2015 PA Super 49

BRAYDEN & MICHAEL GURLEY AND HALEY POWELL, Appellees v. JANSSEN PHARMACEUTICALS, INC., Appellant	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 239 EDA 2014

Appeal from the Judgment Entered December 5, 2013
in the Court of Common Pleas of Philadelphia County
Civil Division at No.: May Term 2011 No. 02251

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

OPINION BY PLATT, J.: **FILED MARCH 16, 2015**

Appellant, Janssen Pharmaceuticals, Inc.,[1] appeals from the judgment entered in favor of Appellees, Haley Powell, Brayden Gurley, and Michael Gurley, following a jury trial. We affirm.

We take the relevant facts and procedural history of this case from the trial court's April 25, 2014 opinion and our independent review of the record. In April 2005, at age eighteen, while living in Iva, South Carolina, Appellee Haley Powell (Haley) experienced an epileptic episode that caused her to

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* Retired Senior Judge assigned to the Superior Court.

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

lose consciousness.[2] In May 2005, Powell's neurologist, Dr. Bret Warner, diagnosed her as having juvenile myoclonic seizures. Dr. Warner initially prescribed Keppra and Lexapro, and Haley discontinued Lexapro within a few weeks. On March 27, 2006, Dr. Warner prescribed Topamax[3] for Haley to control her headaches and seizures, and she continued using Keppra as the main agent in treating her seizure disorder. Haley continued taking Topamax through December 1, 2007.[4] Neither Dr. Warner nor Haley were aware that use of the drug during pregnancy could possibly cause birth defects such as cleft lip, cleft palate, or oral palate. At the time Dr. Warner prescribed Topamax to Haley, the Food and Drug Administration (FDA) categorized it as a Pregnancy Category C drug.[5]

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[2] Haley continued to reside in South Carolina at the time she filed the instant lawsuit. (***See*** Plaintiff Fact Sheet, 10/16/11, at 2).

[3] Appellant manufactures Topamax, an antiepileptic medication used to treat epilepsy and migraines. (***See*** Appellant's Brief at 12, n.5, 21).

[4] Haley filled the last Topamax prescription for a thirty-day supply under her own name on June 27, 2007. Haley then continued using Topamax through her mother, Sandra Powell's, prescription by another doctor. Sandra Powell had been taking the drug to treat migraines. Sandra testified that her family was having financial difficulties and she filled her prescription instead of Haley's to save money on the insurance co-pay.

[5] (***See*** Plaintiff's Exhibits 1207-1208 (Topamax 2006 and 2007 Physicians' Desk Reference excerpts)). On March 4, 2011, the FDA classified Topamax as a Pregnancy Category D drug. (***See*** Appellant'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

(Footnote Continued Next Page)

On November 19, 2007, Haley learned that she was pregnant with her son, Brayden Gurley (Brayden). She and her husband, Michael Gurley, had conceived Brayden in late October 2007. On November 21, 2007, Haley informed Dr. Warner that she was pregnant and he advised her to taper off Topamax. Haley reduced her intake and completely stopped taking the drug by December 1, 2007. When Haley was twenty-seven weeks pregnant, she learned through an ultrasound that her son had a cleft lip on the right side of

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

In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation, 26 F.Supp.3d 449, 453 n.7 (E.D. Pa. 2014); (***see also*** Plaintiff's Exhibit 1221 (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 Finance, LLC***, 41 A.3d 882, 886 n.3 (Pa. Super. 2012).

his mouth.[6] On July 7, 2008, Brayden Gurley was born with a right side unilateral cleft lip and gum line defects. Brayden had surgery to correct the cleft lip on October 1, 2008. He still has a red scar running from under his nose to his lip as a result of the surgery. Brayden's tooth never grew in correctly in the area where there is a notch in his gum, which makes it appear as though he is missing a tooth. Brayden has difficulties with speech and becomes extremely frustrated when people cannot understand him. He treats with a speech therapist twice a week and regularly visits a plastic surgeon as part of a cleft lip and palate team. Treatments that Brayden will need in the future may include graft surgery to repair the notch in his gums, evaluations to test his hearing, psychological evaluations, dental care related to dental abnormalities, and rhinoplasty for his nasal deformity.

On May 19, 2011, Haley Powell, individually and as guardian of Brayden Gurley, along with Michael Gurley, filed a negligence complaint against Appellant based on a products liability theory. Appellees alleged, *inter alia*, that Appellant failed to warn Haley and her physician about the risk of birth defects associated with Topamax use during pregnancy, including the risk of cleft lip, and that this failure to warn resulted in

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[6] Neither Haley nor her husband has a family history of cleft lip or cleft palate. (***See*** N.T. Trial, 11/08/13, at 50-51).

Brayden's birth defect.[7] On April 1, 2013, Appellant filed a motion for summary judgment, which the trial court granted in part and denied in part.[8] On June 10, 2013, Appellant filed a motion *in limine*, requesting that the trial court preclude Appellees from offering evidence or argument that Appellant could have unilaterally changed Topamax's Pregnancy Category from C to D, without FDA approval. On September 26, 2013, the court entered an order granting Appellant's motion *in limine*.[9]

Appellees' failure to warn claim proceeded to a jury trial on October 29, 2013. On November 19, 2013, the jury returned a verdict in favor of Appellees. It awarded Appellees a total sum of $10,955,000.00; $10,620,000.00 for non-economic loss, and $335,000.00 for future health care costs. On November 22, 2013, Appellees filed a post-trial motion

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[7] Appellees assert that Appellant had actual knowledge that Topamax could cause birth defects in humans from 2000, and certainly by 2006, and that it negligently chose to hide that safety information from prescribing healthcare providers. (***See*** Appellees' Brief, at 18-19).

[8] The court granted summary judgment in favor of Appellant with respect to Appellees' strict liability design defect, negligent design, express warranty, punitive damages, and gross negligence claims. It denied the remainder of the motion. (***See*** Order, 8/27/13, at 1).

[9] On January 28, 2014, after the trial in this case concluded, the court issued an order applicable to all Topamax cases. The order clarified that, while plaintiffs could not offer argument or evidence that Janssen could have unilaterally changed Topamax's Pregnancy Category, they were permitted to introduce argument or evidence that Janssen could have sought or requested a change in the drug's Pregnancy Category from the FDA. (***See*** Order, 1/28/14, at 2).

seeking the addition of delay damages to the verdict. Appellant filed a post-trial motion on November 29, 2013, requesting the trial court to grant judgment notwithstanding the verdict (JNOV) or a new trial. On December 3, 2013, the court denied Appellant's post-trial motion. On December 5, 2013, the court granted Appellees' request for delay damages and ordered $700,294.62 added to the verdict, resulting in a total judgment against Appellant in the amount of $11,655,294.62. This timely appeal followed.[10]

Appellant raises three issues for our review:

> 1. Does federal law preempt a state-law negligent failure-to-warn claim where (a) [Appellant] could not have changed the pregnancy category without the Food and Drug Administration's prior permission and assistance; and/or (b) there was clear evidence that the Food and Drug Administration would not have approved the proposed additional warning that [Appellees] advocate?
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> 2. Did the trial court err in permitting the negligent failure-to-warn claim to go to the jury when [Appellees] could not prove causation (a) because the Topamax Haley ingested was prescribed to a different patient in a higher dosage by a doctor who had never treated Haley; and/or (b) because [Appellees] failed to meet their burden of proving that their proposed changes to Topamax's warnings would have caused either doctor not to prescribe Topamax?

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[10] Pursuant to the trial court's order, Appellant timely filed a concise statement of errors complained of on appeal on January 27, 2014. ***See*** Pa.R.A.P. 1925(b). The court entered a Rule 1925(a) opinion on April 25, 2014. ***See*** Pa.R.A.P. 1925(a).

> 3. Did the trial court err in affirming the non-economic damage award of $10,620,000?

(Appellant's Brief, at 5).[11]

> 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.
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> > 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 appraisement 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.
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> > 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

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[11] We note that Appellant's eleven-page Rule 1925(b) statement of errors contains issues that it did not address in its statement of questions involved or in the body of its brief, including a statute of limitations claim. (***See*** Rule 1925(b) Statement, 1/27/14, at 1-11). Because Appellant has abandoned these issues on appeal, we will not address them. ***See*** Pa.R.A.P. 2116(a) ("No question will be considered unless it is stated in the statement of questions involved or is fairly suggested thereby"); ***see also*** Pa.R.A.P. 2119; ***In re Jacobs***, 936 A.2d 1156, 1167 (Pa. Super. 2007) (issue is waived for purposes of appellate review when an appellant does not develop it in brief).

> 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.
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> 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), *affirmed*, 2014 WL 7182170 (Pa. filed Dec. 15, 2014) (citations and quotation marks omitted).

> 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:
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> > [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.
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> > 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.
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> Moreover, our review must be tailored to a well-settled, two-part analysis:
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> > 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 Companies, 939 A.2d 935, 939 (Pa. Super. 2007), *affirmed*, 971 A.2d 1121 (Pa. 2009) (citations omitted).

In its first issue, Appellant argues that it is entitled to JNOV because Appellees' only claim at trial, their state-law negligent failure to warn claim, was preempted by federal law. (***See*** Appellant's Brief, at 23-40). Specifically, Appellant contends that Appellees' claim is preempted because the federal regulatory scheme prevented it from unilaterally changing the Pregnancy Category in Topamax's labeling without prior FDA approval. (***See id.*** at 21, 28). The trial court determined, however, that federal law did not preempt Appellees' claim, and that the issue of preemption is controlled by the United States Supreme Court's decision in ***Wyeth v. Levine***, 555 U.S. 555 (2009). (***See*** Trial Court Opinion, 4/25/14, at 12-13). Upon review of the record and relevant case law, we agree with the trial court.[12]

In ***Wyeth***, the plaintiff contended that Wyeth, the brand-name drug manufacturer of Phenergan, an antihistamine used to treat nausea,[13] had

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[12] "Issues of preemption comprise pure questions of law, of which the standard of review is *de novo* and the scope of review plenary." ***Ruspi v. Glatz***, 69 A.3d 680, 684 (Pa. Super. 2013), *appeal denied*, 81 A.3d 78 (Pa. 2013) (citation omitted).

[13] Phenergan causes irreversible gangrene if it enters a patient's artery. The plaintiff in ***Wyeth*** developed gangrene after receiving an injection of
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breached a state tort-law duty to provide an adequate warning label.[14] ***See Wyeth***, ***supra*** at 558-59. The United States Supreme Court held that federal law did not preempt the lawsuit because it was possible for Wyeth to comply with both state and federal law. ***See id.*** at 573. Specifically, the FDA's Changes Being Effected (CBE) regulation[15] permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval. ***Id.*** Therefore, federal regulations allowed Wyeth to strengthen its label to comply with its state law duty to provide an adequate warning. The Court stated:

> it has remained a central premise of federal drug regulation that **the manufacturer bears responsibility for the content of its label at all times**. **It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market**. ***See***, *e.g.*, 21 CFR § 201.80(e) (requiring a manufacturer to

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Phenergan in April 2000, and as a result, doctors amputated her right hand and forearm. ***See Wyeth***, ***supra*** at 558-59.

[14] A drug's "FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient." U.S. Department of Health and Human Services, U.S. Food and Drug Administration Glossary of Terms (2015). Drug labeling is "[t]he centerpiece of risk management for prescription drugs" because it "communicates to health care practitioners the [FDA's] formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." 71 Fed.Reg. 3934 (2006). A drug's label is a pharmaceutical company's primary mechanism to communicate with physicians. (***See*** N.T. Trial, 10/30/13, at 19-20; N.T. Trial, 11/13/13, at 12).

[15] ***See*** 21 CFR §§ 314.70(c)(6)(iii)(A),(C).

> revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information").
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> * * *
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> Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. **But absent clear evidence that the FDA would not have approved a change to [a drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements**.
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> * * *
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> In short, Wyeth has not persuaded us that failure-to-warn claims . . . obstruct the federal regulation of drug labeling.

Id. at 570-71, 581 (emphases added); ***see also Maya v. Johnson and Johnson***, 97 A.3d 1203, 1213 (Pa. Super. 2014) (rejecting federal preemption argument made by brand name drug manufacturer claiming that it could not be found negligent for failing to add "skin reddening," "rash," and "blisters" to the list of symptoms in drug's Allergy Alert when they were not required by the FDA) (citing ***Wyeth***).

Here, Appellant attempts to circumvent the clear holding in ***Wyeth*** by asserting "[a]t trial, [Appellees] contended that [it] should have unilaterally changed the pregnancy category for Topamax from C to D." (Appellant's Brief, at 28) (record citation omitted). It argues "[b]ecause [Appellees'] first theory—that [Appellant] should have changed the pregnancy category from

C to D—was a change that was within [the] FDA's sole control, it was preempted." (***Id.*** at 27).

After review, we conclude that this argument lacks record support, and we agree with Appellees that it is an "irrelevant red herring." (Appellees' Brief, at 22). As noted above, prior to trial, the court entered an order specifically prohibiting Appellees from presenting any argument or evidence that Appellant could have unilaterally changed the Topamax pregnancy category without FDA-approval. (***See*** Order, 9/26/13). Appellees maintain that they fully adhered to the court's order during trial. (***See*** Appellees' Brief, at 23). Appellant has not directed this Court to any place in the voluminous record where Appellees failed to comply with this order by contending that Appellant should have unilaterally changed its pregnancy category. (***See*** Appellant's Brief, at 28). Moreover, as the ***Wyeth*** Court explained, the FDA's CBE regulation allows drug manufacturers to make certain changes to update and strengthen safety information in its label before receiving the FDA's approval. ***See Wyeth, supra*** at 568; (***see also*** N.T. Trial, 10/30/13, at 19-20). Accordingly, we find this portion of Appellant's argument specious.

Appellant also attempts to evade the ***Wyeth*** decision by relying on the United States Supreme Court's holding in ***PLIVA***, ***Inc v. Mensing***, 131 S.Ct. 2567 (2011), to argue that it "cannot be held accountable under state law for failing to do something that it could not do without the FDA's prior authorization." (Appellant's Brief, at 29) (citing ***PLIVA***, ***supra*** at 2577-78).

However, we agree with the trial court that Appellant's reliance on ***PLIVA*** is misguided. (***See*** Trial Ct. Op., at 14). ***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 pre-emption results." ***Id.*** at 2582. Thus, we conclude that Appellant's argument based on ***PLIVA*** is not legally persuasive.

Appellant next attempts to fit within ***Wyeth's*** holding to establish preemption by arguing there is clear evidence that the FDA would not have approved Appellees' proposed change to the Topamax label to warn that the drug could cause oral clefts in newborns prior to Brayden's conception. (***See*** Appellant's Brief, at 33, 36-37 (citing ***Wyeth, supra*** at 571 ("absent clear evidence that the FDA would not have approved a change to [a drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.")). Appellant maintains that, because the "FDA rejected [its] attempts to link human birth defects to Topamax use[,]"

in its Patient Package Insert (PPI)[16] in 2006, "[i]t follows that [Appellees'] contention that Topamax's label should have stated that Topamax caused oral clefts in humans would not have been approved at that time." (***Id.*** at 36) (record citation omitted). In support of this argument, Appellant points to evidence showing that in September 2005, it submitted a revised version of Topamax's PPI to the FDA, proposing to include the following language: "Birth defects have been reported, including a minor malformation of the penis called hypospadias, in newborns of women who used TOPAMAX during pregnancy." (Appellant's Brief, at 34 (emphasis omitted); Exhibit D-1196, 9/29/05, at 3). Appellant argues that because the FDA did not accept this proposed change to the Topamax PPI,[17] the agency would have also rejected a proposed change to the Topamax label to warn that the drug caused oral clefts in humans. (***See*** Appellant's Brief, at 34-36).

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[16] "A patient package insert contains information for patients' understanding of how to safely use a drug product." U.S. Department of Health and Human Services, U.S. Food and Drug Administration Glossary of Terms (2015).

[17] Specifically, in May 2006, the FDA sent Appellant a draft PPI that did not include Appellant's proposed change and instead included the following language: "Various abnormalities have been described in the offspring of animals exposed to TOPAMAX during pregnancy." (Appellant's Brief, at 35 (emphasis omitted); Exhibit D-1206, 5/02/06, at unnumbered page 5). Although the FDA provided no commentary in this specific section of the draft PPI, it did advise "**[t]he PPI is not expected to contain all known/possible side effects**. . . . If . . . information is important for prescribers and patients, its prominence in the **label** should be elevated[.]" (Exhibit D-1206, 5/02/06, at unnumbered page 5) (emphases added).

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 PPI 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***. Accordingly, Appellant's first issue does not merit relief.

In Appellant's second issue, it claims that the trial court erred in permitting Appellees' negligent failure-to-warn claim to go to the jury where they could not prove that Topamax proximately caused Brayden's cleft lip. (***See*** Appellant's Brief, at 5, 40-53).[18] Specifically, it argues that because Haley ingested Topamax using her mother's prescription instead of her own

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[18] The trial court, after conferring with the parties, gave a modified charge to the jury incorporating South Carolina terminology regarding causation. (***See*** N.T. Trial, 11/14/13, at 108-09, 111-12). The court acknowledged that causation is essentially the same concept in South Carolina and Pennsylvania. (***See id.*** at 112; ***see also*** Trial Ct. Op. at 18 (citing Pennsylvania law with respect to causation)). Specifically, the court instructed the jury that it was to decide the issue: "[W]as [Appellant's] negligent conduct a proximate cause in bringing about Brayden Gurley's harm?" (N.T. Trial, 11/15/13, at 22). The court's standard charge used the term "factual cause." (***See*** N.T. Trial, 11/14/13, at 112).

in the months before her pregnancy, she severed the link between the learned intermediary (the prescribing physician, Dr. Warner) and herself as the patient. (***See id.*** at 42-47). Appellant also claims that Appellees failed to prove that Dr. Warner's prescribing decision would have been different if the Topamax label had warned of an increased risk of cleft lip or cleft palate. (***See id.*** at 47-53). This issue lacks merit.

> Proximate cause is an essential element in a failure to warn case. A proximate, or legal cause, is defined as a substantial contributing factor in bringing about the harm in question. 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.

Maya, supra at 1213-14 (citation omitted).

In cases involving the failure to warn of risks associated with prescription drugs, both Pennsylvania and South Carolina 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.

Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super. 2010), *appeal denied*, 20 A.3d 1209 (Pa. 2011) (citations and quotation marks omitted); ***see also Odom v. G.D. Searle & Co***., 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law and stating that sole issue in case controlled by learned intermediary doctrine is whether an adequate warning to patient's doctor about injury would have deterred doctor from prescribing product).

Here, in order to establish causation, Appellees presented to the jury the following deposition testimony of Dr. Warner:

> Q. Do you expect that the information that is provided to you through the PDR [Physicians' Desk Reference, containing the drug's label] to be accurate and complete?
>
> A. Yes.
>
> Q. Do you expect manufacturers of medications to fully inform you as to the risks of the medication through the PDR?
>
> A: As thoroughly as possible.
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> * * *
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> Q: Did you avoid using Depakote because of the high risk of birth defect?
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> A: Yes.
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> * * *
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> Q: Doctor, when you prescribed Topamax for Haley on March the 27th, 2006, did you do a risk/benefit analysis at that time?
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> A: Yes
>
> Q: Did you have any knowledge in March of 2006 of Topamax putting a patient at an increased risk for cleft lip or cleft palate,

> more specifically, the unborn child at risk for cleft lip or cleft palate?
>
> A: No.
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> * * *
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> Q: If you had been aware of a risk with Topamax and a risk of a cleft lip or cleft palate to an unborn fetus, is that a risk that you would have taken into consideration when prescribing it to Haley in March of 2006?
>
> A: Yes.
>
> Q. If you had been aware of cleft lip or cleft palate as a risk with Topamax when you prescribed it to Haley in March of 2006, would it have altered your prescribing habits?
>
> A: It would have had a major impact, I think.

(Deposition of Dr. Bret Warner, 7/30/12, at 3, 7, 14, 20).

Dr. Warner further testified that on November 28, 2007, after learning that Haley was pregnant, he immediately advised her to taper off Topamax. (***See id.*** at 18). He testified that he had no reason to believe that she had stopped taking Topamax before he instructed her not to, and that he believed that she had been continuously using the drug since he first prescribed it to her in March 2006. (***See id.*** at 19). Haley testified that she ingested Topamax on a daily basis from the time Dr. Warner prescribed it to her until he instructed her to discontinue the drug. (***See*** N.T. Trial, 11/08/13, at 32-34, 36, 38, 41-42).

Based on the foregoing, we conclude that the trial court properly determined that "the evidence introduced [was] of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would

have prevented [Haley] from receiving the drug." ***Maya***, ***supra*** at 1214 (citation omitted). The testimony showed that Dr. Warner was unaware of Topamax's increased risk of cleft lip and/or palate in newborns when he prescribed the drug to Haley, and that knowledge of this risk would have deterred him from prescribing the medication for her. Haley ingested Topamax on a daily basis from the time Dr. Warner prescribed it to her until he instructed her to discontinue it. The fact that Haley obtained the Topamax for a few months using her mother's prescription instead of her own because of the family's financial difficulties does not permit Appellant to evade liability for Brayden's injuries. Accordingly, the trial court did not err in allowing the issue of causation to go to the jury, or in subsequently denying Appellant's motion for JNOV on this issue. ***See Braun***, ***supra*** at 891. The jury clearly credited Dr. Warner and Haley's testimony and this Court will not reweigh the evidence. ***See id.*** Appellant's second issue does not merit relief.

In its third issue, Appellant claims that the evidence does not support the jury's award of $10,620,000.00 in noneconomic damages[19] and that it is therefore entitled to remittitur. (***See*** Appellant's Brief, at 5, 53-58). Appellant argues that the award is excessive in light of Brayden's injuries,

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[19] "Noneconomic loss is composed of (1) pain and suffering, (2) embarrassment and humiliation, (3) loss of ability to enjoy the pleasures of life, and (4) disfigurement." ***Renna***, ***infra*** at 672 n.4 (citation omitted).

under circumstances where his cleft lip has been repaired, he has only a faint scar, and his injury does not prevent him from attending school and developing normal relationships with his peers. (***See id.*** at 54-56). This issue does not merit relief.

> Our standard of review from the denial of a remittitur is circumspect and judicial reduction of a jury award is appropriate only when the award is plainly excessive and exorbitant. The question is whether the award of damages falls within the uncertain limits of fair and reasonable compensation or whether the verdict so shocks the sense of justice as to suggest that the jury was influenced by partiality, prejudice, mistake, or corruption. Furthermore, [t]he decision to grant or deny remittitur is within the sole discretion of the trial court, and proper appellate review dictates this Court reverse such an Order only if the trial court abused its discretion or committed an error of law in evaluating a party's request for remittitur.

Renna v. Schadt, 64 A.3d 658, 671 (Pa. Super. 2013) (citations and quotation marks omitted).

> We begin with the premise that large verdicts are not necessarily excessive verdicts. Each case is unique and dependent on its own special circumstances and a court should apply only those factors which it finds to be relevant in determining whether or not the verdict is excessive. A court may consider the following factors, *inter alia:*
>
> > (1) the severity of the injury; (2) whether the plaintiff's injury is manifested by objective physical evidence or whether it is only revealed by the subjective testimony of the plaintiff (. . . where the injury is manifested by broken bones, disfigurement, loss of consciousness, or other objective evidence, the courts have counted this in favor of sustaining a verdict); (3) whether the injury will affect the plaintiff permanently; (4) whether the plaintiff can continue with his or her employment; (5) the size of the plaintiff's out-of-pocket expenses; and (6) the amount plaintiff demanded in the original complaint.

Gbur v. Golio, 932 A.2d 203, 212 (Pa. Super. 2007), *affirmed*, 963 A.2d 443 (Pa. 2009) (citation omitted).

"In reviewing the award of damages, the appellate courts should give deference to the decisions of the trier of fact who is usually in a superior position to appraise and weigh the evidence." ***Ferrer v. Trustees of Univ. of Pennsylvania***, 825 A.2d 591, 611 (Pa. 2002) (citation omitted).

Here, the trial court stated that:

> [it] did not find that the verdict was excessive or shocking to the conscience given the evidence and issues in this case. In addition, it should be noted that the jury based their verdict on evidence presented by both Appellant and [Appellees] throughout the trial. The jury heard testimony from various physicians that testified to Brayden Gurley's injuries and accompanying treatments that would be needed to correct those injuries. [(***See*** Deposition Testimony of Dr. Russell Reid, 10/08/13, at 14-16; ***see also*** N.T. Trial, 11/07/13 at 127-28, 164-65)]. The jury also heard testimony from Braydon Gurley's stay-at-home mother who is responsible for his care. [She] testified how the surgery for his severe cleft lip has negatively affected his self-esteem, confidence and his ability to have a simple conversation with others. [(***See*** N.T. Trial, 11/08/13, at 58, 60, 63, 66)]. [She] also stated that her son becomes extremely frustrated when people do not understand him and suffers from embarrassment due to the residual scar from his cleft lip surgery. [(***See id.*** at 65-66)]. Additionally, physicians' testimony as to Braydon Gurley's injuries included[:] ongoing visits with a plastic surgeon, dental surgery, speech therapy, auditory evaluations, oral surgery, possible rhinoplasty and treatment for possible psychological issues related to these various corrective surgeries. [(***See*** Deposition Testimony of Dr. Russell Reid, 10/08/13, at 14-16; N.T. Trial, 11/07/13, at 128-29, 164)]. Given the injuries that will plague Brayden Gurley into adulthood, the award determined by the jury can hardly be said to be excessive.

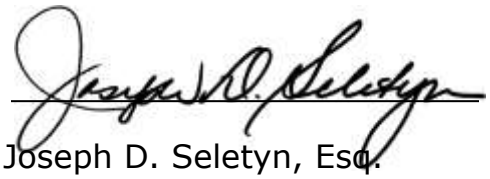
> This verdict does not shock this court's sense of justice nor does it demonstrate the jury was influenced by partiality, prejudice, mistake or corruption. Rather, this verdict shows the jury made an informed and educated finding based on the facts and evidence presented at trial. Brayden Gurley's pain, suffering and loss were significant and demonstrated on the record throughout the trial. Hence, the jury decided on a just and fair award to compensate Brayden Gurley for his injuries.

(Trial Ct. Op., at 35-36).

Upon review of the record, we conclude that it supports the trial court's ruling regarding the jury's damage award. We find no abuse of discretion, and no basis to disturb the jury's verdict. ***See Renna, supra*** at 671. Appellant's final issue on appeal does not merit relief.

Judgment affirmed.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 3/16/2015