.

Cases that cite this headnote

[2] Courts
Defective, dangerous, or injurious products;products liability

Medical device manufacturer fell within Pennsylvania trial court's specific personal jurisdiction in products liability action brought by patient allegedly injured by manufacturer's device, where evidence showed significant connections between manufacturer and Pennsylvania; the device at issue was designed, tested, and manufactured in Pennsylvania, manufacturer visited the plant where the device was made on multiple occasions, and manufacturer relied heavily on a Pennsylvania gynecologist for development, study, and marketing of the device, for which he was paid $1.7 million.

Cases that cite this headnote

[3] Limitation of Actions

Nature of harm or damage, in general

Indiana courts follow a discovery rule in products liability cases under the Indiana Products Liability Act (IPLA), pursuant to which the two-year statute of limitations begins to run from the date the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another. Ind. Code Ann. § 34-20-3-1.

Cases that cite this headnote

[4] Limitation of Actions

Nature of harm or damage, in general

For purposes of the discovery rule in products liability actions under the Indiana Products Liability Act (IPLA), reasonable possibility, while less than a probability, requires more than mere suspicion. Ind. Code Ann. § 34-20-3-1.

Cases that cite this headnote

[5] Limitation of Actions

Nature of harm or damage, in general

The discovery rule applied in product liability actions under the Indiana Products Liability Act (IPLA) is objective in nature—that is, the test is not what the claimant knew or suspected, but what would have caused a person of reasonable diligence to take action that would lead to the discovery of a cause of action, triggering the statute of limitations. Ind. Code Ann. § 34-20-3-1.

Cases that cite this headnote

[6] Appeal and Error

Time for proceedings;limitations and laches

An appellate court can resolve a discovery rule issue, for purposes of determining when statute of limitations accrues on a claim under the Indiana Products Liability Act (IPLA), as a question of law when no material issues of fact are in dispute.

Cases that cite this headnote

[7] Limitation of Actions

Questions for Jury

When issues of fact remain in dispute in a products liability action regarding when statute of limitations accrues on a claim under the Indiana Products Liability Act (IPLA), a jury should resolve the discovery rule question of when the plaintiff knew or should have known that she suffered an injury caused by a product. Ind. Code Ann. § 34-20-3-1.

Cases that cite this headnote

[8] Limitation of Actions

Injuries to the Person

Evidence supported finding that patient allegedly injured by medical device manufacturer's pelvic mesh was not put on notice of a reasonable probability that the mesh caused her injuries until she authorized release of her medical records for litigation, and therefore, her action against manufacturer under Indiana Products Liability Act (IPLA) accrued no earlier than that date for limitations purposes; despite patient's persistent post-surgical pain and incontinence, two experienced gynecologists

failed to diagnose the mesh as the cause of patient's injuries. Ind. Code Ann. § 34-20-3-1.

Cases that cite this headnote

[9] **Products Liability**
Warnings or Instructions

A manufacturer may not delegate its duty to warn under the Indiana Products Liability Act (IPLA). Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[10] **Products Liability**
Learned intermediary

Products Liability
Medical devices and appliances in general

Indiana follows the learned intermediary doctrine for products liability actions against a medical device manufacturer alleging failure to warn under the Indiana Products Liability Act (IPLA); pursuant to such doctrine, a medical device manufacturer's duty to warn for a prescription-only product extends only to the medical profession, and not the ultimate users. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[11] **Products Liability**
Warnings or Instructions

Products Liability
Learned intermediary

Products Liability
Medical devices and appliances in general

Products Liability
Implants and prosthetic devices

Under the Indiana Products Liability Act (IPLA), medical device manufacturer has no duty to warn with respect to potential risks already known to the user, the operating surgeon, or those risks about which the surgeon should know. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[12] **Products Liability**
Learned intermediary

To determine whether a manufacturer has satisfied its duty to warn under the Indiana Products Liability Act (IPLA) by relying upon a sophisticated intermediary, courts should consider the following factors: the likelihood or unlikelihood that harm will occur if the intermediary does not pass on the warning to the ultimate user, the trivial nature of the probable harm, the probability or improbability that the particular intermediary will not pass on the warning and the ease or burden of the giving of the warning by the manufacturer to the ultimate user. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[13] **Products Liability**
Learned intermediary

For the learned intermediary exception to nullify a manufacturer's duty to warn the ultimate customer under the Indiana Products Liability Act (IPLA), the intermediary must have knowledge or sophistication equal to that of the manufacturer or supplier, and the manufacturer must be able to rely reasonably on the intermediary to warn the ultimate consumer. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[14] **Products Liability**
Learned intermediary

A manufacturer's reliance on a learned intermediary is only reasonable under the Indiana Products Liability Act (IPLA) if the intermediary knows or should know of the product's dangers. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[15] **Products Liability**
Learned intermediary

Actual or constructive knowledge of a product's dangers by an intermediary, as necessary to satisfy the learned intermediary doctrine in an action against a manufacturer under the Indiana Products Liability Act (IPLA), may arise where either the supplier has provided an adequate explicit warning of such dangers or the information of the product's dangers is available in the public domain. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[16] **Products Liability**
Learned intermediary
Products Liability
Implants and prosthetic devices

Evidence was sufficient to establish that medical device manufacturer failed to provide adequate warnings to treating physicians about the risks of its pelvic mesh and that patient's treating physician did not know or should not have known about the risks independently, as required for a patient to prevail on a failure to warn claim under the Indiana Products Liability Act (IPLA); manufacturer's indications for use instructions and patient brochures failed to disclose the mesh's full inherent risks, such as inflammation, incontinence, and sexual dysfunction, and manufacturer's worldwide medical director was advised by nonparty company, which originally designed the mesh, to incorporate a warning about possible harm to patient's reproductive organs but manufacturer declined to include such a warning. Ind. Code Ann. § 34-20-4-2.

Cases that cite this headnote

[17] **Products Liability**
Alternative design, in general

The Indiana Products Liability Act (IPLA) does not require proof of a safer alternative design in order to establish a design defect claim. Ind. Code Ann. § 34-20-4-2.

1 Cases that cite this headnote

[18] **Products Liability**
Alternative design, in general
Products Liability
Implants and prosthetic devices

Although patient injured by pelvic mesh implanted in her during pelvic floor surgery did not have to present evidence of a safer alternative design to establish a design defect claim under Indiana Products Liability Act (IPLA), evidence was sufficient to establish the availability of a safer alternative design; prior to product launch of the mesh used by patient, manufacturer's engineer advised use of a different mesh with lower inflammatory response and reduced risk of contraction, and manufacturer fully developed the different mesh prior to patient's initial implant surgery. Ind. Code Ann. § 33-1-1.5-3.

1 Cases that cite this headnote

[19] **Evidence**
Cause and effect
Products Liability
Implants and prosthetic devices
Products Liability
Proximate Cause

Evidence was sufficient to establish that patient's injuries were caused by medical device manufacturer's pelvic mesh implanted in her during pelvic floor surgery, as required for patient to prevail in products liability action against manufacturer under Indiana Products Liability Act (IPLA); patient's urogynecology expert testified that the pelvic mesh had a tendency to cause prolapse and was not soft enough and, contrary to manufacturer's assertions, concluded that the mesh had been correctly implanted. Ind. Code Ann. § 34-20-1-1, et seq.

Cases that cite this headnote

[20] **Pretrial Procedure**
Failure to Comply;Sanctions

The spoliation doctrine is applicable to any case where relevant evidence has been lost or destroyed.

Cases that cite this headnote

[21] **Pretrial Procedure**
Failure to Comply;Sanctions

A party's destruction or loss of proof that is pertinent to a lawsuit, called "spoliation" can result in a variety of sanctions.

Cases that cite this headnote

[22] **Appeal and Error**
Spoliation

In reviewing the propriety of a sanction for spoliation of evidence, an appellate court must determine whether the trial court abused its discretion.

Cases that cite this headnote

[23] **Pretrial Procedure**
Failure to Comply;Sanctions

A trial court weighs three factors in deciding upon an appropriate penalty for spoliation of evidence: (1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future.

Cases that cite this headnote

[24] **Pretrial Procedure**
Failure to Comply;Sanctions

Evaluating the degree of fault of a party responsible for spoliation of evidence requires consideration of two components: the extent of the offending party's duty or responsibility to preserve the relevant evidence, and the presence or absence of bad faith.

Cases that cite this headnote

[25] **Pretrial Procedure**
Failure to Comply;Sanctions

The existence of a duty by a plaintiff responsible for spoliation of evidence to preserve such evidence is established where: (1) the plaintiff knows that litigation against the defendants is pending or likely; and (2) it is foreseeable that discarding the evidence would be prejudicial to the defendants.

Cases that cite this headnote

[26] **Trial**
Failure of party to testify or to call witness or produce evidence

One sanction that a court may choose to impose when evidence is lost or destroyed is to instruct the jury that it may infer that the destroyed evidence would have been unfavorable to the position of the offending party.

Cases that cite this headnote

[27] **Pretrial Procedure**
Failure to Comply;Sanctions
Trial
Failure of party to testify or to call witness or produce evidence

Sanctions for spoliation of evidence include, inter alia, entry of judgment against the offending party, exclusion of evidence, monetary penalties such as fines and attorney fees, and adverse inference instructions to the jury.

Cases that cite this headnote

[28] **Pretrial Procedure**
Failure to Comply;Sanctions

Standards for spoliation of evidence do not apply when a trial court merely considers whether to permit evidence during trial that a party destroyed documents.

Cases that cite this headnote

[29] **Evidence**
Tendency to mislead or confuse
Products Liability
Implants and prosthetic devices
Products Liability
Admissibility of Evidence

Patient, who brought products liability action against medical device manufacturer for injuries allegedly caused by manufacturer's pelvic mesh implanted in her during pelvic floor surgery, was permitted to introduce testimony as to manufacturer's destruction of tens of thousands electronic documents previously in the possession of high-ranking officials relating to the development of the pelvic mesh; absence of such documents was relevant to patient's burden of proof and the credibility of witnesses whose documents were destroyed, such that the probative value outweighed any prejudice to manufacturer. Pa.R.E. 403.

Cases that cite this headnote

[30] **Evidence**
Tendency to mislead or confuse

"Unfair prejudice" for the purposes of admission of evidence means a tendency to suggest decision on an improper basis or to divert the jury's attention away from its duty of weighing the evidence impartially. Pa.R.E. 403.

Cases that cite this headnote

[31] **Evidence**
Tendency to mislead or confuse

Although unfairly prejudicial evidence is to be excluded, 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. Pa.R.E. 403.

Cases that cite this headnote

[32] **Trial**
Deductions or inferences from evidence

Statements made by patient's counsel in his closing argument, in a products liability action against medical device manufacturer, which referred to the files of high-ranking corporate employees having been "wiped out" and that this said "a lot about [manufacturer's] intentions[,]" did not constitute improper argument; patient had introduced evidence of document destruction at trial and counsel was permitted to present such evidence in closing argument along with all logical inferences.

Cases that cite this headnote

[33] **Trial**
Comments on Evidence or Witnesses

A party is entitled to argue the evidence during closing arguments, including all logical inferences.

Cases that cite this headnote

[34] **New Trial**
Negligence and torts in general
Products Liability
Implants and prosthetic devices
Products Liability
Warnings or instructions
Products Liability
Proximate Cause

Jury instructions, in a products liability action under the Indiana Products Liability Act (IPLA), did not amount to a directive for jury to reject medical device manufacturer's argument that surgical errors were responsible for patient's injuries rather than any defect in manufacturer's pelvic mesh implanted in patient, and thus manufacturer was not entitled to a new trial; instructions required jury to find manufacturer "responsible for any harm" from improper surgical placement of the mesh if manufacturer "knew that a

surgeon using the product might place [it] incorrectly" and this did not instruct the jury that surgeon's actions were unrelated to patient's injuries as a matter of law, but rather that manufacturer had a duty to warn surgeon of the mesh's latent dangers. Ind. Code Ann. § 34-20-1-1, et seq.

Cases that cite this headnote

[35] **Products Liability**
Learned intermediary

Products Liability
Medical devices and appliances in general

Under Indiana law, a medical device manufacturer has the duty to warn treating physicians of the device's latent dangers. Ind. Code Ann. § 34-20-3-1, et seq.

Cases that cite this headnote

[36] **Products Liability**
Foreseeable misuse

Products Liability
Misuse of product

Products Liability
Medical devices and appliances in general

Medical device misuse is an intervening cause that relieves the manufacturer of liability under the Indiana Products Liability Act (IPLA) only if the misuse could not have been reasonably foreseen by the manufacturer. Ind. Code Ann. § 34-20-1-1, et seq.

Cases that cite this headnote

[37] **New Trial**
Remission or Reduction of Excess of Recovery

Under 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.

Cases that cite this headnote

[38] **New Trial**
Remission or Reduction of Excess of Recovery

If an award of compensatory damages is excessive, any remittitur must fix the highest amount any jury could properly award; this 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.

Cases that cite this headnote

[39] **Appeal and Error**
Excessive Award;Remittitur

An appellate court, in deciding whether to grand a remittitur, is not free to substitute its judgment for that of the fact finder, but rather must 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.

Cases that cite this headnote

[40] **Damages**
Mode of estimating damages in general

Noneconomic loss in personal injury cases must be measured by experience rather than any mathematical formula.

Cases that cite this headnote

[41] **New Trial**
Actions for personal injuries

Denial of remittitur by trial court as to the amount of compensatory damages, in a products liability action against medical device manufacturer brought by patient who suffered injuries, after manufacturer's pelvic mesh was implanted in her during pelvic floor surgery, did not constitute abuse of discretion; pursuant to state common law, the $5.5 million award of damages was based on extensive and permanent physical harm

to patient's reproductive organs, including permanent loss of bladder capacity despite several remedial surgeries, as well as patient's embarrassment and humiliation resulting from such disfigurement and her loss of sexual function.

Cases that cite this headnote

[42] Damages
Products liability

When a plaintiff complains 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.

1 Cases that cite this headnote

[43] Damages
Products liability

When a plaintiff complains 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.

1 Cases that cite this headnote

[44] Damages
Products liability

Under New Jersey law, medical device manufacturer was subject to $7 million in punitive damages in a products liability action brought by patient allegedly injured by surgical implantation of manufacturer's pelvic mesh; evidence, including manufacturer's own documents, showed that manufacturer knew prior to product launch that nearly twenty percent of women would suffer severe complications from the mesh but failed to study the long-term consequences or develop a process for the mesh's removal, continued to sell the mesh without adequate warnings after post-launch clinical data confirmed its risks, and prioritized product launch and profitability in declining to use a different material for the mesh despite repeated urging by the mesh's original designers. N.J. Stat. Ann. §§ 2A:15-5.12(a), 2A:1-5.10.

1 Cases that cite this headnote

[45] Interest
Unreasonable or vexatious delay in payment

Patient who brought products liability action against medical device manufacturer was not entitled to delay damages on the punitive damages portion of the verdict rather than only the compensatory damages portion, where, as a matter of law, state rule of civil procedure did not extend delay damages to punitive awards. Pa.R.C.P. No. 238.

Cases that cite this headnote

West Codenotes

Prior Version Held Unconstitutional
Pa. R. Civ. P. 238.

***1254** Appeal from the Judgment Entered April 14, 2016, In the Court of Common Pleas of Philadelphia County, Civil Division at No: 3913 MAY TERM 2013, Before Idee C. Fox, J.

Attorneys and Law Firms

Charles L. Becker, Philadelphia, for Hammons.

Dorothy A. Hickok, Philadelphia, for Ethicon, Inc.

BEFORE: OTT, STABILE, JJ. and STEVENS, * P.J.E.

Opinion

OPINION BY STABILE, J.:

In this product liability action, Appellants, Ethicon, Inc. and Johnson & Johnson, Ethicon's parent company (collectively "Ethicon") and Appellee, Patricia Hammons ("Hammons"), appeal and cross-appeal, respectively, from a judgment of $12,850,945.18 entered in favor of Hammons in the Philadelphia Court of Common Pleas.

Hammons alleged that she suffered injuries caused by Ethicon's negligent design of, and failure to provide adequate warnings about, the Prolift Kit, a medical product used to treat prolapsed pelvic organs. Appellants challenge the trial court's denial of (1) their preliminary objections alleging lack of specific personal jurisdiction, (2) their post-trial motions seeking judgment n.o.v. on the basis of the statute of limitations and Appellee's failure to present sufficient evidence, (3) their post-trial motions seeking a new trial based on the trial court's evidentiary and instructional errors, (4) their post-trial motions seeking remittitur on the compensatory damage verdict and vacatur or remittitur of the punitive damage verdict. In her cross-appeal, Hammons argues that the trial court erred by awarding delay damages only on the compensatory damage verdict instead of the entire verdict. We affirm in all respects.

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 place of business in New Jersey. As discussed in greater detail below, Ethicon worked closely with other entities and individuals in Pennsylvania to design, test and manufacture the Prolift Kit ("Prolift").

Our review of the record reveals the following. Pelvic organ prolapse is a pelvic floor disorder that affects the muscles and tissues that hold the pelvic organs, including the bladder, uterus, vagina, small bowel, and rectum, in place. Due to childbirth, advancing age, or other causes, these muscles and tissues can weaken, and one or more pelvic organs "prolapse," or descend into or outside of the vaginal canal or anus. Pelvic organ prolapse is accompanied by a number of other symptoms, including a bulge or feeling of fullness in the pelvic area, back problems, pain during sexual intercourse, urinary problems such as leaking of urine or a chronic urge to urinate, or constipation.

In the early 2000s, a group of surgeons in France developed Prolift in an attempt to improve treatment of pelvic repairs. In 2005, Ethicon brought Prolift to market. Prolift includes a precut piece of surgical mesh and single-use implanting tools called trocars. The mesh is woven from ***1255** non-absorbable polypropylene sutures and is pre-cut into distinct shapes for anterior, posterior or total pelvic repairs. During implantation, the mesh is inserted into the patient's body through the vagina, pulled through the vaginal wall, placed to support prolapsed pelvic organs and anchored with mesh "arms" through a woman's bones and muscles via trocars. Prolift surgery is a quality-of-life decision.

In 2009, Hammons, a post-menopausal woman who lives with her boyfriend in Washington, Indiana, was diagnosed with prolapse of her uterus and bladder. Her physician, Michael Baker, D.O., recommended surgical repair of her bladder prolapse and removal of her uterus and ovaries. On May 5, 2009, Hammons signed a consent form authorizing a total vaginal hysterectomy and "anterior repair with mesh." Defense Trial Exhibit ("DTX")–36. The form stated that Dr. Baker advised Hammons why the procedure was necessary, "the risks thereof, [and] its advantages and possible complications ...." ***Id.*** On the same date, Dr. Baker performed the surgery and implanted the Prolift device in Hammons' body to support her organs. Dr. Baker wrote in his report of the operation, "I discussed the ... risk of injury to bowel, bladder or ureter as well as ... having pain with intercourse or other types of pain following surgery. [Hammons] agreed to these risks and wishes to proceed with surgery despite these risks." DTX–37 at 208–09. Hammons testified, however, that Dr. Baker did not tell her prior to surgery that pain during sexual intercourse was one of the risks of surgery. Notes of Testimony ("N.T."), 12/11/15 (PM), at 32.

On July 20, 2009, Hammons returned to Dr. Baker with complaints of pinching and sharp pain that caused her to stop engaging in intimate relations. Dr. Baker noted sexual dysfunction but did not offer a causal explanation. During the next visit, Dr. Baker diagnosed Hammons with rectal prolapse, or rectocele. She sought referral to a different gynecologist, Dr. Lackey.

In November 2009, Dr. Lackey diagnosed Hammons with pelvic pressure and incontinence, rectocele, a tear in the vaginal septum and dyspareunia (pain during sexual intercourse). In December 2009, Dr. Lackey surgically repaired the rectocele by using Hammons' own tissue to provide support for her rectum. In January 2010, Dr. Lackey told Hammons that she could resume sexual intercourse. It appears that Hammons did not visit Dr. Lackey again until January 2012.

On August 16, 2011, Hammons signed a form authorizing the release of her "implant related medical records" for use in "plaintiff litigation for product liability." DTX–42; N.T., 12/11/15 (PM), at 63.

In January 2012, Hammons returned to Dr. Lackey complaining of pain during intercourse. Dr. Lackey did not identify Prolift as the cause of Hammons' discomfort. On August 14, 2012, Hammons returned to Dr. Lackey complaining of incontinence and recurrent prolapse. Dr. Lackey referred Hammons to urogynecologist Michael Heit in Louisville, Kentucky.

On August 30, 2012, Dr. Heit diagnosed Hammons with symptoms caused by implantation of Prolift mesh and recommended additional surgeries for excision of the mesh and repair of the entire pelvic floor. In November 2012, Dr. Heit surgically excised mesh from Hammons' anterior vaginal wall, repaired two cystotomies (holes in her bladder), placed a ureteral stent and repaired her recurring rectocele. In January 2013, Dr. Heit removed the ureteral stent, noting new penetration of mesh into the left lateral bladder wall. Dr. Heit surgically removed additional mesh from her bladder. In all, Dr. Heit performed three surgeries.

***1256** Hammons continues to suffer from incontinence and pain during intercourse. Because of pain, and because her vagina is shortened and rigid with scar tissue, she has abstained from sex, causing humiliation and impairing her relationship with her boyfriend.

On May 31, 2013, Hammons filed a civil complaint against Ethicon in the Philadelphia Court of Common Pleas ("trial court") alleging negligence, strict liability and other torts at May Term, 2013, No. 3913 ("Individual Docket"). In March 2014, the trial court transferred Hammons' case to a Mass Tort Program action, *In Re Pelvic Mesh Litigation*, which encompassed all pelvic mesh cases pending in Philadelphia.

On March 31, 2014, the trial court issued a case management order dividing the *Pelvic Mesh Litigation* matter into proceedings on a Master Docket and proceedings on each plaintiff's Individual Docket. [1] On the Master Docket, all pelvic mesh plaintiffs collectively were to file a "long form" complaint alleging facts and causes of action that applied globally to all pelvic mesh cases, and each defendant was to file (1) preliminary objections that raised global objections to all pelvic mesh cases or (2) an answer to the long form complaint. Within 25 days after the answer to the long form complaint, each plaintiff was to file a "short form" complaint on her Individual Docket identifying the counts of the long form complaint that she incorporated by reference and asserting any new facts or causes of action not in the long form complaint. Each defendant could then file preliminary objections on the Individual Docket raising objections that applied specifically to the short form complaint. If the defendant did not file preliminary objections, an entry of appearance by counsel for the defendant would constitute a denial of allegations in the short form complaint and an assertion of all applicable new matter and defenses.

On May 14, 2014, the plaintiffs filed an eighteen-count long form complaint on the Master Docket against Ethicon and other defendants, including Secant Medical, Inc. and Secant Medical LLC ("Secant"), a manufacturer of surgical mesh located in Perkasie, Pennsylvania. Among the counts in the long form complaint were strict liability actions for design defect, manufacturing defect and failure to warn. The long form complaint also asserted that personal jurisdiction existed over Ethicon in Pennsylvania.

On May 21, 2014, the plaintiffs served Ethicon with the long form complaint. On June 10, 2014, Ethicon filed preliminary objections to the long form complaint arguing that eleven of the eighteen counts failed to state a cause of action and objecting to the lack of specificity of certain averments. Ethicon did not file any objection to personal jurisdiction. Secant also filed preliminary objections seeking dismissal of the claims under the Biomedical Access Assurance Act, 21 U.S.C. § 1601 *et seq.* On August 22, 2014, the trial court sustained Secant's preliminary objections and dismissed all claims against Secant with prejudice. On September 2, 2014, the trial court overruled Ethicon's preliminary objections. On September 23, 2014, Ethicon filed an answer to the long form complaint with new matter.

On October 7, 2014, Hammons filed a short form complaint on her Individual Docket. On October 28, 2014, Ethicon filed preliminary objections to the short form complaint asserting lack of personal jurisdiction. On November 6, 2014, the trial court entered an order on

the Master Docket directing the parties to take discovery ***1257** on the jurisdictional issue. On March 30, 2015, the trial court overruled Ethicon's motion on the Master Docket to dismiss for lack of personal jurisdiction and Ethicon's preliminary objections on Hammons' Individual Docket asserting lack of personal jurisdiction. The trial court did not provide any explanation for its ruling.

On August 31, 2015, Ethicon moved for summary judgment on the Individual Docket. Among other arguments, Ethicon claimed that it was entitled to summary judgment on Hammons' manufacturing defect claim because there was no evidence that the Prolift device used in her surgery deviated from its intended design. On November 24, 2015, the trial court granted summary judgment to Ethicon on the manufacturing defect claim and other claims. The court left intact Hammons' design defect and failure-to-warn claims.

Hammons' expert witnesses, gynecologist Daniel Elliott, M.D., and urogynecologist Anne Weber, M.D., testified that Prolift was defectively designed. Dr. Elliott testified that Prolift's mesh contains too much suture for implantation through the wall of the vagina. Prolift also requires implantation of approximately 260 yards of a plastic material foreign to the patient's body. Dr. Elliott testified that the mesh is over-engineered and too heavy and dense, and the pores of the mesh are too small for the product to perform properly and as intended. Another expert, Uwe Klinge, M.D., opined that Prolift mesh's one millimeter pores were inadequate. He testified Ethicon should have used a mesh with pores larger than three millimeters. Plaintiff's Exhibit ("P-") 3401 at 10–15; P–3402 at 12–17; P–3408 at 4–10.

Dr. Elliott also testified that the process of implantation recommended by Ethicon actually causes Prolift's mesh pores to collapse. For instance, he explained, pores collapse because the vagina is a dynamic organ that moves, shifts, and changes shape with normal movement. Pores also collapse because implantation requires a physician to pull on the mesh to guide it through the vagina, the vaginal wall, and pelvic muscles to anchor it into place. Lastly, pores collapse when physicians cause tension in the mesh when they pull it under the bladder. Ethicon knew the vagina and pelvic organs create an environment different from any other (such as the abdominal cavity for which the mesh was created) but failed to modify the Prolift mesh and surgical techniques to account for the differences. P–3402 at 27–37; P–3407 at 1–7; P–3408, at 10–17; P–3415 at 6–7.

Dr. Elliott testified that implantation of materials foreign to the body naturally causes chronic foreign body reaction and inflammatory response, and Prolift causes severe inflammatory reaction proportional to the large amount of plastic used. Severe inflammation causes scar tissue formation. Prolift mesh's small pores and pore collapse impede normal tissue growth through the pores. The mesh bands and rolls to exacerbate the inflammatory and scar formation cycle. The process results in platting or bridging, that is, scar tissue becomes rigid, contracts and bunches. As the mesh contracts, it erodes layers of tissue in the vagina and then in neighboring organs. It can become exposed in the vagina and damage the bladder, intestines and other organs, which then might experience dysfunction. Further, mesh that contracts causes tissue irritation and pulls painfully on the patient's muscles, causing chronic muscle pain and pelvic floor muscle spasms. Dr. Elliott testified that the inflammatory response is chronic and triggers a progressive cycle of mesh contraction and erosion that causes pain response and organ dysfunction. He added that pain management techniques are generally unsuccessful, and that Prolift's design precludes successful and complete excision ***1258** without risk of "severe damage" to the pelvic structures. P–3401 at 2–13; P–3402, at 12–37.

Dr. Elliott and Dr. Weber added that Prolift has limited effectiveness in repairing prolapse. Dr. Elliott testified that Ethicon's pre-launch clinical study data indicated more than a twenty percent rate of prolapse recurrence at both six and twelve months following Prolift implantation. Even by Ethicon's predefined criteria, Prolift failed performance expectations because prolapse recurs frequently and shortly after implantation. Dr. Weber testified that she independently analyzed raw clinical data and concluded Ethicon underreported the true rate of recurrence by ten percent. Dr. Weber also noted the existence of clinical experience and studies known to Ethicon that demonstrated nearly twenty percent of women suffered mesh shrinkage with pain during intercourse, and another approximately twenty percent suffered mesh erosions within a year of implantation. N.T., 12/8/15 (A.M.), at 23–64; P–3401 at 6; P–3402, at 21–24; P–3404 at 18; P–3415 at 7.

Dr. Elliott and Dr. Weber concluded that Prolift is unsafe. Dr. Elliott further testified that Ethicon's product warnings were inadequate, because they failed to convey all of the risks of the product, including severe and permanent pain during sexual intercourse.[2] Dr. Baker, the surgeon who implanted the Prolift device, testified that he would not have recommended the product had Ethicon adequately warned him of its risks. Moreover, Ethicon knew about the risks of the product before placing it on the market. Prolift's inventors, Professor Jacquetin and Dr. Cosson, insisted both before and after Prolift's launch on replacement of the Prolene/Gynemesh mesh with a safer mesh alternative called Ultrapro. Dr. Weber agreed that Ultrapro mesh reduced the risk because it contained less mesh, had larger pores and was softer in place. Ultrapro's characteristics were thought to reduce inflammation and scar plating. N.T., 12/7/15 (A.M.), at 57–95; N.T., 12/7/15 (P.M.), at 237–48; P–3401 at 2–3, 9–12; P–3402, at 5–7, 33–35; P–3404, at 9; P–3407 at 8–12; P–3415, at 7–8; P–3417 at 1–4.

The parties agreed that Indiana law defines the elements of Hammons' product liability claims, while New Jersey law provides the standards for determining punitive damages.[3], [4] At the end of a three-week trial, the trial court denied Ethicon's motion for directed verdict. On December 21, 2015, the jury returned a verdict that Ethicon was liable for causing Hammons' injuries and awarded compensatory damages of $5.5 million. After additional evidence, argument, and instructions, on December 22, 2015, the jury assessed an additional $7 million in punitive damages. Both sides filed post-trial motions. The trial court denied Ethicon's post-trial motions and granted delay damages upon only the compensatory award rather than the entire verdict. On May 12, 2016, Hammons filed a praecipe to enter judgment in the amount of $12,850,945.18 on the Individual Docket. Both sides filed timely notices of appeal and timely Pa.R.A.P. 1925(b) statements of errors complained of on appeal.

***1259 ISSUES RAISED ON APPEAL**

In its appeal at 1526 EDA 2016, Ethicon raises ten issues that we have re-ordered for the sake of convenience:

1. Did the trial court commit legal error by exercising personal jurisdiction over [Ethicon], even though [Ethicon is not] incorporated in [and does not] maintain [its] principal place[ ] of business in Pennsylvania, and even though [Hammons'] 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 [Hammons'] claims were barred by the statute of limitations and [Hammons] did not present legally sufficient evidence that Indiana's discovery rule extended the limitations period?

3. Did the trial court commit legal error when it denied [Ethicon]'s directed-verdict and JNOV motions, where [Hammons] failed to present legally sufficient evidence that an inadequacy in Prolift's warnings caused her alleged injuries?

4. Did the trial court commit legal error when it denied [Ethicon]'s directed-verdict and JNOV motions, where [Hammons] failed to present legally sufficient evidence that a safer alternative design to the Prolift medical device was available at the time of her May 2009 implantation?

5. Did the trial court commit reversible error by refusing to instruct the jury that, to prevail on the design-defect claim, [Hammons] was required to show a safer alternative design to Prolift?

6. Did the trial court commit legal error when it denied [Ethicon]'s directed-verdict and JNOV motions, where [Hammons] failed to present legally sufficient evidence that a defect in Prolift, as opposed to potential alternatives, caused her alleged injuries?

7. Did the trial court commit reversible error by admitting evidence and allowing argument that [Ethicon] supposedly spoliated evidence, when there was no showing or finding that spoliation occurred or that [Hammons] was prejudiced?

8. Did the trial court commit reversible error by instructing the jury that [Ethicon]'s awareness of any potential misuse of Prolift by surgeons made them responsible for all misuses of Prolift, whether or not they were foreseeable?

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

> 10. 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.

Hammons raises the following issue in her appeal at 1522 EDA 2016: "Did the trial court improperly mold the jury's verdict to add delay damages calculated only on the compensatory portion of the verdict?" Hammons' Brief at 4.

PERSONAL JURISDICTION

Ethicon first asserts that the trial court erroneously denied its preliminary objections to Hammons' Short Form Complaint, in which Ethicon argued that personal jurisdiction does not exist over Ethicon in Pennsylvania.[5] In support of this argument, Ethicon relies on the United States Supreme Court's recent decision in ***1260** ***Bristol–Myers Squibb Co. v. Superior Court of California, San Francisco County ("Bristol–Myers")***, —— U.S. ——, 137 S.Ct. 1773, 198 L.Ed.2d 395 (2017), which held that California courts lacked specific jurisdiction to entertain product liability claims by nonresidents against a nonresident drug manufacturer, where the nonresidents were not prescribed the drug in California and did not purchase, ingest or suffer injury from the drug there. Hammons responds that Ethicon waived this issue by failing to raise it in preliminary objections to the Long Form Complaint on the Master Docket. In any event, Hammons continues, ***Bristol–Myers*** actually supports the conclusion that "the trial court properly exercised specific jurisdiction over Ethicon, given Ethicon's activities in Pennsylvania relating to this case." Hammons' Supplemental Brief at 1.

[1] We conclude that Ethicon did not waive this issue, because the case management order for pelvic mesh cases did not require Ethicon to contest personal jurisdiction in preliminary objections to the Long Form Complaint.

To begin with, the case management order was a valid exercise of the court's authority. In 1992, the Philadelphia Court of Common Pleas initiated the Mass Tort Program to deal efficiently with large numbers of complex but similar tort cases by coordinating and streamlining pleadings, discovery, pretrial motions, and trial. The legal foundation for the Program is Pa.R.Civ.P. 213, which authorizes courts to consolidate related cases and issue case management orders for their efficient disposition. ***See*** Pa.R.Civ.P. 213(a) ("In actions pending in a county which involve a common question of law or fact ... the court on its own motion ... may order the actions consolidated[ ] and may make orders that avoid unnecessary cost or delay"). The case management order in this case—which appears to be a standard order in all Philadelphia mass tort cases—fits well within the boundaries of Rule 213(a) by delineating applicable procedures in pelvic mesh cases.

The case management order restricts preliminary objections to the Long Form Complaint to issues that apply to **all** pelvic mesh cases. The question whether the trial court had personal jurisdiction over Ethicon did not apply to **all** pelvic mesh cases. While a question of personal jurisdiction over Ethicon exists with regard to out-of-state plaintiffs such as Hammons, it appears fairly certain personal jurisdiction would exist over Ethicon in actions brought by plaintiffs who underwent Prolift surgery in Pennsylvania due to the "affiliation between the forum and the underlying activity." ***Bristol–Myers***, 137 S.Ct. at 1781 ("In order for a court to exercise specific jurisdiction over a claim, there must be an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State ... When there is no such connection, specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State"). Thus, Ethicon was not required to raise objections to personal jurisdiction in preliminary objections to the Long Form Complaint on the Master Docket. Indeed, as Ethicon observes, it was impossible for Ethicon to challenge personal jurisdiction in preliminary objections to the Long Form Complaint, because this complaint "lacked any of the plaintiff-specific allegations required to assert such objections—for example, the state where the plaintiff resides, the state where she had the device implanted, and the state where the injury occurred ... When [Hammons] filed her short-form complaint that added those allegations ... [Ethicon] promptly and timely filed their preliminary objections to personal jurisdiction." Ethicon's Reply Brief, at 3.

***1261** **[2]** On the merits, however, we conclude that personal jurisdiction exists over Ethicon in this case. The

trial court applies the following standards to preliminary objections asserting lack of personal jurisdiction:

> When preliminary objections, if sustained, would result in the dismissal of an action, such objections should be sustained only in cases which are clear and free from doubt. Moreover, when deciding a motion to dismiss for lack of personal jurisdiction the court must consider the evidence in the light most favorable to the non-moving party. A defendant making a challenge to the court's personal jurisdiction has, as the moving party, the burden of supporting its objection to jurisdiction.

De Lage Landen Services, Inc. v. Urban Partnership, LLC, 903 A.2d 586, 589 (Pa. Super. 2006) (citation omitted). "Our standard of review of an order of the trial court overruling ... preliminary objections is to determine whether the trial court committed an error of law. [Furthermore], the appellate court must apply the same standard as the trial court." ***Id.***

The Due Process Clause of the Fourteenth Amendment to the United States Constitution limits the authority of a state to exercise *in personam* jurisdiction over non-resident defendants. ***Burger King Corp. v. Rudzewicz***, 471 U.S. 462, 471–72, 105 S.Ct. 2174, 85 L.Ed.2d 528 (1985). The extent to which the Due Process Clause proscribes jurisdiction depends on the nature and quality of the defendant's contacts with the forum state. ***Id.*** at 474–76, 105 S.Ct. 2174; ***Kubik v. Letteri***, 532 Pa. 10, 614 A.2d 1110, 1114 (1992). Where a defendant "has established no meaningful contacts, ties or relations" with the forum, the Due Process Clause prohibits the exercise of personal jurisdiction. ***Burger King***, 471 U.S. at 472, 105 S.Ct. 2174. However, where a defendant has "purposefully directed" his activities at the residents of the forum, he is presumed to have "fair warning" that he may be called to suit there. ***Id.***

Since ***International Shoe Co. v. Washington***, 326 U.S. 310, 317–18, 66 S.Ct. 154, 90 L.Ed. 95 (1945), the Supreme Court has recognized two types of personal jurisdiction: general and specific. ***Id.***, 326 U.S. at 317–18, 66 S.Ct. 154. The court has general jurisdiction over a foreign corporation when its affiliations with the state are so "continuous and systematic" as to render them essentially at home in the forum State. ***Goodyear Dunlop Tires Operations, S. A. v. Brown***, 564 U.S. 915, 919, 131 S.Ct. 2846, 180 L.Ed.2d 796 (2011). "A court with general jurisdiction may hear any claim against that defendant, even if all the incidents underlying the claim occurred in a different State." ***Bristol–Myers***, 137 S.Ct. at 1780. Recently, however, the United States Supreme Court held that general jurisdiction will not lie in a state in which neither a parent corporation nor its subsidiary is incorporated or has its principal place of business. ***Daimler AG v. Bauman***, 571 U.S. 117, 134 S.Ct. 746, 762, 187 L.Ed.2d 624 (2014). The record does not indicate that any entity within Ethicon's corporate hierarchy is incorporated in Pennsylvania or has its principal place of business in Pennsylvania. Therefore, we need not discuss general jurisdiction concepts further.

If general jurisdiction does not exist over a foreign defendant, it may still be subject to specific jurisdiction in Pennsylvania pursuant to Pennsylvania's long arm statute, 42 Pa.C.S.A. § 5322 ("Bases of personal jurisdiction over persons outside this Commonwealth"). Section 5322(a) contains ten paragraphs that specify particular types of contact with Pennsylvania deemed sufficient to warrant the exercise of specific jurisdiction. In addition, Section 5322(b) operates as a "catchall," providing that jurisdiction may be exercised over ***1262** persons who do not fall within the express provisions of Section 5322(a) to the fullest extent permitted by the Due Process Clause of the United States Constitution. ***Mendel v. Williams***, 53 A.3d 810, 821 (Pa. Super. 2012) (citation omitted). Regardless, if a defendant's activities in Pennsylvania only give rise to jurisdiction under section 5322(a) or (b), the plaintiff's cause of action is limited to those activities that formed the basis of jurisdiction. ***See*** 42 Pa.C.S.A. § 5322(c) ("when jurisdiction over a person is based solely upon this section, only a cause of action or other matter arising from acts enumerated in subsection (a), or from acts forming the basis of jurisdiction under subsection (b), may be asserted against him").

Specific jurisdiction enables a court to adjudicate claims arising from activity that occurs within the forum state's borders and is "therefore subject to the State's

regulation." ***Bristol–Myers***, 137 S.Ct. at 1780. There are three requirements for the exercise of specific jurisdiction. First, the defendant must have "purposefully availed itself of the privilege of conducting activities within the forum State or have purposefully directed its conduct into the forum State." ***Id.*** at 1785. Second, the plaintiff's claim must "arise out of or relate to" the defendant's activities in the forum state. ***Id.*** Third, jurisdiction must be fair and reasonable so as not to offend tradition notions of fair play and substantial justice. ***Id.*** The fairness factors in the third requirement that a court will consider are "the burden on the defendant, the forum State's interest in adjudicating the dispute, the plaintiff's interest in obtaining convenient and effective relief, the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and the shared interest of the several States in furthering fundamental substantive social policies." ***Id.*** at 1786.

In ***Bristol–Myers***, a group of plaintiffs, consisting mainly of non-California residents, filed a mass tort action in California state court alleging injuries caused by a blood thinner drug called Plavix. ***Id.*** at 1778. The Supreme Court held that California did not have personal jurisdiction over the defendant with regard to claims of the non-California residents. ***Id.*** at 1783. California did not have general jurisdiction over Bristol–Myers because the pharmaceutical company was incorporated in Delaware and headquartered in New York. ***Id.*** at 1783–84. Moreover, California lacked specific jurisdiction because there was no connection to the non-residents' claims. The nonresidents did not allege they purchased, ingested or suffered harm from Plavix in California or received treatment for their injuries in California. ***Id.*** at 1778. Nor did they allege that they were prescribed Plavix in California or by California physicians. ***Id.*** The mere fact that California residents were prescribed Plavix or ingested it in California, or allegedly sustained the same injuries as the nonresidents, "[did] not allow the State to assert specific jurisdiction over the nonresidents' claims." ***Id.*** at 1781.

Moreover, Bristol–Myers' decision to contract with a California company to distribute the drug nationally did not provide a sufficient basis for personal jurisdiction. ***Id.*** at 1783. The Court ruled that a defendant's contract with a distributor in the forum state is not itself enough to establish personal jurisdiction in the State. ***Id.*** It noted that there was no allegation that the defendant engaged in relevant acts together with the distributor in California, or that the defendant was derivatively liable for the distributor's conduct. ***Id.***

In short, what was needed—and what was missing—was suit-related conduct, *i.e.*, a connection between the forum and the specific claims at issue, "principally, an ***1263** activity or occurrence that takes place in the forum State." ***Id.*** at 1781. "[A]ll the conduct giving rise to the nonresidents' claims occurred elsewhere." ***Id.*** at 1782.

The Court rejected the California Supreme Court's "sliding scale" theory establishing personal jurisdiction. Under this approach, "the strength of the requisite connection between the forum and the specific claims at issue is relaxed if the defendant has extensive forum contacts that are unrelated to those claims." ***Id.*** What the California court did "resembles a loose and spurious form of general jurisdiction." ***Id.*** For specific jurisdiction, a defendant's general connections with the forum state are not enough. ***Id.***

The connection between Ethicon and Pennsylvania is considerably stronger than the connection between Bristol–Myers and California. Ethicon supervised the design and manufacturing process of pelvic mesh in Pennsylvania in collaboration with Secant Medical, Inc., a Bucks County company. Ethicon also worked closely with an Allentown, Pennsylvania physician, Vincent Lucente, M.D., in developing Prolift. Both of these factors support the exercise of specific jurisdiction over Ethicon in Pennsylvania.

To elaborate, Hammons claims that she suffered bodily injuries due to the properties of the mesh that Ethicon used in its transvaginal mesh product, Prolift. She contends that Ethicon defectively designed and manufactured the mesh with polypropylene material that was toxic, dense and inelastic. Because of its defective design, she asserts, the mesh caused scar plating, erosion of mesh into her pelvic organs, and extensive personal injuries. The record illustrates that Ethicon worked together with Secant in Pennsylvania to design, test and manufacture the Prolift mesh.

Three high-level officials of Secant provided affidavits (R.R. 266b–278b) that Ethicon provided all material specifications for the weaving of mesh at Secant's Pennsylvania plant, including specifications concerning the mesh's elasticity, mass, and density, the specifications

at the center of Hammons' claims. Ethicon delivered polypropylene filament to Secant in Pennsylvania. ***Id.*** Secant knitted the filament into large rolls of mesh in, and tested samples for, compliance with Ethicon's specifications. ***Id.*** Ethicon received the rolls of mesh from Pennsylvania and processed them further. ***Id.*** Emails between Ethicon and Secant officials demonstrate that Ethicon repeatedly communicated its requirements for mesh design and development, manufacturing, quality control, testing, and certification to Secant—all issues central to this litigation. The emails also show that Ethicon employees visited Secant's plant in Pennsylvania on multiple occasions to observe the mesh production process. This evidence establishes an affiliation between Pennsylvania and Hammons' cause of action against Ethicon for defective design of the Prolift device. ***Bristol–Myers***, 137 S.Ct. at 1781.

Trial evidence[6] also shows that Ethicon relied heavily on an Allentown, Pennsylvania gynecologist, Vincent Lucente, M.D., for the development, study, and marketing of Prolift. N.T., 12/8/15 (AM), at 19–60. Ethicon retained Dr. Lucente as its investigator for three important clinical studies that Ethicon funded concerning the outcomes and safety of Prolift mesh: the Gynemesh PS study of Prolift's mesh materials, the US TVM study of the Prolift ***1264** prototype, and the Lucente IIS study. Hammons' Trial Exhibits 750, 2299, 3404, 3410, 3416. Dr. Lucente's role was so important to Ethicon's development of Prolift that Ethicon employees traveled to Pennsylvania in February 2006 to meet with Dr. Lucente for guidance concerning the marketing and development strategy for Prolift. ***Id.*** Dr. Lucente advised it would be a "disaster" for a woman to need revision surgery with Prolift. Hammons' Trial Exhibit 3404. At Ethicon's behest, Dr. Lucente interceded on Ethicon's behalf to persuade the American College of Obstetricians and Gynecologists to remove a designation of these mesh procedures as "experimental." Hammons' Trial Exhibits 2299, 3416. Ethicon paid Dr. Lucente over $1.7 million for his services in Pennsylvania, services that were relevant to Hammons' claims. Hammons' Trial Exhibit 3404. This evidence too provides an affiliation between Pennsylvania and Hammons' design defect claim, thus permitting exercise of specific jurisdiction over Ethicon in Pennsylvania. ***Bristol–Myers***, 137 S.Ct. at 1781; ***see also Cortina v. Bristol–Myers Squibb Company***, 2017 WL 2793808 at *3 (N.D.Cal. June 27, 2017) (two pharmaceutical companies were subject to specific jurisdiction in California based on clinical trials conducted in California that were relevant to plaintiff's claims and part of "causal chain" that led to plaintiff's injury); ***Symbolstix, LLC v. Smarty Ears, LLC***, 152 F.Supp.3d 1027, 1036 (N.D. Ohio 2015) (in copyright infringement action in Ohio, specific jurisdiction existed over Texas company that sold educational mobile device applications, where company's contacts with speech pathologists in Ohio were central to its product development and marketing strategies).

For these reasons, the trial court correctly denied Ethicon's motion to dismiss this action for lack of personal jurisdiction.[7]

STATUTE OF LIMITATIONS

Ethicon argues that the trial court erred in denying its post-trial motions seeking judgment n.o.v. on the ground that Hammons' action is time-barred under Indiana's two-year statute of limitations. Hammons counters that following her May 2009 surgery, Dr. Baker and Dr. Lackey failed to discover over the next several years that Prolift caused her injuries, and since these experienced physicians could not detect the problem, neither could she. She asserts that she only became aware that Prolift caused her injuries when Dr. Heit diagnosed the problem on August 30, 2012, less than two years before May 31, 2013, the date she filed suit.

As an appellate court, we must decide issues such as this by construing the evidence in the light most favorable to the verdict winner, Hammons. Construed in this light, the evidence establishes that August 16, 2011 was the earliest date on which Hammons had notice that Prolift caused her injuries.[8] Since this was less than two years before Hammons filed suit, ***1265** Ethicon's statute of limitation argument fails.

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.

Menkowitz v. Peerless Publications, Inc., 176 A.3d 968, 976–77 (Pa. Super. 2017) (*en banc*) (citation omitted). 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. at 977 (citation omitted).

The Indiana Products Liability Act ("IPLA") imposes liability upon a seller for physical harm caused by a "product in a defective condition unreasonably dangerous to any user or consumer" when:

> (1) the user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
>
> (2) the seller is engaged in the business of selling the product; and
>
> (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

Ind. Code § 34–20–2–1. In an action for design defect, "the party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product." Ind. Code § 34–20–2–2. For purposes of a design defect claim,

> [a] product is in a defective condition under [IPLA] if, at the time it is conveyed by the seller to another party, it is in a condition:
>
> (1) not contemplated by reasonable persons among those considered expected users or consumers of the product; and
>
> (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.

Ind. Code § 34–20–4–1.

In an action for failure to provide adequate warnings, a product is defective if the seller fails to: "(1) properly package or label the product to give reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use of the product; when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." Ind. Code § 34–20–4–2. The plaintiff must show the manufacturer "failed to exercise reasonable care under the circumstances ... in providing the warnings or instructions." Ind. Code § 34–20–2–2.

The IPLA provides that the defendant may raise defenses to product liability ***1266** claims. Ind. Code §§ 34–20–6–1 and 34–20–6–2. The burden of proving any defense is upon the defendant. Ind. Code § 34–20–6–2.

[3] Indiana Code § 34–20–3–1 provides that "any product liability action in which the theory of liability is negligence or strict liability in tort ... must be commenced within two (2) years after the cause of action accrues ..." Although the statute does not define "accrues," Indiana courts

have adopted a "discovery rule" under which "the two-year statute of limitations begins to run from the date the plaintiff knew or should have discovered that she suffered an injury or impingement, and that it was caused by the product or act of another." ***Degussa Corp. v. Mullens***, 744 N.E.2d 407, 410 (Ind. 2001). "[C]ase law regarding medical malpractice claims is instructive" in Indiana product liability cases, "because medical and diagnostic issues are common between the two actions, the statute of limitations for both claims is two years, and discovery is sometimes at issue in determining whether the respective statutes of limitation have been triggered." ***Id.***

In ***Degussa***, the leading Indiana case on this subject, the plaintiff suspected that workplace chemicals caused her persistent cough. On March 17, 1992, her primary care physician diagnosed her with bronchitis and told her that the cough might have several causes, including the workplace. On March 26, 1992, a specialist, Dr. Reihman, told the plaintiff that it was possible that work-related chemical exposure only was triggering an injury caused by something else. In June 1992, after performing tests, Dr. Reihman observed, "The etiology of [the plaintiff's] chronic airflow obstruction and its relationship to her work environment remains unclear." At about the same time, representatives from Degussa Corporation visited the plaintiff at work and told her that their product could not be causing her medical problems.

Dr. Reihman could not determine the cause of the plaintiff's problems and referred her to Dr. Garcia, a pulmonary specialist, for further evaluation. Dr. Garcia treated Mullens and attempted to diagnose her problems from June 1992 until March 1994, when he informed the plaintiff that her lung disease was caused by exposure to Degussa's chemicals in the workplace.

[4] **[5]** On March 25, 1994, the plaintiff filed suit against Degussa. Degussa argued that her lawsuit was time-barred because she did not file suit within two years after March 17, 1992, the date of her first visit with her primary care physician. The trial court denied Degussa's motion for summary judgment, but Indiana's intermediate Court of Appeals reversed. The plaintiff appealed to the Indiana Supreme Court, which reversed the Court of Appeals, and held that the trial court properly denied summary judgment to Degussa, and remanded for trial. The Supreme Court reasoned:

Although "[e]vents short of a doctor's diagnosis can provide a plaintiff with evidence of a reasonable possibility that another's" product caused his or her injuries, a plaintiff's mere suspicion or speculation that another's product caused the injuries is insufficient to trigger the statute. ***Evenson v. Osmose Wood Preserving Co. of Am.***, 899 F.2d 701, 705 (7th Cir. 1990) (applying Indiana law). While [the plaintiff] might have suspected that a chemical from work was the cause of her problems when she first visited Dr. Watkins on March 17, 1992, the best that Dr. Watkins could do to respond to her concerns was to emphasize that there were a range of potential causes. ***See id.*** ("Although [plaintiff] himself suspected at this time [(the time of his visit to the ***1267** doctor and request for CCA chemical tests)] that CCA was the culprit, his attempts to determine the actual cause were rebuffed by his doctors in whom he could place some reliance. What [plaintiff] had ... was not some evidence of a reasonable possibility that CCA was the cause but only a layman's mere suspicion to this effect.")

Circumstances where a physician tells a patient that a product or act is one of several "possible" causes of an injury present a complex of factually and legally relevant questions about how the physician conveyed the information to the patient and what emphasis the physician placed on the potentially tortious cause over other causes. Nevertheless, [the plaintiff] was responsible and diligently followed her physician's recommendations, undergoing further tests and attempting to gather information regarding the cause of her medical problem and its relationship to past respiratory ailments before initiating a lawsuit against Defendants. [The plaintiff] attempted to gather information that would transform speculation into a causal link that was "reasonably possible" or "probable" before she filed suit against Defendants.

On March 17, 1992, [the plaintiff] merely suspected that work products had something to do with her illness and Dr. Watkins said nothing to confirm, deny, or even strengthen her suspicions. In light of the ongoing medical consultation that [the plaintiff] undertook between March 17, 1992, and March 25, 1994, the date [the plaintiff] filed her complaint, we do not believe that the statute was triggered as late as March, 1994, as argued by [the plaintiff]. However, we also see nothing in the record to indicate that on March 17, 1992 (or even

> in the following eight days that would have been outside of the statutory period), [the plaintiff]'s physicians had yet informed her that there was a reasonable possibility, if not probability, that her ailments were caused by work chemicals.

Id., 744 N.E.2d at 411–12.[9] "A reasonable possibility, while less than a probability, requires more than ... mere suspicion." ***Evenson***, 899 F.2d at 705. The discovery rule is objective in nature—that is, the test is not what Hammons knew or suspected, but what would have caused a person of reasonable diligence to take action that would lead to the discovery of her cause of action. ***Anonymous Physician v. Wininger***, 998 N.E.2d 749, 751–52 (Ind. App. 2013); ***Morgan v. Columbus McKinnon Corp.***, 837 N.E.2d 546, 550 (Ind. App. 2005).

[6] **[7]** When the defendant raises the statute of limitations as an affirmative defense, the defendant bears the burden of establishing that the plaintiff filed her action beyond the limitation period. ***McDaniel v. Erdel***, 91 N.E.3d 617, 624 (Ind. App. 2017). If the defendant fulfills this burden, the burden shifts to the plaintiff to establish "an issue of fact material to a theory that avoids the defense," ***id.***, such as the discovery rule.[10] The court can resolve a ***1268** discovery rule issue as a question of law when no material issues of fact are in dispute. ***Kerr v. City of South Bend***, 48 N.E.3d 348, 353 (Ind. App. 2015).[11] When issues of fact remain in dispute, the jury should resolve the discovery rule question. ***Allied Resin Corp. v. Waltz***, 574 N.E.2d 913, 915 (Ind. 1991). When the jury returns a verdict in favor of the plaintiff, the burden shifts back to the defendant at the post-trial stage. To obtain judgment n.o.v., the defendant must demonstrate that even with all factual inferences decided against it, the law nonetheless requires a verdict in its favor on the discovery rule issue. ***Menkowitz***, 176 A.3d at 976–77.

Hammons commenced this action on May 31, 2013. To obtain judgment n.o.v. on its statute of limitations defense, Ethicon had to demonstrate, as a matter of law, that the evidence provided a person of reasonable diligence with a "reasonable possibility" before May 31, 2011 to believe that Prolift caused Hammons' injuries. ***Degussa***, 744 N.E.2d at 411. The evidence does not support this result.

Hammons presented evidence that after her implant surgery on May 5, 2009, she visited Dr. Baker five times over the next few months and reported pelvic pain and urinary and sexual dysfunction. Dr. Baker never attributed these symptoms to Prolift; in fact, he gave her no answers at all. Hammons testified:

> Q. So when you went to see Dr. Baker and you and Mr. Wilson had tried to engage in intercourse and it was painful for you, when you went to see Dr. Baker, you told him about that; is that right?
>
> **A.** Yes, I did.
>
> **Q.** And I understand you feel as if he wasn't responsive to you. He couldn't give you any answers; is that correct?
>
> **A.** That's right.

N.T., 12/11/15 (P.M.), at 34; ***see also id.*** at 36 ("I told him that we couldn't have [a sexual] relationship. I asked him how come I couldn't have sex? And he never did answer me"). Hammons' expert, Ralph Zipper, M.D., reviewed notes of her treating physicians and explained that Dr. Baker's notes did not indicate awareness that the symptoms were mesh-related. Instead, Dr. Baker noted that Hammons' surgery and post-operational healing went very well, and he observed "no erosion." When Hammons returned with complaints of pelvic pain, incontinence, and sexual dysfunction, Dr. Baker offered no explanation and recommended waiting for additional recovery before engaging in sexual intercourse. N.T., 12/11/15 (P.M.) at 97–102; N.T., 12/10/15 (A.M.) at 37–52; P–3418 at 15–20.

Hammons visited Dr. Lackey after Dr. Baker failed to offer a remedy, and Dr. Lackey diagnosed rectocele (rectal prolapse), pelvic pressure and pain with intercourse. On December 15, 2009, he surgically repaired the rectocele with Hammons' own tissue. His post-operative note did not mention the Prolift device; nor was he aware that the product implanted in Hammons was from Prolift. On January 28, 2010, Dr. Lackey cleared Hammons to resume sexual intercourse. It does not appear that Hammons visited Dr. Lackey again (or another physician) before May 31, 2011.

[8] Accepting this evidence as true, we hold that the trial court properly denied judgment n.o.v. on the statute of limitations ***1269** issue. The parties hotly disputed whether Hammons knew, or should have known through the exercise of reasonable diligence, that her symptoms were a manifestation of injury caused by Prolift, as

opposed to, or in addition to, the typical condition that surgery produces. Ethicon argued that a reasonable person in Hammons' position would have realized the possibility that Prolift was to blame, given her prolonged and persistent post-surgical pain and incontinence. The evidence shows, however, that as of January 28, 2010, two experienced gynecologists failed to diagnose Prolift as the cause of her 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. Nor does the record include any fact between January 28, 2010 and May 31, 2011 that placed Hammons on notice that Prolift caused her injuries. Although we recognize that "events short of a doctor's diagnosis can provide a plaintiff with evidence of a reasonable possibility that another's product caused her injuries," ***Degussa***, 744 N.E.2d at 411, we do not see any events here that established this possibility as a matter of law prior to the limitation period. It was proper for the jury to resolve this fact-sensitive question.

Ethicon argues that on August 16, 2011, Hammons signed a form authorizing the release of Hammons' "implant related medical records" for use in "plaintiff litigation for product liability." DTX–42; N.T., 12/11/15 (PM), at 63. This language, Ethicon contends, established a "reasonable possibility" as of this date that Prolift was the cause of her injuries. ***Degussa***, 744 N.E.2d at 411. This alone, however, did not entitle Ethicon to judgment n.o.v. because less than two years elapsed between August 16, 2011 and the date Hammons filed this lawsuit, May 31, 2013.

Recognizing this fact, Ethicon argues that the authorization form demonstrates the existence of a "reasonable possibility" **more than** two years before Hammons filed suit, because Hammons "identifies no ... new facts that allegedly put her on notice *after* her apparent and persistent symptoms in 2009 but *before* the August 16, 2011 release of records." Ethicon's Reply Brief at 14 (emphasis in original). We disagree. As discussed above, viewed in the light most favorable to the verdict winner, Hammons, the evidence demonstrates the jury could conclude that as of January 28, 2010, the date Dr. Lackey cleared Hammons to resume sexual intercourse, she was not on notice of a "reasonable possibility" that Prolift caused her injuries. Further, contrary to Ethicon's argument, Hammons did not have the burden at the post-trial stage to disprove that some "new fact" put her on notice "before the August 16, 2011 release of records." Instead, Ethicon had the burden at the post-trial stage to identify this "new fact" in the record. Ethicon has not met this burden. Based on the language in the release form, Ethicon speculates that Hammons could not suddenly have had an epiphany about Prolift on August 16, 2011. She had to have realized earlier that something was wrong with the device. But when did she arrive at this realization? The record does not say. Without some fact of record that proves notice arose before May 31, 2011, Ethicon cannot obtain judgment n.o.v. on the statute of limitations issue.

ADEQUACY OF WARNINGS

Ethicon argues that it is entitled to judgment n.o.v. because Hammons failed to prove that Ethicon's warnings were inadequate. We disagree.

As stated above, Hammons had the duty to prove that Ethicon failed to "(1) properly package or label the product to give ***1270** reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use of the product; when [Ethicon], by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." Ind. Code § 34–20–4–2.

[9] The duty to warn arises because a product manufacturer should have superior knowledge of its product. ***Nat. Gas Odorizing, Inc. v. Downs***, 685 N.E.2d 155, 163 (Ind. App. 1997). Because "the injured person is helpless to protect himself from the actually defective product, it is only reasonable therefore that as between the injured user and the one who places the product on the market the latter should bear the loss." ***Ortho Pharm. Corp. v. Chapman***, 180 Ind.App. 33, 388 N.E.2d 541, 548 (1979). A manufacturer may not delegate its duty to warn. ***Nat. Gas Odorizing***, 685 N.E.2d at 163 & n.10.

[10] **[11]** Indiana follows the learned intermediary doctrine, under which Ethicon's duty to warn for a prescription-only product like Prolift "extends only to the medical profession, and not the ultimate users." ***Ortho Pharm. Corp.***, 388 N.E.2d at 548–59. A manufacturer "ha[s] no duty to warn with respect to such potential [risks] ... already known to the user, the operating surgeon," or those risks about which the surgeon should

know. ***Phelps v. Sherwood Med. Indus.***, 836 F.2d 296, 300, 303–04, 305 (7th Cir. 1987).

[12] **[13]** **[14]** **[15]** To determine whether a manufacturer has satisfied its duty to warn by relying upon a sophisticated intermediary, courts should consider the following factors:

> [T]he likelihood or unlikelihood that harm will occur if the [intermediary] does not pass on the warning to the ultimate user, the trivial nature of the probable harm, the probability or improbability that the particular [intermediary] will not pass on the warning and the ease or burden of the giving of the warning by the manufacturer to the ultimate user.

Nat. Gas Odorizing, 685 N.E.2d at 163. Further, for the exception to apply, "the intermediary must have knowledge or sophistication equal to that of the manufacturer or supplier, and the manufacturer must be able to rely reasonably on the intermediary to warn the ultimate consumer." ***Id.*** at 164. Reliance is only reasonable if the intermediary knows or should know of the product's dangers. ***Id.*** Actual or constructive knowledge may arise where either the supplier has provided an adequate explicit warning of such dangers or the information of the product's dangers is available in the public domain. ***Id.*** Of note here,

> whether a manufacturer has discharged its duty under the sophisticated intermediary doctrine is almost always a question for the trier of fact. The manufacturer's reliance on the intermediary's alleged sophistication may be more or less reasonable given the product's nature, complexity and associated dangers, the likelihood that the intermediary will communicate warnings to the ultimate consumer, the dangers posed to the ultimate consumer by an inadequate or nonexistent warning, and the feasibility of requiring the manufacturer to directly warn the product's ultimate consumers. Ultimately, those factors must be balanced by the trier of fact.

Id.

[16] With these standards in place, we turn to the evidence adduced during trial. Viewed in the light most favorable to Hammons, the verdict winner, the evidence shows that at the time of Prolift's product launch in March 2005, Ethicon was aware of serious risks caused by Prolift but failed to make these risks clear in its ***1271** indications for use ("IFU") and patient brochures.

In March 2005, Ethicon began marketing Prolift. Concurrent with this product launch, Ethicon issued an IFU which stated:

> WARNINGS AND PRECAUTIONS
>
> * * * *
>
> Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
>
> Avoid placing excessive tension on the mesh implant during handling.
>
> * * * *
>
> The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
>
> Transient leg pain may occur and can usually be managed with mild analgesics.
>
> Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.
>
> ADVERSE REACTIONS

> Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
>
> Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

P–1005, at 5–6; P–1010.

Ethicon's Prolift brochures used similar language, calling the risks "rare." Ethicon encouraged women to make their own decisions regarding prolapse, without providing any information concerning the crucial risks associated with the product, but warning only about the risks of surgery:

> What are the risks? All surgical procedures present some risks. Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.

P–2881 at 6–8. The purpose of the patient brochure was to facilitate discussions between the patient and her physician about the benefits and risks of the Prolift system. P–3415, at 458–59.

The IFU and brochures failed to disclose the full extent of the risks posed by Prolift—risks that Ethicon knew about prior to the March 2005 product launch. In November 2004, French surgeons who had been using the Prolift kit for several years published an article addressing Gynemesh Soft, the same mesh material used in the Prolift system, opining that retraction was impossible to forecast and highly variable and that its after-effects included dyspareunia (painful sexual intercourse). On January 11, 2005, before the product launch of the Prolift kit, Axel Arnaud, the scientific director of Gynecare Europe, sent an email to Ophelie Berthier, the product director who oversaw the marketing launch of Prolift worldwide, proposing to add the following warning to the IFU:

> Warning: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggests the risk of such a complication is ***1272** increased in cases of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

P–3401, at 566–68. Berthier advised it was urgent to incorporate the changes in the IFU version in the procedure CD–ROM. Berthier's email was forwarded to Charlotte Owens, M.D., Ethicon's worldwide medical director at the time of the product launch in 2005, and Sean O'Bryan, Ethicon's senior project manager for regulatory affairs, along with a question whether it was acceptable to add this warning without FDA approval. On January 13, 2005, O'Bryan responded that he would leave it to Owens and Arnaud to decide. P–3412, at 146. Scott Ciarrocca, the project's research and development project leader, replied several minutes later, "We have already printed launch stock. This would be a next revision addition, but they want it in there ASAP." ***Id.*** at 148. Thus, Ethicon rejected Arnaud's suggestion because incorporating it into the IFU would require replacing the previously printed IFU's, thus incurring additional costs and delaying the product launch. ***Id.*** at 148, 154–55.

Owens testified that she understood the IFU had to be clear, unambiguous, accurate, and supported by data, and she claimed the IFU communicated all contraindications, warnings, precautions, and adverse reactions to physicians. P–3413, at 260–62. Owens acknowledged that she approved the IFU even though she knew there might be long-term complications. ***Id.*** at 254–55. On January 14, 2005, Owens issued a clinical

expert report to document the safety and functionality of the Prolift system to treat pelvic floor repair. She relied on a Gynemesh PS clinical study performed by physicians using Gynemesh PS for vaginal and abdominal placements. Her report on Prolift listed the same potential complications identified in the Gynemesh PS study, such as "[i]nfection, mesh exposure, fistula, hematoma, and contraction." P–3413, at 197–99. She reported there were no instances of tissue contraction in the Gynemesh clinical evaluation. ***Id.*** But at the time Owens authored this clinical expert report, she was familiar with the 2004 article published by the French surgeons that identified retraction as a potential complication along with such aftereffects as severe pain. Owens did not cite the French surgeons' article in her report or discuss the possibility of retraction. ***Id.*** She admitted that before Prolift's market launch, she knew the mesh could erode, migrate, or lead to inflammation, and that removal of mesh could be very difficult even though Ethicon did not conduct studies on how to remove it. ***Id.*** at 310–312.

Likewise, Piet Hinoul, M.D.—an urogynecologist who joined Gynecare in 2008 as a worldwide medical director —confirmed that on the day of the launch Ethicon was aware of potential complications, such as urinary incontinence, urinary retention or obstruction, ureteral obstruction, voiding dysfunction, pain, pelvic pain, and pain with intercourse. P–3404, at 382–83.

Dr. Elliott, one of Hammons' expert witnesses, reviewed Ethicon's IFU, sales brochures, and internal documents and testified that Ethicon's warnings were inadequate because they failed to convey Prolift's full risk profile, namely, "all the known complications, their severity, their frequency." He explained that by May 2009, Ethicon knew Prolift posed significant risk to women on various issues: chronic, severe, and progressive inflammation; failure to integrate into tissue; scar plate and fibriotic bridge formation; excessive mesh contraction; pain during sexual activity and ambulation; recurrent exposure of mesh; chronic pelvic floor muscle spasms; chronic urinary and sexual dysfunction; and additional surgeries for mesh removal. P–3401 at 3–9, 18–20; P–3402 ***1273** at 37–48; P–3403, at 5–7; P–3404, at 12–17; P–3413 at 6–10; P–3415 at 2–6.

Dr. Klinge, another expert witness for Hammons, testified that physicians are "dependent on the information that is provided by the manufacturer for the long-term risks or for the risks that are connected to th[e] device. There is no other way to get this information." P–3408. The medical device manufacturer has the duty to warn treating physicians about serious adverse events caused by the device so that the physician can have an appropriate risk-benefit discussion with the patient. P–3408 at 203–09.

Testimony from other Ethicon employees revealed that Ethicon controlled information that reached physicians through other channels. Ethicon trained physicians on Prolift implantation but educated them only about risks disclosed in the IFU. Ethicon also controlled the message in published medical literature and diluted input from independent clinicians on the safety and efficacy of Prolift. P–3414 at 2; P–3416 at 1–7.

The evidence shows that Ethicon failed to disclose the risks inherent in Prolift to Dr. Baker, who implanted the Prolift device. Dr. Baker testified he depended upon Ethicon for information about Prolift's risks, and that he relied upon Ethicon's IFU and brochures to recommend Prolift to Hammons. In 2006, Dr. Baker received training from Ethicon to perform the procedure. He had no other independent knowledge of Prolift's risks or performance. Dr. Baker stated that had he known about the high risk of severe and permanent complications from Prolift, he would not have offered it to Hammons. P–3418 at 2–26. Dr. Elliott testified that Ethicon should have "absolutely" included these warnings in the IFU. He added that Prolift is not appropriate for most women, but only those with high-grade recurring prolapse. He testified that the IFU and marketing documents affirmatively misled treating physicians, because it warned of only minimal inflammatory reaction, normal healing, limited scarring, rare complications and transient pain. The IFU misrepresented that Prolift did not degrade and remained. P–3401 at 7–8; P–3402 at 37–52; P–3408 at 15–17; P–3409 at 2–7.

Viewed in the light most favorable to Hammons, the verdict winner, this evidence establishes that Ethicon failed to provide adequate warnings to Dr. Baker about the risks of Prolift, and that Dr. Baker neither knew nor should have known independently about these risks. Ethicon led Dr. Baker to believe that the risks of the device were not nearly as serious as they actually were. As a result, he did not convey the full extent of the risks to Hammons.

Ethicon argues that Dr. Baker's notes following Hammons' initial surgery in 2009 demonstrate that he fully advised her of the risks: "I discussed the ... risk of injury to bowel, bladder or ureter as well as ... having pain with intercourse or other types of pain following surgery. [Hammons] agreed to these risks ..." DTX–37 at 208–09. In making this argument, Ethicon construes the evidence in the light most favorable to itself instead of in the light most favorable to Hammons, the correct standard. Ethicon ignores Hammons' testimony that Dr. Baker did not inform her of the risks and Dr. Baker's testimony that Ethicon did not advise him of the extent of the risks posed by Prolift. Moreover, Ethicon failed to establish, as a matter of law, that Dr. Baker was on constructive notice of Prolift's risks, *i.e.*, that he should have realized the risks even if Ethicon failed to expressly identify them. As a result, he could not convey to Hammons the severe and permanent risks of the device. He would not have recommended ***1274** the device to Hammons had he known of the actual risks.

There was sufficient evidence for the duty to warn issue to go to the jury in this case. The jury was free to determine, as it did, that Ethicon violated its duty to warn Hammons' physician about the risks of Prolift. The trial court properly denied Ethicon's motion for judgment n.o.v. on this issue.

SAFER ALTERNATIVE DESIGN

[17] In its next two arguments, Ethicon asserts that (1) Hammons' design defect claim fails as a matter of law, thus entitling Ethicon to judgment n.o.v., because Hammons failed to prove the existence of a feasible safer alternative design, and (2) the trial court erred by failing to instruct the jury that Hammons was required to prove that a safer alternative design was available. We disagree with both arguments. The IPLA does not require proof of a safer alternative design. Even if it did, Hammons provided evidence that a safer alternative design existed during the relevant time period in this case.

Earlier this year, the United States District Court for the Northern District of Indiana, Hammond Division, comprehensively discussed this issue in another action against Ethicon involving Prolift, ***Kaiser v. Johnson & Johnson***, 2018 WL 739871 (N.D. Ind., Feb. 7, 2018). The district court's excellent analysis deserves recitation.

The district court began by describing the original version of the IPLA and important amendments to this act in 1995:

> In 1978, the Indiana Legislature enacted the IPLA. At the time, the IPLA provided that it "govern[s] all products liability actions, including those in which the theory of liability is negligence or strict liability in tort; provided however, that this chapter does not apply to actions arising from or based upon any alleged breach of warranty." Ind. Code § 33–1–1.5–1 (1978). While the IPLA codified most aspects of the Restatement (Second) on Torts § 402A regarding strict liability, it spoke nothing of the treatment of actions sounding in negligence. As a result, the IPLA left claims based on negligence to the common law. ***See Corbin v. Coleco Industries, Inc.***, 748 F.2d 411, 416–17 (7th Cir. 1984) (discussing the history of the IPLA). In 1983, the IPLA was amended, removing the reference to negligence actions, presumably recognizing the confusion that was created by the Indiana Legislature in 1978. ***See*** Ind. Code § 33–1–1.5–1 (1983) ("[T]his chapter governs all actions in which the theory of liability is strict liability in tort."); ***Miller v. Todd***, 551 N.E.2d 1139, 1143 (Ind. 1990) (discussing the history of the IPLA); ***Moore v. Sitzmark Corp.***, 555 N.E.2d 1305, 1308 (Ind. App. 1990) ("[A]n action [for negligent design] is not subject to the terms of the Indiana Product Liability Act; rather, it is a common law action.").
>
> In 1995, the IPLA was amended yet again. The idea was to bring all product liability actions under one umbrella. The 1995 version specifically applies to "all actions brought by a user or consumer against a manufacturer or seller for physical harm caused by a product regardless of the substantive legal theory or theories upon which the action is brought." ***See*** Ind. Code § 33–1–1.5–1 (1995); P.L. 278–1995, Sec. 1 (effective July 1, 1995). The 1995 amendments brought some much needed clarity to product liability cases in Indiana by eliminating strict liability claims for all design defect and failure to warn claims and instead imposing a negligence standard in all such cases. It did so by adding the "reasonable care" language, quoted above, that remains in effect today. ***See*** Ind. Code § 33–1–1.5–3 (1995); ***1275** P.L. 278–1995, Sec. 1 (effective July 1, 1995). In 1998, the IPLA was amended once more, but this amendment did nothing more than move

the IPLA to Title 34. ***See*** Ind. Code §§ 34–20–1–1 to 34–20–9–1.

What this history shows us is that, until 1995, the standard for product liability claims sounding in negligence was established by the common law. During that time, the Courts held that, under Indiana law, a plaintiff "must offer a safer, more practicable product design than the design in question" to succeed on a negligent design defect claim. ***Whitted v. General Motors Corp.***, 58 F.3d 1200, 1206 (7th Cir. 1995) (citing ***Miller v. Todd***, 551 N.E.2d 1139, 1143 (Ind. 1990)). Therefore, until July 1, 1995, a plaintiff was required to show that a safer alternative design to succeed on a negligent design defect claim.

I cite to ***Whitted*** for this explanation quite intentionally. It was decided on June 29, 1995, before the 1995 amendments establishing the negligence standard for design defect and failure to warn cases went into effect. Yet ***Whitted***, or in a few circumstances its contemporaries or progeny, is the case relied upon in most of the authority on which Ethicon relies for its assertion that proof of safer alternative design continues to be a required element of a negligent design defect claim. ***See***, ***e.g.***, ***Simmons v. Philips Elec. N. Am. Corp.***, No. 2:12-CV-39-TLS, 2015 WL 1418772 (N.D. Ind. Mar. 27, 2015) (quoting ***Whitted***); ***Hathaway v. Cintas Corp. Serv. Inc.***, 903 F.Supp.2d 669, 675 (N.D. Ind. 2012) (quoting ***Whitted***); ***McClellon v. Thermo King Corp.***, 2013 WL 6571946, at *10 (S.D. Ind. 2013) (quoting ***Whitted*** and citing ***Barnard v. Saturn Corp., a Div. of General Motors Corp.***, 790 N.E.2d 1023, 1032 (Ind. App. 2003), which relies on a 1989 Indiana Court of Appeals case applying the old statute); ***Hartman v. EBSCO Industries, Inc.***, 2013 WL 5460296, at *7 (N.D. Ind. 2013) (quoting ***Rodefer v. Hill's Pet Nutrition, Inc.***, No. IP 01-123-C H/K, 2003 WL 23096486, at *9 (S.D. Ind. Nov. 7, 2003), which cites ***Whitted***). In fact, it appears that all of the authority cited by Ethicon in support of its argument that a safer alternative design is a *prima facie* element of a negligent design defect claim traces back to pre–1995 amendment to the IPLA.

Kaiser, 2018 WL 739871, at *3–4.

The district court then explained that the Indiana Supreme Court held in 2010 that the IPLA did not require proof of a safer alternative:

Admittedly, the Indiana Legislature was not particularly clear in 1995 regarding whether it intended to completely do away with the safer alternative design requirement. As a result, many federal and state courts in Indiana held course and continued to require it as an element of a plaintiff's negligent design defect claim. But matters changed in 2010 when the Indiana Supreme Court finally addressed the issue. In ***TRW Vehicle Safety Systems, Inc. v. Moore***, 936 N.E.2d 201 (Ind. 2010), the plaintiff brought a negligent design defect claim, among others, against the defendant seatbelt manufacturer, TRW, and the defendant vehicle manufacturer, Ford, after the plaintiff's decedent was ejected through the sunroof of his vehicle when his seatbelt developed slack in a rollover that followed a tire failure. ***TRW Vehicle Safety Systems, Inc.***, 936 N.E.2d at 208. The jury apportioned 5% of the fault to TRW and 31% of the fault to Ford. ***Id.*** The Court of Appeals reversed, finding insufficient evidence to support the jury's verdict. ***Id.*** The Indiana Supreme Court disagreed.

1276** Ford and TRW argued that the evidence presented at trial was insufficient because it failed to establish the requisite standard of care and prove that their conduct fell below that. ***Id. at 208–209. Specifically, they argued that plaintiff failed to present evidence of the proper standard of care, to offer testing, data, studies, or other evidence to show a safer, more practicable product design, and to rebut evidence that its proposed alternative design itself presented safety concerns. ***Id.*** at 209. In response, the Indiana Supreme Court explained:

The [IPLA] generally imposes strict liability for physical harm caused by a product in an unreasonably dangerous defective condition. Ind. Code § 34–20–2–1. For actions based on an alleged product design defect, however, the Act departs from strict liability and specifies a different standard of proof: '[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product.' Ind. Code § 34–20–2–2. Thus the statute itself prescribes the applicable standard of care. We decline to require proof of any additional or more particular standard of care in product liability actions alleging a design defect.

Id. at [209]. The opinion included a footnote at the end of the last sentence that reads:

> The American Law Institute recommends a different approach, prescribing specific sub-elements of a claim for strict product liability based on design defect. It views a product as 'defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.' Restatement (Third) of Torts: Products Liability § 2(b) (1997). Our legislature did not adopt this analytical framework but instead enacted in 1998 a negligence standard for product liability claims based on defective design. ***See*** Ind. Code § 34–20–2–2.

Id. at 209 n.2. The Indiana Supreme Court, therefore, plainly held that proof of alternative design is not required under Indiana law. It may, however, be probative evidence of the defendant's use of reasonable care. *Id.* at 209.

Id. at *4–5.

The district court concluded that it was bound to apply the Indiana Supreme Court's decision in ***TRW***, and that other decisions to the contrary rested on outdated common law:

> One would think that ***TRW*** put to bed the question of whether, under Indiana law, a safer alternative design is a necessary element of a design defect claim. But in the eight years that followed that decision, many state and federal courts in Indiana continued to find that proof of alternative design is required for a design defect claim, citing to ***Whitted*** or its progeny in support of that assertion. These courts are, therefore, relying on outdated common law, which was superseded by the negligence standard spelled out in the 1995 amendments to the IPLA as confirmed by the Indiana Supreme Court in ***TRW*** ... [T]he Indiana Supreme Court could not have been any clearer in ***TRW*** in holding that proof of an safer alternative design is not required under the IPLA. As the Indiana Supreme Court correctly pointed out in ***TRW***, the Indiana Legislature could have adopted the standard set out in the Restatement (requiring proof of safer alternative design), but it chose ***1277** not to. ***TRW Vehicle Safety Systems, Inc.***, 936 N.E.2d at 209 n.2. It has not chosen to amend that language to add in a safer alternative design requirement in the eight years since the Indiana Supreme Court decided ***TRW***.

What nails the point home that proof of a safer alternative design is not required under Indiana law is the fact that the Indiana Model Civil Jury Instructions do not say a single thing that suggests that proof of a safer alternative design is an element of a negligence product liability claim. ***See*** Indiana Model Civil Jury Instruction 2305. One would think that if proof of a safer alternative design was required in Indiana design defect cases, the Indiana Model Civil Jury Instructions would reflect that fact. Yet they don't say boo about it.

Other courts have read ***TRW*** in the same way as I do. In ***Hammons v. Ethicon, Inc. et al.***, No. 1305003913, 2016 WL 6821815 (Pa. Com. Pl. Sept. 30, 2016), [12] a case involving an Indiana woman implanted with Ethicon's Prolift device, the Court of Common Pleas of [Philadelphia County] held that proof of an alternative design is not a required element under Indiana law. Citing and quoting ***TRW***, that court ultimately held that, under Indiana law, "[t]estimony of an alternative design can be probative evidence as to the issue of the defendant's failure to use reasonable care and can support a reasonable inference of negligent design but is not [a] requirement." ***Hammons***, 2016 WL 6821815 at *5.

Likewise, in ***Bailey v. Cottrell, Inc.***, [313 Ga.App. 371] 721 S.E.2d 571 ([Ga. Ct. App.] 2011), a Georgia case interpreting Indiana law, the court held that Indiana specifically has rejected a risk utility test in favor of a common law negligence analysis. One of the factors under the risk utility test is whether there is a safer alternative design. But as the Georgia Court of Appeals recognized, the risk utility test was jettisoned in Indiana in favor of a straight-forward negligence approach. In arriving at that conclusion, the Georgia court cited to the Indiana Supreme Court's analysis in ***TRW*** and its explicit rejection of the Restatement (Third) of Torts: Products Liability § 2(b) (1997). ***Bailey***, 721 S.E.2d at 574–75 (citing ***TRW Vehicle Safety Systems v. Moore***, 936 N.E.2d at 209, n.2.).

While the road to ***TRW*** admittedly was rocky, and confusion still remains in this state, I believe that

> the Indiana Supreme Court has made itself clear. As a result, I agree with the Kaisers that proof of safer alternative design is not a *prima facie* requirement of their case. To hold otherwise would be in contradiction of the clear Indiana Supreme Court precedent established in ***TRW***, to which I am bound.

Id. at *5–*6. We agree with ***Kaiser's*** thorough analysis and hold that the IPLA does not require proof of a safer alternative design.

As it did in ***Kaiser***, Ethicon relies on pre-***TRW*** decisions that rest on outdated common law and on post-***TRW*** decisions that rely on pre-***TRW*** cases. Ethicon also attempts to downplay footnote 2 in ***TRW*** as "[doing] little other than not[ing] that Indiana had yet to adopt the Restatement (Third) of Torts." Ethicon's Reply Brief at 20. Ethicon overlooks the precept that the Indiana Supreme Court is "mindful of both what [a statute] 'does say' and what it 'does not say.' " ***Indiana Alcohol and Tobacco Commission v. Spirited Sales, LLC***, 79 N.E.3d 371, 376 (Ind. 2017) (citation omitted). The Supreme Court's purpose in footnote 2 of ***TRW*** was to show ***1278** what the 1995 amendment to the IPLA did not say—that is, the legislature excluded "safer alternative" language to signify its rejection of this element.

[18] Even if a "safer alternative" was necessary, Hammons introduced evidence that such a product was available, the Prolift+M kit. In January 2005, before Prolift's product launch, Ethicon engineer Gene Kammerer suggested the possibility of using Ultrapro mesh for pelvic floor repair in place of Gynemesh. In an email dated April 13, 2005, he wrote that surgeons and customers wanted a better mesh to reduce contraction and scar tissue and that Ultrapro would make the procedure better for patients and give Ethicon a significant advantage over the competition. Kammerer said Ultrapro had a lower inflammatory response, left behind less material than Prolene Soft, and had a larger pore size than Gynemesh PS to better allow the ingrowth of tissue and reduce the risk of scar plating and contraction. Over the next four years, Ethicon developed Ultrapro mesh for pelvic floor repair, which it marketed as the Prolift+M Pelvic Floor Repair System. One of Prolift's inventors, Dr. Cosson, developed the Ultrapro mesh before Hammons' initial implant surgery. N.T., 12/7/15 (A.M.), at 57–95; N.T., 12/7/15 (P.M.), at 237–48; P–3401 at 2–3; P–3404 at 9; P–3407 at 4, 12; P–1318, 3373, 3381.

In short, Ethicon's request for judgment n.o.v. fails, as does its claim that the trial court erred by declining to give a safer alternative design instruction to the jury.

CAUSATION

Ethicon argues that Hammons failed to establish that a defect in Prolift caused her injuries. We disagree.

[19] Hammons introduced the causation testimony of Ralph Zipper, M.D., an expert in urogynecology, including pelvic reconstructive surgery, vaginal mesh, vaginal mesh procedures, and Prolift. Dr. Zipper reviewed Hammons' medical history, the records of her treating physicians, and performed a physical examination, all of which he described for the jury. N.T., 12/9/15 (P.M.), at 24, 29–163. Dr. Zipper testified that Hammons presented to Dr. Baker with anterior pelvic organ prolapse. At that time, he explained, Hammons' bladder bulged just beyond the opening of her vagina. She experienced no pain, dyspareunia, or incontinence. She experienced these symptoms several weeks after implantation. Dr. Zipper explained that implantation with Prolift generated a chronic and progressive chain of inflammation, scar plate formation, tissue contraction and erosion, deformation of the vagina and pain. Dr. Zipper added that the mesh had eroded through Hammons' vaginal wall and adhered to the bladder, causing her bladder to lose elasticity and creating urinary symptoms. Because of her vaginal scars, Hammons lost elasticity and length in her vagina and experienced severe dyspareunia and permanent sexual dysfunction. ***Id.*** at 29–32, 117–32.

Dr. Zipper excluded other potential causes of injury such as error by Dr. Baker. He testified that Dr. Baker followed Ethicon-established protocol when implanting the Prolift device and also performed optional procedures recommended by Ethicon to increase the chances of success. He noted that Dr. Heit's examination of Hammons confirmed that Dr. Baker performed the mesh implantation procedure correctly. ***Id.*** at 39–40, 97–104, 155.

Dr. Zipper testified that Hammons has a poor prognosis. Her injuries continued after Dr. Heit removed part of the mesh, since part of the mesh remains embedded in her bladder. She has tenderness near the top of her vagina

and underneath her bladder and a recurrence of prolapse for multiple organs. Her vagina is significantly ***1279** foreshortened and has everted, or turned inside out. She also lost bladder capacity and has bladder spasms. She developed worsening of urgency and frequency of urination. Her dyspareunia and sexual dysfunction has continued since her initial surgery in May 2009. ***Id.*** at 134, 142–52.

Dr. Zipper opined that Hammons has few choices for further treatment because there are no reasonable surgical or nonsurgical means to cure her urinary and sexual dysfunction. Her pain and bladder-related complications can be alleviated to some extent but not treated. ***Id.*** at 161–63.

Taken as a whole, this evidence sufficed to present the question of causation to the jury. Although Ethicon contends that Dr. Zipper failed to identify a specific defect of Prolift that caused her injuries, we find he testified with the requisite degree of precision. He observed that the Prolift mesh "degrades" and has a "tendency to cause prolapse in areas where you're not even operating." N.T., 12/9/15 (P.M.), at 31. He added that the device "did what we now know mesh and mesh with arms does. It contracted and it pulled and it caused pain and it caused pain with intercourse that just didn't go away. And it also caused prolapse in other areas of her vagina." ***Id.*** at 30. Pelvic mesh, Dr. Zipper said, needs to be both soft and durable. N.T., 12/10/15, at 64. Prolift mesh, he stated, was not soft, ***id.***, and therefore caused injury.

Ethicon argues that Dr. Zipper failed to rule out Dr. Baker's surgical technique as the cause of Hammons' injuries. The evidence demonstrates otherwise. Dr. Zipper testified that Dr. Baker attended Ethicon's training and performed Plaintiff's Prolift implant as recommended by Ethicon by securing the mesh to the apex of the vagina. Dr. Zipper also explained that Dr. Heit found the mesh "bunched in the midline under the bladder neck and distal bladder base," and that this bunching demonstrated that the mesh was defective rather than improperly placed. N.T., 12/9/15 (A.M.) at 40–41; 74, 98–102. Dr. Zipper concluded that "every bit of the medical record shows that [Prolift] was put in correctly. It's only years later that someone [Ethicon] suggested it wasn't." N.T., 12/10/15 (P.M.), at 50. Ethicon points to testimony by other physicians that mesh bunches only because of surgical error, not defects in the mesh itself. Ethicon's Opening Brief at 42. Once again, Ethicon construes the evidence in the light most favorable to itself, the incorrect standard at the judgment n.o.v. and appellate stages of review. The jury was free to resolve conflicts between Hammons' and Ethicon's experts in any way it saw fit. It chose to decide the issue in favor of Hammons. No basis exists to disturb the jury's determination.

EVIDENCE OF SPOLIATION

Ethicon seeks a new trial on the ground that the trial court improperly admitted the deposition testimony of James Mittenthal, Ethicon's corporate designee, that Ethicon destroyed thousands of documents possessed by high-ranking Ethicon employees relating to the development of Prolift. Hammons created the inference that Ethicon destroyed thousands of documents by eliciting Mittenthal's testimony that over 20,000 documents were in computerized files of several Ethicon officials, while the computer hard drives of other high-ranking officials were wiped clean. P–3411, at 744. Ethicon admits that it destroyed multiple documents but claims that its conduct was "inadvertent." Ethicon's Reply Brief at 26, 31. Notably, however, Ethicon destroyed these documents even though counsel in pelvic mesh litigation had issued notices directing Ethicon to preserve these documents. N.T., 12/3/15 (A.M.), at 16. The trial court permitted Mittenthal's testimony but declined to give an adverse inference instruction to the jury. Ethicon strenuously argues that the ***1280** admission of Mittenthal's testimony prejudiced the jury.

The trial court gave the following reasons for permitting Mittenthal's testimony:

> Despite preservation notices concerning pelvic mesh litigation, thousands of documents were destroyed and could not be produced to [Hammons]. Included in this destruction were documents created by employees who were significantly involved in the development, testing, and marketing of Prolift. The custodial file of Dr. Owens, the world wide medical director of [Ethicon's] Women's Health and Urology Program during the development of Prolift, the individual responsible for managing and improving premarket activities, had been destroyed. The Court allowed [Hammons] to present evidence of the unavailability of documentation and also allowed [Ethicon] to present evidence concerning

> the reasons for the destruction, which they claimed, was appropriate and inadvertent.
>
> [Ethicon] contends that admission of Mr. Mittenthal's deposition testimony amounted to a sanction for spoliation. The decision to allow this evidence before the jury so that counsel could argue or explain the failure to produce documents from these files at trial is not a discovery sanction. [Hammons] specifically asked for an adverse jury instruction. This was rejected by the court.
>
> A jury is entitled to know what documentation was and was not available to counsel in preparing and presenting their case. Given this information the jury without any need for instruction from the court could understand why other documents had not been presented to them draw whatever conclusions were appropriate from this evidence.

Trial Court Opinion, 9/30/16, at 17.

Ethicon argues that "without any factual or legal analysis of the issue, the trial court simply allowed [Hammons] to present [Mittenthal's testimony] that spoliation occurred and left the jury to decide what to do with that information." Ethicon's Opening Brief at 47. This decision, Ethicon continues, was a misapplication of spoliation standards and a "sanction" against Ethicon. The trial court knew this sanction was wrong, says Ethicon, given its subsequent decision not to give an adverse inference instruction to the jury. We do not agree.

Instead of admitting Mittenthal's testimony without any analysis, the court held a lengthy hearing outside the jury's presence in which it admitted certain passages of Mittenthal's deposition testimony and excluded others. N.T., 12/2/16 (A.M.), at 52–72. More importantly, the court was not required to apply spoliation standards to this issue; nor did it do so. It applied the correct analytical framework—principles of relevance and prejudice—and acted within its discretion by admitting selected portions of Mittenthal's testimony. Because the trial court did not utilize spoliations standards, its ruling was not a spoliation sanction.

[20] [21] [22] [23] [24] [25] [26] To explain why spoliation standards do not apply, we begin by describing the spoliation doctrine:

As we observed in ***Rodriguez v. Kravco Simon Co.***, 111 A.3d 1191 (Pa. Super. 2015), penalties for spoliation of evidence have been applied since the early 17th century. The spoliation doctrine is applicable to any case "where 'relevant evidence' has been lost or destroyed." ***Mount Olivet Tabernacle Church v. Edwin L. Wiegand Div.***, 781 A.2d 1263, 1269 (Pa. Super. 2001), ***aff'd sub nom. Mount Olivet Tabernacle Church v. Edwin Wiegand Div.***, 571 Pa. 60, 811 A.2d 565 (2002). A party's destruction or loss of proof that is pertinent to a lawsuit can result in a variety of sanctions. ***1281** ***Parr v. Ford Motor Co.***, 109 A.3d 682 (Pa. Super. 2014).

In reviewing the propriety of a sanction for spoliation, "we must determine whether the court abused its discretion." ***Id.*** at 701 (citation omitted). The trial court weighs three factors in deciding upon an appropriate penalty for spoliation, "(1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future." ***Id.*** at 702 (citation omitted). For purposes of

> evaluation of the first prong, "the fault of the party who altered or destroyed the evidence," requires consideration of two components, the extent of the offending party's duty or responsibility to preserve the relevant evidence, and the presence or absence of bad faith. The duty prong, in turn, is established where: (1) the plaintiff knows that litigation against the defendants is pending or likely; and (2) it is foreseeable that discarding the evidence would be prejudicial to the defendants."

Id. (citations omitted).

One sanction that a court may choose to impose when evidence is lost or destroyed is to instruct the jury that it may infer "that the destroyed evidence would have been unfavorable to the position of the offending party." ***Rodriguez***, ***supra***, at 1196. The rationale for this spoliation inference is "nothing more than the common sense observation that a party who has notice that evidence is relevant to litigation and who proceeds to destroy evidence is more likely to have been threatened by" the proof in question. ***Id.***

Gavin v. Loeffelbein, 161 A.3d 340, 353–54 (Pa. Super. 2017).

[27] Sanctions for spoliation include, *inter alia*, entry of judgment against the offending party, exclusion of evidence, monetary penalties such as fines and attorney fees, and adverse inference instructions to the jury. *Mt. Olivet Tabernacle Church*, 781 A.2d at 1272–73. The court decides whether to impose sanctions by applying the three-prong test articulated in *Gavin*: degree of fault, degree of prejudice and whether a lesser sanction is available. *Gavin*, 161 A.3d at 353–54.

[28] Spoliation standards do not apply, however, when the trial court merely considers whether to permit evidence during trial that a party destroyed documents. A decision cited in Ethicon's brief, *Caparotta v. Entergy Corp.*, 168 F.3d 754 (5th Cir. 1999), is instructive.[13] There, the district court declined to give an adverse inference instruction to the jury but permitted the plaintiff to introduce evidence that the defendant had destroyed documents. The Fifth Circuit observed that the decision whether to give an adverse inference instruction is distinct from the decision whether to admit evidence of document destruction for the jury to consider with other trial evidence:

> Entergy correctly points out that under this court's holding in *Vick v. Texas Employment Commission*, 514 F.2d 734, 737 (5th Cir. 1975), an adverse inference drawn from the destruction of records is predicated on bad conduct by the defendant. Because the district court ***1282** found no bad faith, Entergy argues that evidence of the inadvertent destruction of documents should not have been presented to the jury.
>
> Entergy is correct to the extent that it argues the spoliation doctrine did not apply and that the jury could not be instructed that the destroyed evidence was unfavorable to Entergy. However, *Vick* does not apply to the issue of whether the district court could nonetheless admit the fact of the destruction of documents for the jury to weigh with the other evidence in the case because such evidence was relevant.

Caparotta, 168 F.3d at 757. The proper test was not spoliation standards but the usual evidentiary standards of relevance and prejudice. *Id.* at 757–58.

[29] Here, as in *Caparotta*, the trial court denied Hammons' request for an adverse inference instruction but permitted Hammons to introduce evidence of Ethicon's destruction of documents. *Caparotta* teaches that the test governing admission of this evidence is relevance and prejudice, not the three-prong spoliation test. As an appellate court, we review the trial court's application of relevance and prejudice standards for abuse of discretion. *Commonwealth v. Tyson*, 119 A.3d 353, 357 (Pa. Super. 2015). "[A]n abuse of discretion is not merely an error of judgment, but is rather the overriding or misapplication of the law, or the exercise of judgment that is manifestly unreasonable, or the result of bias, prejudice, ill-will[,] or partiality, as shown by the evidence or the record." *Commonwealth v. Cameron*, 780 A.2d 688, 692 (Pa. Super. 2001).

We hold that the trial court acted within its discretion by permitting Hammons to present Mittenthal's testimony that Ethicon destroyed large numbers of documents within the computer files of high-ranking Ethicon officials. As the trial court observed in its opinion, Mittenthal testified that the entire computerized files of multiple officers involved in Prolift's development were wiped away. P–3411, at 4, 16–19, 20–21. Since other high-ranking officials at Ethicon had thousands of documents in their files, it was reasonable to infer that the destroyed documents numbered in the thousands, if not in the tens of thousands. The absence of these documents was relevant, because Hammons had the burden of proof, and the jury might have held the documents' absence against her unless she demonstrated why they were missing. Moreover, the absence of the documents was relevant to the jury's consideration of the credibility of witnesses whose documents were destroyed. For example, Owens testified that she frequently communicated by email about Prolift with Prolift's inventors, Professor Jacquetin and Dr. Cosson. She testified that Jacquetin and Cosson never indicated Prolift should not have been launched in March 2005, or that Prolift was counter-indicated in sexually active women. D–23 at 5–7. Because Ethicon wiped clean Owens' custodial file, Hammons' counsel was hampered in cross-examining Owens, because counsel could not challenge her credibility on whether these purported conversations took place or their content. Mittenhall's testimony about Ethicon's destruction of records allowed Hammons to explain to the jury why Owens' email exchange was not presented for their consideration.

[30] **[31]** Not only was this evidence relevant, but it also was admissible under Pa.R.E. 403, which provides: "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." "Unfair prejudice" means "a tendency to suggest decision on an improper basis or to divert ***1283** the jury's attention away from its duty of weighing the evidence impartially." ***Castellani v. Scranton Times, L.P.***, 633 Pa. 230, 124 A.3d 1229, 1245 (2015) (citing Pa.R.E. 403 (Comment)). It is important to remember, however, that

> 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 ...

Commonwealth v. Gonzalez, 112 A.3d 1232, 1238 n.6 (Pa. Super. 2015). In other words, to paraphrase what our Supreme Court once said, a party may strike hard blows so long as it does not strike foul blows. ***Commonwealth v. Cherry***, 474 Pa. 295, 378 A.2d 800, 804 (1977) ("while [a prosecutor] may strike hard blows, he is not at liberty to strike foul ones"). The evidence of document destruction in this case was highly relevant for the reasons provided in the preceding paragraph. Its probative value outweighed any prejudice to Ethicon. Indeed, we do not consider Ethicon to have suffered "unfair prejudice," Rule 403's operative term.

[32] Ethicon also argues that Hammons' counsel made inflammatory and prejudicial references to document destruction during closing argument. Counsel stated:

> And remember Mr. Mittenthal, and he was the fellow who told us about the thousands of pages of documents that were destroyed by Ethicon, these entire corporate files of high-ranking corporate employees were wiped out. He told us that relevant documents may have been destroyed, and to quote, "tens of thousands of documents" were destroyed and it is possible that key documents are missing. Now you know, I would rather believe that that happened innocently, that it wasn't done maliciously, that they didn't mean to destroy documents that things happen in companies. Right?

N.T., 12/16/15 (PM) at 15–16. Several moments later, counsel added that the loss of documents "tells you something about the corporate mindset," and "tells you a lot about their intentions." ***Id.*** at 16.

[33] We do not consider this argument improper. A party is entitled to argue the evidence during closing arguments, including all logical inferences. ***Commonwealth v. Williams***, 532 Pa. 265, 615 A.2d 716, 721–22 (1992) (where evidence of flight and concealment was introduced at trial, prosecutor was entitled to remark during summation that evidence of flight is "relevant and admissible to establish an inference of guilt"); ***Hyrcza v. West Penn Allegheny Health Sys.***, 978 A.2d 961 (Pa. Super. 2009) ("[S]o long as no liberties are taken with the evidence, a lawyer is free to draw such inferences as he wishes from the testimony and to present his case in the light most suited to advance his cause and win a verdict in the jury box"). Having introduced evidence of document destruction during trial, counsel had the right to present argument on this evidence in his closing argument along with all logical inferences.

JURY INSTRUCTION RELATING TO HARM CAUSED BY PROLIFT

Ethicon objects to the jury instruction that "if Ethicon knew that a surgeon using the product might place the Prolift incorrectly, then they're responsible for any harm which comes from the Prolift having been improperly placed." N.T., 12/18/15, at 35. Ethicon asserts that the trial court "essentially instructed the jury to return a ***1284** verdict for [Hammons] when it erroneously told jurors that [Ethicon was] responsible for all misuse of Prolift." Ethicon's Brief at 51. We disagree.

> Our standard of review regarding jury instructions is limited to determining whether the trial court committed a clear abuse of discretion or error of law which controlled the outcome of the case. Error in a charge occurs when the charge as a whole is inadequate or not clear or has a tendency to mislead or confuse rather than clarify a material issue. Conversely, a jury instruction will be upheld if it accurately reflects the law and is sufficient to guide the jury in its deliberations.
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> The proper test is not whether certain portions or isolated excerpts taken out of context appear erroneous. We look to the charge in its entirety, against the background of the evidence in the particular case, to determine whether or not error was committed and whether that error was prejudicial to the complaining party. In other words, there is no right to have any particular form of instruction given; it is enough that the charge clearly and accurately explains the relevant law.

Krepps v. Snyder, 112 A.3d 1246, 1256 (Pa. Super. 2015).

[34] Here, the trial court gave the following pertinent instructions:

> A product is defective if the seller fails to properly package or label the product with reasonable warnings about the dangers of the product or fails to give reasonably complete instructions about the proper use of the product. A manufacturer has a duty to warn of hidden dangers. **If Ethicon knew that a surgeon using the product might place the Prolift incorrectly, then they're responsible for any harm which comes from the Prolift having been improperly placed.**
>
> * * * *
>
> A person's conduct is legally responsible for causing an injury if the injury would not have occurred without the conduct and the injury was a natural, probable and foreseeable result of the conduct. And that's what we call responsible cause or cause in all these questions that you're going to have about cause. And there can be more than one responsible cause of an injury. Now, sometimes an unrelated event can break the connection between a defendant's negligent action and the injury. If this event was not reasonably foreseeable, it is an intervening cause. When an intervening cause breaks the connection between the defendant's negligent act and a plaintiff's injury, a defendant's negligent act is no longer a responsible cause of that plaintiff's injury.

N.T., 12/18/15, at 34–36 (emphasis added).

[35] **[36]** Quoting the bolded instruction in isolation, Ethicon argues that the trial court wrongly instructed the jury to hold Ethicon liable for any physician misuse. Under Indiana law, a medical device manufacturer has the duty to warn treating physicians of the device's "latent dangers." ***Nat. Gas Odorizing***, 685 N.E.2d at 162. Device misuse is an intervening cause that relieves the manufacturer of liability only if the misuse could not have been reasonably foreseen by the manufacturer. ***Montgomery Ward & Co. v. Gregg***, 554 N.E.2d 1145, 1156 (Ind. App. 1990). The above instructions were consistent with Indiana law and consistent with Indiana's standard instruction on the duty to warn.

Ethicon claims that this instruction amounted to a directive to reject Ethicon's argument that Hammons' injuries were caused by Dr. Baker's surgical errors instead of any defect in Prolift. This is incorrect. The trial court did not even mention Dr. Baker, let alone instruct the jury that ***1285** his actions were unrelated to Hammons' injuries as a matter of law. Ethicon also made arguments about Dr. Baker's responsibility for Hammons' injuries, which the jury was free to accept or reject. N.T., 12/17/15 (A.M.), at 99. The trial court made no instructional error.

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 $5.5 million. The trial court upheld the verdict based on Hammons' "persistent pain and inability to have sex ... the effect on her relationship with her boyfriend, the effect on her self-image ... the embarrassment and humiliation she has suffered," and her multiple surgeries. Trial Court Opinion,

9/30/16, at 21. We conclude that the trial court acted within its discretion.

Our initial task is to determine whether Pennsylvania or Indiana law applies to this issue. The parties do not appear to agree on this subject. Hammons cites Pennsylvania cases in her brief, whereas Ethicon cites Indiana cases. Because remittitur is a procedural mechanism under Pennsylvania law rather than substantive law, the law of the forum state, *i.e.*, Pennsylvania, governs this issue.

"Procedural law is the set of rules which prescribe the steps by which the parties may have their respective rights and duties judicially enforced[,]" whereas "[s]ubstantive law is the portion of the law which creates the rights and duties of the parties to a judicial proceeding." ***Sheard v. J.J. DeLuca Co., Inc.***, 92 A.3d 68, 76 (Pa. Super. 2014). "In conflicts cases involving procedural matters, Pennsylvania will apply its own procedural laws when it is serving as the forum state." ***Commonwealth v. Sanchez***, 552 Pa. 570, 716 A.2d 1221, 1223 (1998). In contrast, where Pennsylvania substantive law conflicts with another state's law, Pennsylvania courts apply the law of the state which has the most significant interest in the question. ***Murray v. Janssen Pharmaceuticals, Inc.***, 180 A.3d 1235, 1252–53 (Pa. Super. 2018).

In Pennsylvania, remittitur is a procedural matter: it is the "procedural [process] by which an excessive verdict of the jury is reduced." ***Refuse Management Systems, Inc. v. Consolidated Recycling and Transfer Systems, Inc.***, 448 Pa.Super. 402, 671 A.2d 1140, 1149 (1996). Accordingly, we apply Pennsylvania law to Ethicon's challenge to the amount of compensatory damages. [14] ***Sanchez***, 716 A.2d at 1223.

[37] **[38]** **[39]** Under Pennsylvania law, the decision to grant a remittitur depends on whether the award of compensatory damages ***1286** 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***, 573 Pa. 310, 825 A.2d 591, 611 (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).

[40] Each personal injury case "is unique and dependent on its own special circumstances." ***Kemp v. Philadelphia Transportation Co.***, 239 Pa.Super. 379, 361 A.2d 362, 364 (1976). Thus, noneconomic loss must be measured by experience rather than any mathematical formula. ***Martin v. Soblotney***, 502 Pa. 418, 466 A.2d 1022, 1025 (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).

[41] Hammons sought damages for all noneconomic losses recognized under Indiana law, including pain and suffering; embarrassment and humiliation; disfigurement; and loss of ability to enjoy the pleasures of life. See Ind. Model Civil Jury Instructions 703 (General elements of damages) and comments. To determine damages within these categories of noneconomic loss, the jury is entitled to consider the plaintiff's age; the nature and extent of her injuries; the effect of the injuries on her ability to function as a whole person; whether the injuries are permanent; the physical pain and mental suffering she experienced and will experience in the future as a result of the injuries; the aggravation of a previous injury, disease, or condition; and the disfigurement and/or deformity resulting from the injuries. ***Id.***

Dr. Zipper examined Hammons and explained that she has tenderness near the top of her vagina and underneath her bladder. Hammons' prolapse has recurred, implicating multiple organs. She has a significantly foreshortened vagina, and her vagina has everted (turned inside

out). She testified her vagina is shortened and rigid with scar tissue because of Prolift implantation and subsequent surgeries to remove mesh. Since May 2009, she has suffered pain with sexual intercourse and has experienced incontinence. She also continues to suffer pain when walking because mesh "arms" are embedded in her muscles. These conditions are permanent. N.T., 12/9/15 (P.M.), at 32–33, 142–52, 161–63; N.T., 12/11/15 (P.M.), at 78–83, 136–38. Dr. Zipper also described that Hammons has permanent loss of bladder capacity and bladder spasms that cause a feeling of "urgency" and frequent urination. These conditions also are permanent. ***Id.*** Hammons has undergone three major surgeries ***1287** but has no reasonable surgical or nonsurgical means of treatment to cure her urinary and sexual dysfunction. Her life expectancy as of the time of trial was another 21.2 years. N.T., 12/9/15 (P.M.), at 32–33, 142–52, 161–63; N.T., 12/11/15 (P.M.), at 78–83, 136–38; N.T., 12/18/15, at 40. Hammons testified her sexual dysfunction has affected the relationship with her boyfriend of sixteen years, her self-image and her happiness. She is embarrassed and humiliated by her physical deformity. N.T., 12/9/15 (P.M.), at 32–33, 142–52. Collectively, this evidence demonstrates Hammons 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.

Ethicon asks us to remit the verdict by comparing Hammons's losses 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. It is safe to say that Hammons has suffered, and will continue to suffer for another two decades, far greater physical and emotional trauma from Prolift than the plaintiff in ***Smalls*** suffered from asbestos exposure or the plaintiff in ***Hartner*** suffered from her knee injury.

PUNITIVE DAMAGES

Prior to trial, the parties agreed that New Jersey law governed the issue of punitive damages. The jury awarded Hammons $7 million in 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.

[42] **[43]** 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
>
> ***1288** (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 complains 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 complains 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 WL 7666693 (2016).

[44] In ***Gross***, the New Jersey Appellate Division rejected Ethicon's arguments and affirmed a $7.76 million punitive verdict against Ethicon based on evidence of its wanton and willful misconduct concerning Prolift. Hammons presented substantially the same evidence in this case. The evidence revealed that Ethicon knew before launch that Prolift failed frequently and shortly after implantation. Ethicon knew that nearly twenty percent of women would suffer from mesh shrinkage that caused pain with sexual intercourse and ambulation, and approximately twenty percent would suffer from mesh erosion of surrounding vaginal tissue and other organs within one year of implantation. Post-launch clinical data corroborated evidence that Prolift had significant risks of injury and high rates of complications. N.T., 12/4/15 (P.M.), at 93–100; N.T. 12/7/2015 (A.M.) at 37–41; 48–50; N.T., 12/8/15 (A.M.), at 19–99; P–3402 at 3–52; P–3408 at 1–18.

Testimony also showed that Ethicon knew that women would require additional surgeries to correct mesh injuries. By 2006, Ethicon documents revealed that the company knew women who turned "to surgery to deal with a bad Prolift" would be a "disaster." And Ethicon knew human tissue continues to react to mesh for decades because it is designed as a permanent implant. Yet Ethicon failed to study any long-term consequences or to develop any process to remove Prolift from women who suffered complications. ***Id.*** Ethicon recognized Prolift's risks but nevertheless continued to sell the product without adequate warnings. The issues were so serious that Prolift's inventors and designers, Professor Jacquetin and Dr. Cosson, expressed their concerns about the mesh to Ethicon and repeatedly urged Ethicon to replace Prolene soft/Gynemesh with Ultrapro, an existing, safer mesh product. Nevertheless, the Prolift+M (with Ultrapro) project went into "limbo" because it would have delayed launch and affected Prolift's profitability. By 2008, two-thirds of surgeons who implanted Prolift were reluctant to use the device in sexually active patients. Physicians asked Ethicon for a mesh that was lighter, softer and caused fewer erosions and less pain, but Ethicon continued to sell the product as designed and without adequate warnings. ***Id.***

Ethicon also sold the product and failed to disclose known information to treating physicians about the severity, incidence, and permanence of complications. Before launch, Ethicon rebuffed its scientific director, Dr. Arnaud, who proposed disclosures in the IFU that would have properly warned that: (1) mesh erosion and retraction of the Prolift mesh could result in "anatomic distortion" of the vaginal cavity that would "interfere with sexual intercourse," and (2) this risk should be "taken in consideration when the procedure is planned in a sexually active woman." Ethicon ***1289** refused to include this warning because Prolift's IFU had already been printed for launch. Later printings also failed to include the warning. ***Id.***

At the same time, Ethicon actively misrepresented Prolift's essential properties in the Prolift IFU. Ethicon's employees acknowledged Prolift's IFU description was "unsupportable" and lacked foundation in clinical data. They said that the IFU's characterization of Prolene/Gynemesh as "soft" was an "illusion." They also said the claim of "bi-directional elastic property" that "allows adaption to various stresses encountered by the body" had no support in data. Ethicon had pulled a mesh "out of our existing bag of tricks" for Prolift. P–3401 at 3; P–3416 at 6–7. Ethicon's medical director described the mesh as "the best of a bad lot." P–3415 at 5. Such evidence permitted the jury to find Ethicon acted with wanton and willful disregard of Hammons' rights. N.J. Stat. § 2A:15–5.10 & 2A:15–5.12.

Ethicon contends punitive damages are unavailable under New Jersey law because the parties stipulated that Prolift was "properly and lawfully marketed." Ethicon's Brief at 57. The New Jersey Products Liability Act ("NJPLA") provides a defense to punitive damages for a manufacturer whose medical device "was approved or licensed; or is generally recognized as safe and effective" by the Food and Drug Administration. N.J. Stat. § 2A:58C–5c ("FDA punitive damage exemption"). Ethicon's brief, however, completely fails to analyze whether the stipulation that Prolift is "properly and lawfully marketed" satisfies the FDA punitive damage exemption. The only decision Ethicon cites, ***Pavlova v. Mint Mgt. Corp.***, 375 N.J.Super. 397, 868 A.2d 322, 328 (App.Div. 2005), does not analyze

the FDA punitive damage exemption at all. Thus, this argument fails. [15]

Ethicon also argues that Prolift's IFU warned of the "majority of risks" relevant to Hammons' injuries. Ethicon's Brief at 59. In so many words, Prolift argues that *some* labeling is sufficient to avoid punitive damages, even if the labeling is incomplete. Perhaps this argument would have force if the omissions from labeling are unimportant, but the omissions in this case clearly were material. Here, however, Ethicon's IFU, sales brochures, and other physician communications omitted crucial warnings of severe complications experienced by Hammons, so much so that the jury could find punitive liability against Ethicon. ***See In re C.R. Bard, Inc.***, 2013 WL 2432871, at *7 (S.D. W. Va. June 4, 2013) ("the fact that [defendant] provided warnings regarding certain issues is simply not dispositive" as to punitive damages liability); ***Thom v. Bristol–Myers Squibb Co.***, 353 F.3d 848, 853 (10th Cir. 2003) (same).

DELAY DAMAGES

[45] In her cross-appeal, Hammons argues 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 disagree.

1290** Pa.R.Civ.P. 238 governs the application of delay damages. In 1983, our Supreme Court held in ***Colodonato v. Consolidated Rail Corp., 504 Pa. 80, 470 A.2d 475 (1983), that Rule 238 limits the calculation of delay damages to compensatory damages. Hammons contends that ***Colodonato*** no longer controls due to an amendment to Rule 238 in 1988. We do not find the amendment expands Rule 238's reach to punitive damages.

The 1979 version of Rule 238, which was in effect at the time the Supreme Court decided ***Colodonato***, provided in relevant part:

> (a) Except as provided in subdivision (e), in an action seeking monetary relief for bodily injury, death or property damage, or any combination thereof, the court or the arbitrators appointed under the Arbitration Act of June 16, 1836, P.L. 715, as amended, 5 P.S. § 30 et seq., or the Health Care Services Malpractice Act of October 15, 1975, P.L. 390, 40 P.S. § 1301.101 et seq., shall
>
> (1) add to the amount of compensatory damages in the award of the arbitrators, in the verdict of a jury, or in the court's decision in a nonjury trial, damages for delay at ten (10) percent per annum, not compounded, which shall become part of the award, verdict or decision ....

In 1986, the Supreme Court held in ***Craig v. Magee Memorial Rehabilitation Center***, 512 Pa. 60, 515 A.2d 1350 (1986), that former Rule 238 was unconstitutional because it created an uncontestable presumption that all fault in the time it takes to proceed to trial lies with the defendant. The 1988 amendments resolved that issue by excluding the time during which the plaintiff caused a delay of the trial. ***Conner v. Munsey***, 533 Pa. 143, 620 A.2d 1103, 1104 (1993).

Under the 1988 amendments, Rule 238 provided in relevant part:

> (a)(1) At the request of the plaintiff in a civil action seeking monetary relief for bodily injury, death or property damage, damages for delay shall be added to the **amount of compensatory damages** awarded against each defendant or additional defendant found to be liable to the plaintiff in the verdict of a jury, in the decision of the court in a nonjury trial or in the award of arbitrators appointed under section 7361 of the Judicial Code, 42 Pa.C.S. § 7361, and shall become part of the verdict, decision or award.
>
> (2) Damages for delay shall be awarded for the period of time from a date one year after the date original process was first served in the action up to the date of the award, verdict or decision.
>
> (3) Damages for delay shall be calculated at the rate equal to the prime rate as listed in the first edition of the Wall Street Journal published for each calendar year for which the damages are awarded, plus one percent, not compounded.
>
> (b)(1) The period of time for which damages for delay shall be calculated under subdivision (a)(2) shall exclude the period of time, if any,
>
> (i) after the defendant made a written offer which complied with the requirements of subdivision (b)(2), provided that the plaintiff obtained a recovery which

did not exceed the amount described in subdivision (b)(3), or

(ii) during which the plaintiff caused delay of the trial.

[Emphasis added]. Amended Rule 238(b) keyed the time frame for the calculation of damages to a new (a)(2), with deductions of any of the time found under (b)(1)(i) or (ii).

The rule was restructured slightly for the amended rule to make sense. In both versions, the provision for delay damages identified: (1) the actions to which it applies; (2) limited its application to compensatory damages; (3) the rate; and (4) the ***1291** time to be used in computing delay damages. There is nothing about the amendment, the explanation provided by the Civil Procedural Rules Committee, or the case law construing the rule that suggests the Supreme Court meant "compensatory damages" in 1988 to mean anything other than what it meant in 1979. The language that was critical to the Supreme Court's holding in ***Colodonato*** remained unchanged. ***Id.***, 470 A.2d at 477 ("The language of section (a)(1) of the rule makes it clear that the delay damage provision therein specifically relates to that portion of an award, verdict, or decision ... which comprises compensatory damages").

Following the 1988 amendments, this Court has cited ***Colodonato*** in construing the scope of delay damages as limited. ***See Hodges v. Rodriguez***, 435 Pa.Super. 360, 645 A.2d 1340, 1349–50 (1994) (citing ***Colodonato*** for the proposition that delay damages are inapplicable to punitive damages). Hammons does not cite any post-amendment decisions that hold or suggest that Rule 238 applies to punitive damages. To the contrary, both the Supreme Court and this Court have consistently "emphasized the narrow breadth of the Rule." ***Touloumes v. E.S.C., Inc.***, 587 Pa. 287, 899 A.2d 343, 348–49 (2006); ***see also Anchorstar, Jr. v. Mack Trucks, Inc.***, 533 Pa. 177, 620 A.2d 1120, 1121 (1993) (refusing to extend delay damages to loss of consortium claims); ***Musumeci v. Penn's Landing Corp.***, 433 Pa.Super. 146, 640 A.2d 416, 420–22 (1994) (no delay damages for personal injury claim governed by federal maritime law); ***Thompson v. T.J. Whipple Constr. Co.***, 985 A.2d 221, 230 (Pa. Super. 2009) (delay damages not recoverable when terms of high-low agreement would be contravened); ***Wagner v. Orie & Zivic***, 431 Pa.Super. 337, 636 A.2d 679, 681 (1994) (refusing to extend delay damages to legal malpractice with regard to personal injury claim based on pre-amendment Supreme Court holding).

For these reasons, we hold that the 1988 amendments to Rule 238 did not make delay damages applicable to an award of punitive damages.

Judgment affirmed. Ethicon's application to strike supplemental trial court record denied. Hammons's application for post-submission communication to report about developments in the trial court concerning orders under appeal denied.

All Citations

190 A.3d 1248, Prod.Liab.Rep. (CCH) P 20,374, 2018 PA Super 172

Footnotes

* Former Justice specially assigned to the Superior Court.

1 The order referred to each plaintiff's individual docket as the "Original Docket." We substitute the term "Individual Docket" for "Original Docket."

2 We discuss the question of whether Ethicon failed to provide adequate warnings in greater depth below. ***See*** pp. 1269–74, ***infra***.

3 To the extent the parties agree on the governing law, we accept their agreement for purposes of our decision, and we see no need to explore the reasons for their agreement.

4 The parties do not agree whether Pennsylvania or Indiana law applies to Ethicon's post-trial motion to reduce the amount of Hammons' compensatory damages. We resolve this issue ***infra*** at pp. 1285–86.

5 We note that Ethicon raised this issue in its Pa.R.A.P. 1925(b) statement, but the trial court did not analyze it in its opinion.

6 We may affirm "on any ground." ***Wilson v. Plumstead Tp. Zoning Hearing Bd.***, 594 Pa. 416, 936 A.2d 1061, 1065 n.3 (2007). Thus, we need not confine our reasons for affirming to evidence adduced during proceedings on Ethicon's preliminary objections to jurisdiction.

7 While Ethicon objected to personal jurisdiction, it did not raise any objection to venue during this case. Venue and personal jurisdiction are different issues. Personal jurisdiction concerns whether the defendant has engaged in sufficient activity within Pennsylvania to be subject to this state's regulation. Venue concerns whether the forum chosen by the plaintiff (here, Philadelphia County) is a proper locality within which to bring her action. ***See*** Pa.R.Civ.P. 2179 (identifying counties in which venue lies for personal actions against corporations).

8 As noted above, August 16, 2011 was the date Hammons signed a form authorizing the release of her "implant related medical records" for use in "plaintiff litigation for product liability." DTX–42; N.T., 12/11/15 (PM), at 63.

9 The trial court stated incorrectly that a claim accrues when the treating physician informs the patient of the "probability" that her injury was caused by an act or product of another. Trial Court Opinion, at 8. We apply the proper "reasonable possibility" standard below.

10 Pennsylvania law provides the same shifting burden of proof. A defendant asserting an affirmative defense such as the statute of limitations has the initial burden of proof as to that affirmative defense. ***Sabella v. Appalachian Development Corp.***, 103 A.3d 83, 93 (Pa. Super. 2014). When the defendant meets this burden, the burden shifts to the party relying on the discovery rule as a rejoinder to the statute of limitations defense. ***Wilson v. El–Daief***, 600 Pa. 161, 964 A.2d 354, 362 (2009).

11 Pennsylvania law is the same. ***See*** ***Nicolaou v. Martin***, 153 A.3d 383, 395 (Pa. Super. 2016) (*en banc*) (affirming summary judgment in medical malpractice case where plaintiff failed as matter of law to raise genuine issue of fact as to applicability of discovery rule).

12 This, of course, is the trial court's opinion in the case before us.

13 Decisions of lower federal courts may have persuasive, but not binding, authority on this Court. ***Gongloff Contracting, L.L.C. v. L. Robert Kimball & Assoc., Architects and Engineers, Inc.***, 119 A.3d 1070, 1078 n.6 (Pa. Super. 2015).

14 One distinction between the present case and ***Murray*** bears emphasis. ***Murray*** was a products liability action against a pharmaceutical manufacturer for failure to warn about the risks of a drug (risperidone). The plaintiff resided in Maryland, was prescribed risperidone in Maryland and suffered harm from the drug in Maryland. Following a verdict for the plaintiff, the trial court reduced his compensatory damage award in accordance with Maryland's statutory cap on noneconomic damages. Both the trial court and the parties referred to this reduction as a "remittitur." ***Id.***, 180 A.3d at 1252. On appeal, the plaintiff argued that the trial court erred in applying Maryland law because remittitur is a procedural mechanism governed by Pennsylvania law. We upheld the trial court's decision on the ground that it did not actually exercise a remittitur but correctly resolved a conflict of substantive law (Maryland's cap on damages versus Pennsylvania's lack of any cap). In the present case, Ethicon does not point to any pertinent substantive conflict between Pennsylvania and Indiana damages law; nor are we aware of any. Instead, Ethicon merely asked the trial court to perform a remittitur, a "procedural mechanism" governed by Pennsylvania law. ***Id.***

15 From other decisions involving Ethicon, it appears that the path that Prolift took to reach the market does not satisfy the FDA punitive damage exemption. Ethicon apparently went through the FDA's 510(k) clearance process, in which the FDA permits marketing of a product if it concludes that the device is 'substantially equivalent' to a pre-existing, previously approved device. ***Lewis v. Johnson & Johnson***, 991 F.Supp.2d 748, 751–52 (S.D.W.Va. 2014) (pelvic mesh decision). ***Lewis*** held, after exhaustive analysis, that 510(k) clearance of Ethicon's pelvic mesh products did not constitute a finding by the FDA that the products were safe or effective. ***Id.*** at 751–56.