

APRIL CZIMMER

Appellee

v.

JANSSEN PHARMACEUTICALS, INC.

Appellant

IN THE SUPERIOR COURT OF
PENNSYLVANIA

No. 459 EDA 2014

Appeal from the Judgment Entered January 2, 2014
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): May Term 2011 No. 3459

BEFORE: LAZARUS, J., MUNDY, J., and PLATT, J.*

OPINION BY MUNDY, J.:

FILED AUGUST 20, 2015

Appellant, Janssen Pharmaceuticals, Inc. (Janssen),¹ appeals from the trial court's order entering judgment in favor of Appellee, April Czimmer, as guardian of Blake Czimmer, a minor,² following a jury trial. After careful review, we affirm.

We take the relevant facts and procedural history of this case from the trial court's January 2, 2014 opinion and our independent review of the

* Retired Senior Judge assigned to the Superior Court.

¹ Janssen is a Pennsylvania Corporation with a principal place of business in New Jersey. **See** Janssen's Answer and New Matter, 3/15/13, at 2-3 ¶ 10.

² As April and Blake Czimmer have the same surname, we will refer to them by their first names for clarity.

record. April has a history of migraine headaches dating back to when she was a young teenager.³ In August 2006, physician's assistant Lisa Basye prescribed Topamax⁴ to April to treat her migraines, and April continued to use the drug until February 2007. At the time Basye prescribed Topamax to April, the Food and Drug Administration (FDA) categorized it as a Pregnancy Category C drug.⁵

³ April resided in Virginia during the relevant time-period and continued to reside in that state when she filed the instant lawsuit. **See** Plaintiff's Fact Sheet, 12/23/11, at 2.

⁴ Janssen manufactures Topamax, an antiepileptic medication used to treat epilepsy and migraines. **See** Janssen's Brief at 10.

⁵ **See** Plaintiff's Exhibits 1210-1211 (Topamax 2006 and 2007 Physicians' Desk Reference excerpts). On March 4, 2011, the FDA classified Topamax as a Pregnancy Category D drug. **See** Janssen's Answer and New Matter, 3/15/13, at 6 ¶ 26.

The FDA has established 5 categories to indicate the potential of a drug to cause birth defects if used during pregnancy. Category A means that there are adequate, well-controlled studies which have failed to demonstrate a risk to the fetus. Few drugs are in category A because controlled studies of medication use during pregnancy are ethically prohibited. Category B means animal studies show no risk, but there are no adequate and well-controlled studies of use by pregnant women. Category C means that animal reproduction studies have shown an adverse effect on the fetus, but there are no adequate and well-controlled studies in humans, and so pregnant women should weigh the potential benefits against the potential risks. Category D is used when there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may still warrant use of the drug. Category X is the lowest category, used when use of the drug is not recommended
(Footnote Continued Next Page)

In December 2006, April became pregnant with her son, Blake. Blake was born on September 24, 2007, with a severe cleft lip and cleft palate with a hole above his lip. Since his birth, he has undergone four surgeries to repair his oral clefts and associated injuries. Blake will need to undergo a number of surgeries in the future, including jaw reconstruction and a bone graft at the time of maturity. He will also need speech therapy, treatment for his hearing, and a psychological evaluation.

On May 31, 2011, April commenced this lawsuit against Janssen by filing a writ of summons in the Philadelphia County Court of Common Pleas. On November 7, 2011, she filed a short-form complaint against Janssen alleging, in part, that it negligently failed to warn her prescribing health care provider of the risks of potential birth defects associated with Topamax, including cleft lip and/or palate, if used during pregnancy. On March 25,

(Footnote Continued) _____

for any pregnant women, as the risks clearly outweigh any benefits

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 26 F.Supp.3d 449, 453 n.7 (E.D. Pa. 2014); ***see also*** Plaintiff's Exhibit 1224, 3/08/13 (listing FDA Pregnancy Categories).

We note that decisions of the federal district courts are not binding on Pennsylvania courts, but we may look to them as persuasive authority. ***See Dietz v. Chase Home Fin., LLC***, 41 A.3d 882, 886 n.3 (Pa. Super. 2012).

2013, Janssen filed a motion for summary judgment, which the trial court granted in part and denied in part.⁶

On October 15, 2013, the case proceeded to a jury trial on the negligent failure to warn claim. On October 30, 2013, the jury returned a verdict in favor of April, as guardian of Blake. It awarded \$4,002,184.68 in damages, comprised of \$3,440,000.00 for the non-economic loss of pain and suffering and \$562,184.68 for future health care costs. On November 8, 2013, Janssen filed a post-trial motion requesting the trial court to grant judgment notwithstanding the verdict (JNOV) or a new trial. On January 2, 2014, the trial court entered an order and opinion denying Janssen's post-trial motion. The trial court also entered judgment on the jury's verdict, adding \$207,713.38 in delay damages, resulting in a total judgment against Janssen for \$4,209,898.06. This timely appeal followed.⁷

On appeal, Janssen raises the following issues for our review.

1. Does federal law preempt a state law negligent failure to warn claim where (a) [Janssen] could not have provided [April's] proposed warning without the Food and Drug Administration's prior permission and

⁶ The trial court granted summary judgment in favor of Janssen with respect to April's strict liability, negligent design, warranty, punitive damages, and loss of consortium claims. The court denied the remainder of the motion. **See** Trial Court Order, 7/16/13.

⁷ The trial court did not order Janssen to file a concise statement of errors complained of on appeal pursuant to Pennsylvania Rule of Appellate Procedure 1925(b), nor did it issue a Rule 1925(a) opinion. **See** Pa.R.A.P. 1925.

assistance, and/or (b) there was clear evidence that [the] FDA would not have approved that proposed warning?

2. In a case governed by Virginia law, did the trial court err in applying a “substantial factor” standard of causation that the Supreme Court of Virginia has expressly rejected as contrary to the law of Virginia?

3. Did the trial court err (a) by permitting a negligent failure to warn claim to proceed to the jury in an action involving a prescription drug warning, when the prescribers of that drug testified that they knew, at the time they prescribed the drug, of the alleged risk of harm that formed the basis of the claim, and/or (b) by excluding relevant evidence related to those prescribers’ knowledge of the risk?

4. Did the trial court err (a) by permitting an award of damages for Blake Czimmer’s future healthcare costs incurred during his minority, when his parents’ claim for those damages was time-barred and Blake did not have a right of action to recover them, and/or (b) by failing to ask the jury to decide whether the parents had brought their claim within the applicable limitations period?

Janssen’s Brief at 5.

We begin by stating our standard of review of a trial court’s denial of post-trial motions for JNOV and a new trial.

An appellate court will reverse a trial court’s grant or denial of a JNOV only when the appellate court finds an abuse of discretion or an error of law. Our scope of review with respect to whether judgment n.o.v. is appropriate is plenary, as with any review of questions of law.

In reviewing a motion for judgment n.o.v., the evidence must be considered in the light most favorable to the verdict winner, and he must be given the benefit of every reasonable inference of fact arising therefrom, and any conflict in the

evidence must be resolved in his favor. Moreover, a judgment n.o.v. should only be entered in a clear case and any doubts must be resolved in favor of the verdict winner. Further, a judge's appraisal of evidence is not to be based on how he would have voted had he been a member of the jury, but on the facts as they come through the sieve of the jury's deliberations.

There are two bases upon which a judgment n.o.v. can be entered: one, the movant is entitled to judgment as a matter of law, ... and/or two, the evidence was such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant[.] With the first a 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 with the second the court reviews the evidentiary record and concludes that the evidence was such that a verdict for the movant was beyond peradventure.

Questions of credibility and conflicts in the evidence are for the [fact-finder] to resolve and the reviewing court should not reweigh the evidence. If there is any basis upon which the jury could have properly made its award, the denial of the motion for judgment n.o.v. must be affirmed.

Braun v. Wal-Mart Stores, Inc., 24 A.3d 875, 890-91 (Pa. Super. 2011)

(brackets in original; citations and quotation marks omitted), *affirmed*, 106

A.3d 656 (Pa. 2014).

In reviewing a trial court's denial of a motion for a new trial, the standard of review for an appellate court is as follows:

[I]t is well-established law that, absent a clear abuse of discretion by the trial court, appellate courts must not interfere with the trial court's authority to grant or deny a new trial.

* * *

Thus, when analyzing a decision by a trial court to grant or deny a new trial, the proper standard of review, ultimately, is whether the trial court abused its discretion.

Moreover, our review must be tailored to a well-settled, two-part analysis:

We must review the court's alleged mistake and determine whether the court erred and, if so, whether the error resulted in prejudice necessitating a new trial. If the alleged mistake concerned an error of law, we will scrutinize for legal error. Once we determine whether an error occurred, we must then determine whether the trial court abused its discretion in ruling on the request for a new trial.

ACE Am. Ins. Co. v. Underwriters at Lloyds and Cos., 939 A.2d 935, 939 (Pa. Super. 2007) (citations omitted), *affirmed*, 971 A.2d 1121 (Pa. 2009).

In its first issue on appeal, Janssen contends it is entitled to JNOV because federal law preempts April's state-law negligent failure to warn claim. Janssen's Brief at 20. Specifically, Janssen argues that it could not have provided the proposed warning about potential oral birth defects without the approval of the United States Food and Drug Administration (FDA), and there was clear evidence that the FDA would not have approved such a warning. ***Id.*** Janssen asserts that the doctrine of "impossibility preemption" precludes the state-law claim of failure warn. ***Id.*** at 21, *citing PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). This Court rejected an identical argument by Janssen in ***Gurley v. Janssen Pharm., Inc.***, 113 A.3d 283 (Pa. Super. 2015), as follows.

Appellant's reliance on **PLIVA** is misguided. **PLIVA** involved federal preemption of state-law failure to warn claims brought against generic drug manufacturers, and is not applicable to the instant case involving a brand-name drug manufacturer. **See PLIVA, supra** at 2574. The **PLIVA** Court explained that, while a brand-name manufacturer is responsible for the accuracy and adequacy of its label, a generic manufacturer is responsible for ensuring that its warning label is the same as the brand name's label. **See id.** The Court stated: "It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers ... [D]ifferent federal statutes and regulations may ... lead to different preemption results." **Id.** at 2582. Thus, we conclude that Appellant's argument based on **PLIVA** is not legally persuasive.

Gurley, supra at 291 (brackets and elipses in original, citation to trial court opinion omitted). For the same reasons, Janssen's identical argument in this case is meritless.

Appellant also contends April's failure to warn claim is preempted because the FDA would not have approved the warnings April proposed Janssen provide in its labeling. Janssen's Brief at 25, *citing Wyeth v. Levine*, 555 U.S. 555 (2009). Specifically, Janssen claims that, before Blake's conception, it attempted to insert a warning of genital birth defects in the Topamax labeling, but the FDA precluded such a change to the label. Again, this Court rejected this identical argument in **Gurley** as follows.

Upon review, we cannot credit Appellant's contention that it presented "**clear evidence** that the FDA would not have approved a change to [Topamax's] **label**," to warn of increased risk of cleft

lip/palate. **Wyeth, supra** at 571 (emphases added). Appellant's proposed change to the P[atient] P[ackage] I[nsert (PPI)]^[8] in 2005 involved a warning regarding a minor malformation in the genitalia of some newborns born to mothers taking Topamax; it did not address increased risk of cleft lip/palate. Further, Appellant's proposed change in 2005 was to the PPI, directed at patients, and not to the Topamax label, directed at prescribers. Therefore, we conclude that Appellant has failed to establish federal preemption of Appellees' state failure to warn claim under **Wyeth**.

Gurley, supra at 291-292 (first brackets in original, emphasis in original, parallel citation omitted). For the same reasons, we conclude Janssen's preemption argument based on **Wyeth** does not merit relief. Accordingly, the trial court did not err as a matter of law in denying Janssen JNOV based on preemption. **See Braun, supra**.

In its second issue on appeal, Janssen asserts that it is entitled to a new trial because the trial court erroneously used the phrase "substantial factor" in its jury instructions on factual cause. Janssen's Brief at 34. Our deferential standard of review is as follows.

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

⁸ "A patient package insert contains information for patients' understanding of how to safely use a drug product." **Gurley, supra** at 291 n.16, quoting U.S. Department of Health and Human Services, U.S. Food and Drug Administration Glossary of Terms (2015).

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.

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) (citations and internal quotation marks omitted). Further, “to obtain a new trial based on the trial court’s treatment of a jury’s question, the moving party must demonstrate in what way the trial error caused an incorrect result.” ***Jeter v. Owens-Corning Fiberglas Corp.***, 716 A.2d 633, 636 (Pa. Super. 1998) (citation omitted).

Herein, Janssen contends the trial court disregarded Virginia law, which the parties and trial court agreed applied to the negligent failure to warn claim.⁹ Specifically, Janssen argues the trial court’s jury instructions

⁹ Janssen and the trial court agree that Virginia law applies to April’s negligent failure to warn claim. **See** Janssen’s Brief at 31-32; Trial Court Opinion, 1/2/14, at 12; N.T., 10/09/13, at 73. April does not dispute that
(Footnote Continued Next Page)

and verdict sheet overlooked the Virginia Supreme Court's disapproval of using the phrase "substantial factor" to explain factual causation.¹⁰ Janssen's Brief at 36-37. Janssen's argument invites us to isolate the words "substantial factor" and take them out of the context of the entire charge. Pursuant to our standard of review, we decline to do so. **See Krepps, supra.** Instead, we examine the jury instructions in their entirety and conclude that they accurately reflected the law and provided sufficient guidance to the jury. **Id.**

Our review of the record reveals the trial court provided the following instructions to the jury prior to closing arguments.

And then, of course, in a negligence case, in order to find liability, it's a two-step process. Not only must you find negligence, but you have to find the requisite causal connection between that negligence and harm to the plaintiff.

In this case the plaintiff is the child, Blake.

...

So you will have three -- as many as three questions to answer. And it depends on your answer to the preceding question whether you go forward.

(Footnote Continued) _____

Virginia law applies but instead maintains that the trial court's jury instruction "was correct as a matter of Virginia law." Appellee's Brief at 29.

¹⁰ The trial court opinion states that Janssen failed to preserve this issue. Trial Court Opinion, 1/2/14, at 12. This statement is not supported by the record, which reveals that Janssen raised the difference in Virginia law regarding the use of "substantial factor" to explain causation. N.T., 10/29/13 (afternoon), at 34, 43.

The first question would be: Did the defendant, Janssen, negligently fail to adequately warn physicians/healthcare providers -- like Ms. Basye [who] was a physician assistant -- of the extent of the risk of birth defects stemming from the use of Topamax?

That's the negligence question. And if you answer that, that they were not negligent, you answer the question "No." That ends your inquiry. You don't have to go to causation. That makes sense.

And I gave you a rote instruction. But it would make sense. I don't think you need my rote instruction.

If you answer that "Yes," then you have to go to the causation question, which is: Was the Defendant Janssen's negligence a substantial factor - - or sometimes called a factual cause -- in bringing about Blake Czimmer's cleft lip/cleft palate? That's the issue of causation.

If you find negligence, did it cause the cleft lip or cleft palate? I'll define the legal term "substantial factor" sometimes called "factual cause" in my -- in my charge.

N.T., 10/30/13 (morning),¹¹ at 12-14.

After closing arguments, the trial court instructed the jury with respect to causation as follows.

¹¹ The morning and afternoon session of each day of trial were transcribed separately, and the two sessions are not consecutively paginated. Therefore, for clarity, we refer to the notes of testimony by both the date and session.

But when we talk about liability and negligence, it's a two-step process. Not only must you find negligence, but you must find a causal connection between that negligence and harm, in this case, to the child. One without the other is not enough. So you would reach the damage question only if you've answered "yes" to the negligence and causation questions, and then you would proceed to damages.

... If you find negligence but no causation, you don't answer Question 3 involving damages.

Now, the plaintiff has the burden of proving by what we call a fair preponderance or fair weight of the evidence the liability and damages in this case; that is to say, the plaintiff must prove the negligence of Janssen and that that negligence caused the cleft lip or cleft palate in Blake and Blake's damages all by what we call a fair preponderance or fair weight of the evidence.

...

... As I've said, in order to find liability here, you have to find negligence, and you have to find the requisite causal connection between that negligence and harm to the child in this case as I have put it in Question 2.

...

But what I said or what I've given you in Question 2 is: Was the Defendant Janssen's negligence a substantial factor in bringing about Blake Czimmer's cleft lip/cleft palate? That's the issue here. Did he suffer the cleft lip or cleft palate arising from the negligence of the Defendant Janssen?

Now, I sometimes use the word "factual cause" in place of substantial factor. A few years ago we had a state judicial conference in Hershey, and we have it every summer. And we have about 50

judges in there. And they were discussing causation in cases like this, and there were 50 different opinions as to how to define it. And I found, some said use factual cause. Some said use substantial factor. I think the words are synonymous. So I have placed substantial factor in my question. But if you want to use factual cause in thinking about it, you can.

But whether you use substantial factor or factual cause, it's a legal cause. In order for the plaintiff, Blake Czimmer, to recover in this case, the defendant's negligent conduct must have been a substantial factor or factual cause in bringing about his cleft lip/cleft palate. That is what the law recognizes, as I have said, as a legal cause. A substantial factor or factual cause is an actual real factor, although the result may be unusual or unexpected. But it is not an imaginary or fanciful factor or a factor having no connection or only an insignificant connection with the child Blake's cleft lip or cleft palate.

Now, keep in mind, you can have more than one cause that is a substantial factor or factual cause in bringing about a given end.

N.T., 10/30/13 (morning), at 127-128, 134-136.

Accordingly, the verdict sheet provided to the jury contained three questions, two relating to negligence, and one to damages. **See** Verdict Sheet, 10/30/13, at 1. The second question regarding causation asked, "Was [Appellant's] negligence a substantial factor in bringing about Blake Czimmer's cleft lip/cleft palate?" **Id.**

Janssen contends that the trial court's use of "substantial factor" overlooks the Virginia Supreme Court's rejection of that language to explain causation. Janssen's Brief at 36-37, citing **Ford Motor Co. v. Boomer**, 736

S.E.2d 724, 730 (Va. 2013). In **Boomer**, the Virginia Supreme Court rejected the trial court's use of "substantial contributing factor" without further definition to define proximate cause because that language was vague and confusing to the jury. **Boomer, supra**. The plaintiff in **Boomer** sued Ford Motor Company for wrongful death due to mesothelioma caused by exposure to asbestos in Ford's automobile brakes. **Id.** at 726. The Virginia Supreme Court explained that determining causation in mesothelioma cases presents a challenge because identifying a particular exposure as causative is difficult due to the long latency period and the potential for multiple exposures to asbestos over an individual's lifetime. **Id.** at 729. In such "multiple-causation" cases, the **Boomer** court acknowledged that the traditional "but for" conceptualization of causation would make recovery difficult, if not impossible, due to the difficulty of proving which exposure was the sole "but for" cause of the injury. **Id.** In an attempt to guide the jury on the nuances of causation in multiple-causation cases, the trial court instructed the jury that the plaintiff must prove that either the exposure to asbestos in defendant's products or the defendant's failure to warn of asbestos in its products was a "substantial contributing factor" in causing plaintiff's injury. **Id.**

The Virginia Supreme Court rejected the "substantial contributing factor" language because without further definition its impact on the burden of proof was ambiguous. **Id.** at 730. On one hand, the jury could view a

“contributing” factor as something less than “but-for” cause, which would lower the burden of proof. **Id.** Alternatively, the jury could interpret “substantial” as elevating the burden of proof to something more than a mere preponderance. **Id.** To avoid this confusion, the Virginia Supreme Court articulated the standard for factual causation in multiple causation cases was “exposure to the defendant’s product alone must have been *sufficient to have caused the harm[.]*” **Id.** at 731 (italics in original).

In this case, looking at the trial court’s charge as a whole, we conclude that the use of “substantial factor” does not implicate the same concerns as in **Boomer** because here the trial court defined the term and its impact on the burden of proof. **Compare** N.T., 10/30/13 (morning), at 127-128, 134-136 (explaining “substantial factor”) **with Boomer, supra** at 730 (stating “the circuit court in this case never defined the term ‘substantial contributing factor’ in its jury instructions[,] ... [so] some jurors might construe the term to lower the threshold of proof required for causation while others might interpret it to mean the opposite[.]”). The trial court’s charge gave context and meaning to the term “substantial factor” that was absent in **Boomer**. The charge clarified that the plaintiff had to prove that “negligence caused the cleft lip or cleft palate in Blake ... by [] a fair preponderance or fair weight of the evidence.” N.T., 10/30/13 (morning), at 128. The charge also explained that the causation question on the verdict sheet of “[w]as the Defendant Janssen’s negligence a substantial factor in bringing about Blake

Czimmer's cleft lip/cleft palate?" was asking the but for causation question of "[d]id he suffer the cleft lip or cleft palate **arising from** the negligence of the Defendant Janssen?" *Id.* at 135 (emphasis added); **see also Boomer, supra** at 732 (defining a sufficient cause as one "arising from negligence"). The trial court further clarified that "substantial factor" was synonymous with "factual cause." N.T., 10/30/13 (morning), at 135. The plain meaning of "factual cause" is that the "harm would not have occurred absent the conduct." *Boomer, supra* at 731, *quoting* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26 (2010); **see also** BLACK'S LAW DICTIONARY, cause (9th ed. 2009) (defining factual cause as "but for cause").

Moreover, the trial court instructed the jury that it had to find Janssen's negligence was "an actual real factor" in "bringing about [the] cleft lip/cleft palate," "not an imaginary or fanciful factor or a factor having no connection or only an insignificant connection." N.T., 10/30/13 (morning), at 136. Looking at the charge in its entirety, the trial court instructed the jury it had to find, by a preponderance of the evidence, that Blake's cleft lip or palate arose from Janssen's negligence, *i.e.*, that Janssen's negligence was a factual, or but for, cause of Blake's injury. Even though the charge contained the words "substantial factor," it adequately defined causation such that the jury would not misconstrue the burden of proof. Therefore, the trial court did not commit a clear abuse of discretion or error of law

because the charge as a whole accurately reflects the law. **See Krepps, supra.**

Further, in the context of the whole charge, Janssen has failed to demonstrate in what way the use of the words “substantial factor” caused an incorrect result. Janssen merely contends that the “[u]se of substantial factor was prejudicial because Virginia has found it misleading, confusing, and capable of imposing a more lenient burden of proof than the factual cause standard actually requires.” Janssen’s Brief at 41, *citing, Boomer, supra* at 730 & RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26 cmt. j (2010). We decline to isolate the words “substantial factor” from the context of the entire charge. **See Krepps, supra.** Instead, as explained above, the trial court’s charge as a whole adequately explained that the jury had to find that Blake proved by a preponderance of the evidence that he suffered cleft lip or cleft palate arising from Janssen’s negligence. This is not ambiguous, and it does not impose a more lenient burden of proof. Instead, it is an accurate description of the law. Accordingly, the trial court did not commit a clear abuse of discretion or error of law that controlled the outcome of the case. **See id.** Therefore, Janssen’s second issue on appeal does not warrant relief. **See ACE Am. Ins. Co., supra.**

Janssen’s third issue on appeal presents two sub-issues regarding the testimony of Basye, the physician’s assistant who prescribed Topamax to

April, and we address them in turn. First, Janssen argues that the trial court erred in denying JNOV because the evidence did not establish causation, as it did not show a warning pertaining to cleft lip or cleft palate would have avoided Blake's injury. Janssen's Brief at 42. Specifically, Janssen claims Basye understood the risk of birth defects associated with Topamax use during pregnancy because it was a category C drug. *Id.* at 42-44. Janssen essentially argues that a warning about cleft lip or cleft palate would not have altered Basye's decision to prescribe Topamax to April. The record belies this contention.

Assuming that a plaintiff has established both duty and a failure to warn, a plaintiff must further establish proximate causation by showing that had defendant issued a proper warning [], he would have altered his behavior and the injury would have been avoided. To create a jury question, the evidence introduced must be of sufficient weight to establish ... some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug.

Gurley, supra at 292 (alterations in original), *quoting Maya v. Johnson & Johnson*, 97 A.3d 1203, 1213-1214 (Pa. Super. 2014), *appeal denied*, 112 A.3d 653 (Pa. 2015).

In cases involving the failure to warn of risks associated with prescription drugs, Pennsylvania courts apply the "learned intermediary doctrine."

Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the

facts which make the drug likely to be dangerous. The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.

Id. at 292-293, quoting **Cochran v. Wyeth, Inc.**, 3 A.3d 673, 676 (Pa. Super. 2010), *appeal denied*, 20 A.3d 1209 (Pa. 2011). While the Virginia Supreme Court has not explicitly adopted the learned intermediary doctrine, it has seemingly approved it in cases involving prescription drugs. **Pfizer, Inc. v. Jones**, 272 S.E.2d 43, 44 (Va. 1980); **Talley v. Danek Medical, Inc.**, 179 F.3d 154, 162 (4th Cir. 1999) (predicting the Virginia Supreme Court would adopt the learned intermediary doctrine).

Here, April established causation through Basye's deposition testimony, presented to the jury, that she would not have prescribed Topamax if Janssen had informed her of the specific risk of cleft lip or cleft palate. Her testimony was presented to the jury, in part, as follows.

Q. As a P[hysician's] A[ssistant], did you have the authority to determine which medications would be appropriate to treat a patient who had symptoms of migraine?

A. Yes.

...

Q. Do you expect the information that is provided in the PDR[, Physician's Desk Reference, containing the drug's label,] to be complete and accurate?

A. Yes, I do. I believe that it's basically the best source for a lot of information on all the drugs that we prescribe at the time.

Q. Can you adequately perform a risk benefit analysis if the PDR is not accurate and complete?

[A.] No.

...

Q. Let me ask you ask you about Categories C and D. When you're prescribing a medication to a woman in her child-bearing years, do you pay attention as to whether or not a medication is a C versus a D?

A. Yes.

Q. Which one has more risk of harm to an unborn fetus, a C or a D?

[A.] Category D.

Q. Do you prescribe Category D medications to women in their child-bearing years?

A. Not to my knowledge.

Q. As you sit here today in reviewing [April's] medical records, if Topamax had been a Category D when you first prescribed it to April, would you have chosen Topamax to treat her migraines?

[A.] I don't believe so.

...

Q. If you had been aware back in August of 2006 when you prescribed Topamax that there was a risk

to her unborn fetus of cleft lip and cleft palate, would that have altered your prescribing habits?

[A.] Yes.

Q. Would you have prescribed Topamax to April [] in August of 2006 if you had known there was a risk to her unborn fetus?

A. No.

Q. Would you have ever prescribed Topamax to [April] if you had known that there was an increased risk of cleft lip and cleft palate?

A. I don't believe so.

...

Q. Does that PDR, that label, warn you as a prescriber that Topamax carries with it an increased risk of cleft lip and cleft palate?

[A.] No.

Q. Did you have any knowledge back in 2006 or 2007 that Topamax could cause cleft lip or cleft palate?

A. No.

Q. Would [] [April] have received Topamax from you if you had known that?

[A.] No.

[Q.] If Topamax had been a Class -- Category D medication in 2006 and 2007 when you were prescribing it to [April], would you have prescribed it?

A. No.

Based on the foregoing, the evidence was of sufficient weight to allow the jury to conclude that Basye would not have prescribed Topamax to April if Janssen had adequately warned Basye that Topamax carried the risk of cleft lip or cleft palate. **See Gurley, supra.** Viewing the evidence in the light most favorable to Blake and April, the record belies Janssen's contention that Blake and April did not establish causation. **See id.** Accordingly, this claim does not warrant relief. **See Braun, supra.**

In Janssen's second sub-issue, within its third issue on appeal, it contests the trial court's rulings to exclude some evidence for the purpose of impeaching Basye. Janssen's Brief at 46-47. Our standard of review is as follows.

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

Pursuant to Rule of Evidence 402, relevant evidence is generally admissible, and irrelevant evidence is inadmissible. Further, relevant evidence may be excluded if its probative value is outweighed by its potential for unfair prejudice, defined as a tendency to suggest decision on an improper basis or to

diver[t] the jury's attention away from its duty of weighing the evidence impartially.

Conroy v. Rosenwald, 940 A.2d 409, 417 (Pa. Super. 2007) (bracket in original; citations omitted).

Janssen contends the trial court erred in excluding evidence that "demonstrates Ms. Basye understood the risks Plaintiffs' [sic] claim Janssen failed to convey." Janssen's Brief at 47. This included evidence that Basye prescribed April another Category D drug, Paxil, during her child-bearing years and evidence of Basye's refusal to refill April's Topamax prescription once she became pregnant because of the risk to the fetus. **Id.** at 47. The trial court explained that it excluded the testimony regarding the circumstances under which Basye prescribed Paxil because it "was not relevant since it is an entirely different drug and was prescribed under entirely different circumstances. The [trial] [c]ourt did not want to open the door to a side trial as to why Paxil was prescribed." Trial Court Opinion, 1/2/14, at 13-14. We discern no abuse of discretion in the trial court's decision to exclude evidence relating to Paxil, as it does not tend to prove or disprove whether Janssen provided an adequate warning regarding Topamax. **See Conroy, supra**. Therefore, the trial court's ruling to exclude

evidence of Paxil does not warrant a new trial because it was reasonable and not an abuse of discretion.¹² **See ACE Am. Ins. Co., supra.**

The trial court also properly excluded evidence of Basye's refusal to refill April's Topamax prescription once she became pregnant as such evidence is not relevant to the question of whether Janssen provided an adequate warning before Basye prescribed Topamax to April. Moreover, Janssen cannot show the exclusion of this evidence was prejudicial because it was cumulative of other evidence in the record that Janssen introduced to support its contention that Basye knew of the risks associated with taking Topamax during pregnancy at the time she prescribed it to April. **See** Janssen's Motion for Post-Trial Relief, 11/8/13, at 5-10. Therefore, the trial court did not abuse its discretion in denying Janssen's motion for a new trial based on excluding portions of Basye's testimony. **See ACE Am. Ins. Co., supra.**

In its fourth issue on appeal, Janssen contends it was entitled to JNOV on the award of future healthcare costs to Blake that he will incur as an unemancipated minor, until he attains the age of 18, as his parents' claim

¹² Even if the trial court erred in excluding the evidence of Paxil, it is a harmless error. The overwhelming evidence established that Basye would not have prescribed Topamax to April if she knew of the risk of birth defects.

for those healthcare costs was time-barred.¹³ Janssen's Brief at 49-56. Our review is guided by the following. "The question of whether a statute of limitations has run on a claim is usually a question of law for the trial judge, but, at times, a factual determination by the jury may be required." **Sch. Dist. of Borough of Aliquippa v. Md. Cas. Co.**, 587 A.2d 765, 768 (Pa. Super. 1991) (citations omitted). "The issue of which limitations period applies to a particular cause of action is a question of law. As such, we exercise *de novo* review which is plenary in scope." **Burger v. Blair Med. Assocs., Inc.**, 964 A.2d 374, 378 (Pa. 2009) (citations omitted).

We begin by addressing which state's statute of limitations applies in this case. Because the Czimmers' claims accrued in Virginia but were filed in Pennsylvania, we apply the Pennsylvania Uniform Statute of Limitations on Foreign Claims Act, 42 Pa.C.S.A. § 5521. According to that statute, we must apply the statute of limitations of the state with the shorter limitations period, including accrual and tolling rules. 42 Pa.C.S.A. § 5521(b). Pennsylvania has a two-year statute of limitations for a claim brought on behalf of an unemancipated minor to recover future health care expenses incurred until the minor reaches majority, while Virginia has a tolling

¹³ Blake's father, Aaron Czimmer, and April brought claims for Blake's pre-majority health care costs in the trial court. The trial court, however, dismissed the parents' claims as time-barred, but permitted Blake to recover for those expenses in his own right. Thus, on appeal, the Appellee is April, as guardian on behalf of Blake.

provision that expands the limitations period to five years for such claims. **Compare** 42 Pa.C.S.A. § 5524(2) (codifying two-year statute of limitations), **Wilson v. El-Daief**, 964 A.2d 354, 361 (Pa. 2009) (noting claim accrues when injury is sustained), 42 Pa.C.S.A. § 5533(b) (providing that an unemancipated minor’s cause of action is tolled until minor attains majority), **and Fine v. Checcio**, 870 A.2d 850, 858-859 (Pa. 2005) (describing Pennsylvania’s “discovery rule” tolling doctrine), **with** Va. Code Ann. § 8.01-243(B) (extending two-year statute of limitations for personal injury actions to five years when a minor’s parents assert claims on behalf of the minor for personal injury), **Id.** § 8.01-230 (prescribing claim accrues from the date injury is sustained), **Id.** § 8.01-229(2)(a) (stating that unemancipated minor’s claim is tolled), **and Chalifoux v. Radiology Assocs. of Richmond, Inc.**, 708 S.E.2d 834, 837 (Va. 2011) (noting Virginia has not adopted the “discovery rule”). Because Pennsylvania’s statute of limitations is shorter, we apply Pennsylvania law.¹⁴

“Under Pennsylvania Law[,], personal injury to a minor gives rise to two separate and distinct causes of action, one the parents['] claim for medical expenses and loss of the minor’s services during minority, the other the minor’s claim for pain and suffering and for losses after minority.”

¹⁴ The parties and trial court also agree that Pennsylvania’s two-year limitations period for personal injury actions applies to the future health care costs incurred until Blake attains the age of 18. Janssen’s Brief at 50; Appellee’s Brief at 55; Trial Court Opinion, 1/2/14, at 9.

Bowmaster ex rel. Bowmaster v. Clair, 933 A.2d 86, 88 (Pa. Super. 2007), quoting ***Hathi v. Krewstown Park Apartments***, 561 A.2d 1261, 1262 (Pa. Super. 1989), vacated sub nom., ***E.D.B. ex rel. D.B. v. Clair***, 987 A.2d 681 (Pa. 2009); accord ***Baumann v. Capozio***, 611 S.E.2d 597, 599 (Va. 2005) (recognizing the same two causes of action for personal injury to a minor under Virginia law).

The two-year statute of limitations on a minor's independent cause of action that accrues before the age of 18 is tolled until the minor turns 18 by Section 5533 of the Judicial Code, which provides as follows.

§ 5533. Infancy, insanity or imprisonment

...

(b) Infancy.--

(1) (i) If an individual entitled to bring a civil action is an unemancipated minor at the time the cause of action accrues, the period of minority shall not be deemed a portion of the time period within which the action must be commenced. Such person shall have the same time for commencing an action after attaining majority as is allowed to others by the provisions of this subchapter.

(ii) As used in this paragraph, the term "minor" shall mean any individual who has not yet attained 18 years of age.

...

42 Pa.C.S.A. § 5533(b)(1)(i)-(ii). Accordingly, the limitations period for a minor's claim is measured from the time the minor turns 18 irrespective of

when the claim accrues. ***Fancsali ex rel. Fancsali v. Univ. Health Ctr. of Pittsburgh***, 761 A.2d 1159, 1164 (Pa. 2000). Even though the statute of limitations is tolled, a parent or guardian may still commence an action on behalf of a minor at any time after it accrues. ***Id.*** Such an action does not affect the limitations period; it remains suspended until the minor turns 18. ***Id.***

The minority tolling provision, however, does not apply to the parents' nonderivative claim for medical expenses and loss of the minor's services during minority. ***Hathi, supra*** at 1263. Accordingly, the limitations period for the parents commences when the minor's cause of action accrues. ***Fancsali, supra.***

Based on these principles, Blake's parents' claim for medical expenses he will incur during the period of time before he turns 18 is time-barred. A two-year statute of limitations applies to Blake's parents' claim for personal injuries resulting from Janssen's negligence. 42 Pa.C.S.A. 5524(2). The claim accrued on September 24, 2007, the day on which Blake was born with a cleft lip/palate. As such, his parents had until September 24, 2009 to commence their cause of action. They did not file this action until May 31, 2011, over one and one-half years after the limitations period had expired.

Therefore, their claim was time-barred.¹⁵ ***See Hathi, supra; Fancsali, supra.***

The trial court found that the parents' claim for healthcare costs during minority was barred by the statute of limitations.¹⁶ Trial Court Opinion, 1/2/14, at 9. Despite this, the trial court allowed Blake to proceed in his own right on the claim for future medical costs he will incur until he turns 18. ***Id.*** The jury awarded Blake \$562,184.68 for future health care costs.¹⁷ Verdict Sheet, 10/30/13, at 1. Janssen contends the trial court should have entered JNOV on the future medical costs issue because Blake, as a minor, does not have an independent right to recover these expenses when his

¹⁵ We note that on appeal, April attempts to argue that the trial court erred in not applying the discovery rule to toll the statute of limitations on the parents' claim for future medical expenses. Appellee's Brief at 55-58. However, after a careful review of the record, we agree with the trial court that the parents have waived this argument, as they did not raise it in the trial court. Trial Court Opinion, 1/2/14, at 10; Pa.R.A.P. 302(a).

¹⁶ In its second sub-issue of its fourth issue on appeal, Janssen argues that the trial court erred in failing to ask the jury to decide whether Blake's parents had brought their claim within the applicable limitations period. Given that the trial court properly concluded that the parents' claim was time-barred, this issue is meritless.

¹⁷ In addition, the jury awarded Blake \$3,440,00.00 for pain and suffering, which Janssen does not claim is barred by the statute of limitations. Verdict Sheet, 10/30/13, at 1.

parents' claim for the same is time-barred because the right to recover belongs to Blake's parents alone.¹⁸ Janssen's Brief at 53-55.

Traditionally, Pennsylvania courts have held that the right to recover medical expenses a minor incurs before attaining the age of 18 accrues only to the parents, and the minor cannot independently recover those expenses. ***E.g., Bowmaster, supra*** at 89 (concluding "it is clear [the unemancipated minor] could not have asserted a claim for medical expense in her own right during her time of minority[']"). In ***Bowmaster***, the parents of a minor born with severe birth defects filed an action against the hospital on her behalf two months before her 18th birthday. ***Id.*** at 87. The parents did not assert an independent cause of action on their behalf for medical expenses paid during the time before she turned 18. ***Id.*** at 88. Notice of the lawsuit was given to the Pennsylvania Department of Public Welfare (DPW), as the minor had been receiving medical assistance throughout the time before she turned 18, and DPW asserted a lien for the amount of benefits it had paid out to cover the minor's medical expenses. ***Id.*** at 87. The parents

¹⁸ Janssen also argues that the trial court violated the law of the case doctrine when it allowed Blake to recover despite a March 25, 2013 order from the Honorable Arnold L. New that denied the Czimmers' motion to transfer the parents' claim to Blake. Janssen's Brief at 52-53. This argument is misplaced. The trial court found the parents' claim was barred by the statute of limitations and, thus, did not transfer it. Notwithstanding that determination, the trial court decided that Blake, in his own right, could recover future medical expenses during his minority. Trial Court Opinion, 1/2/14, at 10-11.

eventually settled the claims on behalf of the minor against the hospital. **Id.** The parents sought to avoid DPW's lien by asserting that the settlement proceeds did not represent any reimbursement for the medical expenses the parents incurred on behalf of the minor because such a claim was not part of the lawsuit. **Id.** at 88. DPW asserted it was entitled to reimbursement under the Fraud and Abuse Control Act (FACA), 62 P.S. §§ 1401-1418. **Id.** This Court held that DPW was not entitled to reimbursement because the parents were the true beneficiary of the benefits DPW paid during the minor's minority, and those payments were not part of the suit because the parents were not parties. **Id.** at 91. In so concluding, the Court relied on the Pennsylvania common law principle that an unemancipated minor cannot recover medical expenses incurred during the time before he or she turns 18. **Id.**

After **Bowmaster**, the Commonwealth Court decided a factually similar case, but reached the opposite conclusion. **Shaffer-Doan v. Commonwealth Dep't of Pub. Welfare**, 960 A.2d 500, 516 (Pa. Commw. Ct. 2008). In **Shaffer-Doan**, a minor's parents asserted both a claim on behalf of their minor son for medical expenses he anticipated incurring after he turned 18 and a claim on their own behalf for medical expenses that they would incur before the minor turned 18. **Id.** at 503. The trial court granted partial summary judgment as to the parents' claim because it was time-barred. **Id.** The parties then settled. **Id.** When DPW asserted a lien

against the settlement proceeds, the parents attempted to avoid the lien by arguing that the settlement did not represent payment for any medical expenses incurred before the minor turned 18, which was identical to the argument of the parents in **Bowmaster**. *Id.* at 506. In its opinion, the Commonwealth Court examined and ultimately rejected this Court's approach in **Bowmaster**. *Id.* at 512-514. Instead, the Commonwealth Court applied the language of the FACA and "conclude[d] that a minor is not prevented from seeking medical expenses incurred while he is a minor, so as to enable DPW to recover its lien for monies it has expended, as long as such a claim is not duplicated by the parents." *Id.* at 516 (footnote omitted).

While **Shaffer-Doan** was pending in the Commonwealth Court, our Supreme Court granted allowance of appeal in **Bowmaster**, under the name of **E.D.B. ex rel. D.B. v. Clair**. *E.D.B., supra* at 683. In its decision, the Supreme Court recognized the conflict between this Court's holding in **Bowmaster** and the Commonwealth Court's conclusion in **Shaffer-Doan**. *Id.* at 687. In vacating **Bowmaster**, the Court approved of **Shaffer-Doan's** critique of **Bowmaster** as based on the antiquated view that children were the property of their father. *Id.* at 688. The Court decided that DPW was entitled to reimbursement solely on statutory grounds, declining to decide the larger question of whether a minor has an independent right to recover for the medical expenses incurred before the

age of 18. *Id.* at 691 n.10 (noting, “[w]e have cited the Commonwealth Court’s thoughtful summary of the history of the rights and duties of parents with respect to their children. However, we must point out that the broad question of the continuing validity of the common law doctrine that bars an individual from bringing suit for medical expenses incurred during his or her minority is not before us and is not the basis for our decision[.]”) (citation omitted). Thus, while not explicitly deciding the question of whether a minor may recover for medical expenses incurred before the age of 18, the Supreme Court in judicial dicta called into doubt the continuing validity of the common law doctrine that supplied the rationale for the ***Bowmaster*** decision. *Id.*

The Supreme Court held that, “pursuant to the [FACA], a Medicaid beneficiary has a cause of action against his or her tortfeasor to recover and reimburse DPW for Medicaid benefits received during the beneficiary’s minority.” *Id.* at 691. Earlier in its opinion, the Court noted that “DPW’s claim in this case is far less than one-half of [the minor’s] monetary recovery.” *Id.* at 690 n.8. Because the monetary award occurred pursuant to a settlement, we cannot determine how much of the total amount was apportioned as compensation for the minor’s medical expenses incurred pre-majority as opposed to post-majority. Nonetheless, the Court’s decision recognizes a minor’s statutory cause of action for medical expenses incurred during minority, and does not appear to put a limit on the amount of pre-

majority medical expenses that the minor can recover. In fact, capping the amount at the total of benefits already received would contradict the reasoning of the Court that it is in the public interest to protect taxpayers from assuming a cost that should be paid by a tortfeasor. **See id.** at 691. Instead, allowing the minor to recover all pre-majority medical expenses, whether incurred or anticipated, would best serve the public interest and avoid giving a windfall to tortfeasors who are sued earlier in a minor's life.

In light of the Supreme Court's holding in **E.D.B.**, vacating this Court's order in **Bowmaster**, we conclude the common law doctrine prohibiting a minor from recovering damages for medical expenses incurred before age 18 is no longer viable.¹⁹ The common law doctrine rested on the premise that parents, specifically fathers, were solely responsible for the support of minors, including medical expenses, and minors were the property of their fathers until turning 18. The common law rule was motivated by a desire to allow the party who actually suffered the damages, *i.e.* the parents with a support obligation, to recover for the loss caused by a tortfeasor, and to

¹⁹ We recognize that "[i]t is beyond the power of a Superior Court panel to overrule a prior decision of the Superior Court, **Commonwealth v. Hull**, 705 A.2d 911, 912 (Pa. Super. 1998), except in circumstances where intervening authority by our Supreme Court calls into question a previous decision of this Court. **Commonwealth v. Prout**, 814 A.2d 693, 695 n.2 (Pa. Super. 2002)." **Commonwealth v. Pepe**, 897 A.2d 463, 465 (Pa. Super. 2006), *appeal denied*, 946 A.2d 686 (Pa. 2008), *cert. denied*, 555 U.S. 881 (2008). We conclude that **E.D.B.** called into question the reliance of **Bowmaster** on the aforementioned common law doctrine.

prevent double recovery by both the parents and the minor for the same expenses. ***Shaffer-Doan, supra*** at 509-511. However, as the Commonwealth Court in ***Shaffer-Doan*** explained, the development of the law and legislation has come to recognize that the cause of action to recover pre-majority medical expenses belongs to both the parents and the minor. ***See id.*** at 513, *citing DeSantis v. Yaw*, 434 A.2d 1273, 1275 (Pa. Super. 1981). ***E.D.B.*** represents the latest expansion of a minor's right to recover medical expenses during minority. Thus, we conclude the minor has an independent right to recover medical expenses incurred before turning 18, as long as the parents do not duplicate the claim. We base our conclusion on the primary public policy that a tortfeasor should be responsible for the harm its tortious conduct causes. We cannot discern any reason to allow a tortfeasor to avoid penalty based on the failure of the minor's parents to bring a timely action. This is an unwarranted windfall in favor of a responsible tortfeasor due to a victim's age. Therefore, the trial court did not err in declaring that Blake was not time-barred from independently recovering his pre-majority medical expenses. Accordingly, the trial court did not err in denying Janssen's motion for JNOV. ***See Braun, supra.***

Based on the foregoing, we conclude all of Janssen's issues on appeal are meritless. The trial court did not commit a clear abuse of discretion or error of law that would warrant JNOV or a new trial. ***See id.; ACE Am. Ins. Co., supra.*** Therefore, we affirm the January 2, 2014 judgment.

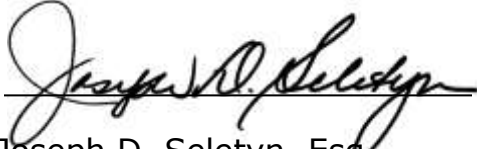
J-A30037-14

Judgment affirmed.

Judge Lazarus joins the opinion.

Judge Platt files a dissenting opinion.

Judgment Entered.

A handwritten signature in black ink, appearing to read "Joseph D. Seletyn", written over a horizontal line.

Joseph D. Seletyn, Esq.
Prothonotary

Date: 8/20/2015