In the Superior Court of Pennsylvania

No. 239 EDA 2014

BRAYDEN & MICHAEL GURLEY and HALEY POWELL

v.

JANSSEN PHARMACEUTICALS, INC.,

Appellant.

BRIEF FOR PLAINTIFFS/APPELLEES

On appeal from the judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania, Civil Trial Division, dated December 5, 2013 at May Term 2011 No. 2251

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I. COUNTERSTATEMENT OF THE SCOPE AND STANDARDS OF REVIEW

As the Supreme Court of Pennsylvania explained in *Birth Center* v. *St. Paul Cos.*, 787 A.2d 376, 383 (Pa. 2001), when conducting appellate review of a trial court's ruling on a motion for judgment notwithstanding the verdict, "[w]e view the evidence in the light most favorable to the verdict winner and give him or her the benefit of every reasonable inference arising therefrom while rejecting all unfavorable testimony and inferences."

Earlier, in *Moure* v. *Raeuchle*, 604 A.2d 1003 (Pa. 1992), the Supreme Court explained:

> [T]he 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.

Id. at 1007; *see also Quinby* v. *Plumsteadville Family Practice, Inc.*, 907 A.2d 1061, 1074 (Pa. 2006) (same).

This Court is familiar with the very heavy burden a party bears in order to obtain j.n.o.v.:

> A JNOV can be entered upon two bases: (1) where the movant is entitled to judgment as a matter of law; and/or, (2) the evidence was such that no two reasonable minds could disagree that the verdict should have been rendered for the movant. When reviewing a trial court's denial of a motion for JNOV, we must consider all of the evidence admitted to decide if there was sufficient competent evidence to sustain the verdict. In so doing, we must also view this evidence in the light most favorable to the verdict winner, giving the victorious party the benefit of every reasonable inference arising from the evidence and rejecting all unfavorable testimony and inference. Concerning any questions of law, our scope of review is plenary. Concerning questions of credibility and weight accorded the evidence at trial, we will not substitute our judgment for that of the finder of fact. If any basis exists upon which the jury could have properly made its award, then we must affirm the trial court's denial of the motion for JNOV. A JNOV should be entered only in a clear case.

American Future Systems, Inc. v. *Better Business Bureau*, 872 A.2d 1202, 1215 (Pa. Super. Ct. 2005) (citation omitted), *aff'd*, 923 A.2d 389 (Pa. 2007).

With regard to Janssen's remittitur request, in *Rettger* v. *UPMC Shadyside*, 991 A.2d 915 (Pa. Super. Ct. 2010), this Court explained:

> 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.

Id. at 932. Furthermore, this Court recognized that the decision to grant or deny remittitur is within the trial court's sound discretion, and will be overturned only upon a showing of abuse of discretion or error of law. *Id.* This Court will not substitute our judgment for that of the fact–finder, and this Court will view the record with consideration of the evidence accepted by the jury. *See Smalls* v. *Pittsburgh–Corning Corp.*, 843 A.2d 410, 414 (Pa. Super. Ct. 2004).

II. COUNTERSTATEMENT OF THE CASE

A. Relevant Factual History

This lawsuit was brought by plaintiffs Brayden Gurley, a minor, by Haley Powell, as his guardian, and Haley Powell and Michael Gurley, individually, in negligence and failure to warn for injuries sustained as a result of Haley's ingestion of Topamax during her pregnancy. R.101a–06a (Plaintiffs' short form complaint). Haley took Topamax® for migraine headaches and hand tremors during the first trimester of her pregnancy. R.873a–74a (Tr. 11/8/13 a.m. at 41–42). Her son Brayden was born on July 7, 2008 with a right unilateral cleft lip and alveolar ridge defects. R.881a–82a, 887a–88a, 897a (Tr. 11/8/13 a.m. at 49–50, 55-56, 65). Topamax is

manufactured, sold, and marketed by defendant Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.

On April 26, 2005, at age 18, after an apparent convulsive episode at school and a brief loss of consciousness, Haley Powell began treating with Bret J. Warner, M.D., a neurologist. R.841a–43a (Tr. 11/8/13 a.m. at 9–11). Haley's mother, Sandra Powell, accompanied Haley to this visit and to subsequent visits. R.840a (Tr. 11/8/13 a.m. at 8). Prior to her marriage in January 2008, Haley lived with her parents in her childhood home. R.719a–20a (Tr. 10/31/13 p.m. at 13–14). While they were living together, Sandra would purchase and obtain all of Haley's medications. R.733a–35a (Tr. 10/31/13 p.m. at 27–29).

On May 6, 2005, Dr. Warner diagnosed Ms. Powell with Juvenile Myoclonic Epilepsy ("JME") and began treatment of her epilepsy with Keppra®, a Pregnancy Category C drug. R.1432a–33a (Ex. P–62, Dr. Warner Tr. at 29). He decided Keppra was a better option for her seizures than Depakote, a Pregnancy Category D drug. *Id.* In particular, Dr. Warner stated that Keppra did not have the same known risk of birth defects as Depakote, and thus was a better option for a woman in her childbearing years like Haley. *Id.* Haley continued taking Keppra, suffering only one

"break-through seizure" on November 11, 2005. R.1436a (Dr. Warner Tr. at 40).

On March 27, 2006, Dr. Warner prescribed Topamax to Haley for her complaints of intermittent tension headaches and migraines. R.1438a–39a (Dr. Warner Tr. at 46–48). At that time, Topamax was a Pregnancy Category C drug. R.1446a (Dr. Warner Tr. at 73). Dr. Warner did not offer any information about the birth defect risks of Topamax at the time he prescribed it to Haley or thereafter. R.1439a (Dr. Warner Tr. at 49–50). Dr. Warner's testimony, based on his medical records, confirmed that Haley took Topamax twice a day from 2006 through mid-December 2007, as Dr. Warner had instructed. R.1440a, 1441a, 1443a, 1444a (Dr. Warner Tr. at 52, 56, 61, 65).

On June 27, 2007, Ms. Powell filled a Topamax prescription for 30 pills before her pregnancy began. R.865a–66a (Tr. 11/8/13 a.m. at 33–34). After exhausting her June 27 Topamax medication in approximately late July, she began taking Topamax that was filled under her mother's prescriptions. R.866a–69a (Tr. 11/8/13 a.m. at 34–37); R.734a–35a (Tr. 10/31/13 p.m. at 28–29). Sandra Powell, Haley's mother, had herself begun taking Topamax in February 2007 for migraines, and continued to receive

prescriptions for the medication until early May 2010. R.715a-16a (Tr. 10/31/13 p.m. at 9–10). When Sandra began taking Topamax, she was given samples to use while her dosage was adjusted. *Id.* During the time Sandra was trying to find the optimal dosage of Topamax that did not produce side effects for her, she would cut the Topamax tablets in half with her doctors' knowledge. R.717a–18a (Tr. 10/31/13 p.m. at 11–12). Sandra continued to experience side effects with Topamax and, by May 2007, had weaned herself off of Topamax. R.717a (Tr. 10/31/13 p.m. at 11).

By the time Haley finished her June 27, 2007 Topamax prescription, economic concerns existed that required both Haley and Sandra to try to conserve money. R.733a–35a (Tr. 10/31/13 p.m. at 27–29). Haley and Sandra decided that to help reduce the cost of Haley's multiple medications and insurance co-pays, Sandra would fill the remainder of her Topamax prescriptions and provide the tablets to Haley. *Id.* Because Sandra's Topamax prescription was for 60 pills, her prescription would last two months, whereas Haley's prescription would have to be filled with a monthly co–pay. R.865a–67a (Tr. 11/8/13 a.m. at 33–35). In late July 2007, Haley began taking the Topamax pills left over from her mother's earlier Topamax samples. R.865a–66a (Tr. 11/8/13 a.m. at 33–34). To comply with

Haley's prescribed dosage of 50 mg. twice a day, Sandra would cut the pills in half, as she had done for herself. R.734a (Tr. 10/31/13 p.m. at 28).

From March 2006 through mid-December 2007, without interruption, Haley took Topamax. R.855a, 864a–69a, 873a–74a (Tr. 11/8/13 a.m. at 23, 32–37, 41–42); R.735a–36a (Tr. 10/31/13 p.m. at 29–30). Indeed, Dr. Warner's records on July 16, 2007 and November 28, 2007 state that Haley was taking Topamax. R.1443a–44a (Ex. P–62, Dr. Warner Tr. at 60–61, 62–65). According to Dr. Warner, Haley was always a cooperative and compliant patient, and she consistently took Topamax as prescribed. R.1440a (Dr. Warner Tr. at 52).

On November 19, 2007, Haley found out she was pregnant, and she called Dr. Warner's office regarding her medications. R.873a (Tr. 11/8/13 a.m. at 41). Two days later, Dr. Warner instructed Haley to begin to taper off of Topamax. R.873a–74a (Tr. 11/8/13 a.m. at 41–42.

The evidence introduced at trial, summarized above, established that Ms. Powell continuously ingested Topamax from 2006 until approximately mid-December 2007. This was confirmed by Sandra Powell, Haley's mother. Sandra testified that she personally saw Haley take Topamax on a daily basis in the prescribed amount, until she was instructed to taper off of

Topamax. R.716a, 720a (Tr. 10/31/13 p.m. at 10, 14). Further, because Sandra and Haley lived together, Sandra would not only hand Haley Topamax pills every day, but would also see Haley take Topamax. R.734a–35a (Tr. 10/31/13 p.m. at 28–29).

Neither Haley nor Dr. Warner was aware that Topamax could cause birth defects, including cleft lip and/or palate, during the time Haley took Topamax. R.855a (Tr. 11/8/13 a.m. at 23); R.1439a (Ex. P–62, Dr. Warner Tr. at 49–50). Indeed, the evidence at trial showed that Dr. Warner relied on the information contained in the Topamax label, and if the label had said that Topamax could cause birth defects such as cleft lip and/or palate, he would not have prescribed Topamax to Haley. R.1428a–29a, 1431a–32a, 1439a, 1445a–46a (Dr. Warner Tr. at 13–14, 26–27, 49, 69–70, 72–73). It was not until March 2011 that Haley and her husband Michael became aware of a causal connection between Topamax and their son Brayden's injuries. R.885a (Tr. 11/8/13 a.m. at 53).

Brayden was born on July 7, 2008, with right unilateral cleft lip (diagnosed in utero) and alveolar ridge defects. R.881a–82a, 887a–88a, 897a (Tr. 11/8/13 a.m. at 49–50, 55-56, 65). On October 1, 2008, Dr. James Wallace performed Brayden's cleft lip repair. R.726a–28a (Tr. 10/31/13

p.m. at 20–22); R.827a–29a (Tr. 11/7/13 a.m. at 165–67). The alveolar ridge defects have not yet been surgically corrected. R.826a (Tr. 11/7/13 a.m. at 164). Brayden suffers from dental complications, including misalignment of his teeth and an overbite. R.822a–23a (Tr. 11/7/13 a.m. at 127–28). He also suffers from speech and language disorders, both of which are directly related to his cleft lip and alveolar ridge defects. R.822a–24a (Tr. 11/7/13 a.m. at 127–29). He will require additional surgeries and associated treatments to address multiple complications, which will likely include middle ear fluid accumulation, hearing loss, dental abnormalities, speech difficulties, and psychosocial problems that children born with clefts, such as Brayden, endure. R.1476a–79a (Plt. Exh. 48, Deposition of Dr. Reid at 51–58).

B. Relevant Procedural History

Plaintiffs filed this lawsuit in the Court of Common Pleas of Philadelphia County in May 2011. R.1a (docket entries)

In September 2013, Judge Arnold L. New entered an order stating that under FDA regulations Janssen did not have the ability to unilaterally change the pregnancy category applicable to Topamax from C to D. R.548a

(Judge New's Sept. 2013 order). As Judge New later stated in clarifying his order, although Janssen had the ability to request a change in the pregnancy category applicable to Topamax, the FDA's approval was necessary before Janssen could alter its warning label to identify Topamax as in pregnancy category D rather than in pregnancy category C. R.1422a–23a (Judge New's clarifying order).

As a result, at the conclusion of the trial of this case, plaintiff through her counsel did not urge the jury to hold Janssen liable for having failed to place Topamax into pregnancy category D. R.1105a–48a, 1150a–66a (Tr. 11/15/13 a.m. at 11–54, 101–17). Rather, plaintiff advanced a traditional negligent failure to warn claim against the manufacturer of a brand–name prescription drug, focusing on the specific warnings of Topamax's established potential to cause birth defects, including cleft lip and cleft palate, about which Janssen was aware in 2006 and 2007 and which Janssen unquestionably had the ability to add to the warning label for the medication without needing to obtain any advance permission from the FDA.

This case proceeded to trial before the Honorable George W. Overton. Judge Overton allowed the parties to present to the jury all of the

relevant and contested evidence on the issues of what sort of birth defect warnings Topamax should have contained in 2006 and 2007 based on the risks of the drug known to Janssen at that time, whether the drug would have been prescribed to Ms. Powell had the drug contained accurate and appropriate birth defect warnings in 2006 and 2007, and whether the drug was the factual cause of Brayden Gurley's cleft lip and cleft aveolus. The jury, after hearing all of the relevant evidence, resolved each of these issues in plaintiff's favor. R.1251a–53a (Tr. 11/18/13 at 15–17).

Following the jury's verdict, Janssen filed a timely post–trial motion requesting either judgment notwithstanding the verdict or a new trial. R.1357a (Janssen's post–trial motion). On April 25, 2014, Judge Overton issued a 36–page lengthy and detailed opinion thoroughly and decisively rejecting all of the grounds for j.n.o.v. or a new trial that Janssen had presented, including Janssen's request for a remittitur. *See* Appendix A to Brief for Appellant. Janssen thereafter appealed from the denial of its post–trial motion to this Court. In its appellate brief, Janssen is no longer expressly seeking a new trial. *See*, *e.g.*, Brief for Appellant at 58 ("Conclusion and Relief Sought").

III. SUMMARY OF THE ARGUMENT

Janssen's Brief for Appellant in this case is even more notable for the arguments it fails to make as for the arguments it actually does make. Janssen fails to argue that its medication, Topamax, was not the cause of Brayden Powell's birth defects. Janssen does not argue that it was prevented from presenting to the jury any evidence relevant to Janssen's federal preemption defense. And Janssen does not argue that the jury failed to find as a fact that Ms. Powell ingested Topamax at the dosage and frequency prescribed by Ms. Powell's own physician at all relevant times, as her own prescribing physician's records and testimony confirmed.

Instead of taking issue with any of those points, Janssen's appeal advances three grounds. First, on the issue of federal preemption, Janssen leads with an irrelevant red herring. Counsel for plaintiffs did not ask, nor did the trial court allow, the jury to find Janssen liable based on Janssen's failure to categorize Topamax as a pregnancy category D medication. Thus, Janssen's argument that federal law would preempt liability predicated on the medication's pregnancy category completely misses the mark, since the jury was neither asked to, nor was the jury permitted to, make any such finding.

Janssen's second preemption–related argument is equally without merit. The defendant argues that it introduced clear evidence to satisfy the demanding defense that the federal Food and Drug Administration would not permit Janssen to warn prescribers of Topamax's known human birth defect risk because the FDA did not allow Janssen to add that sort of a warning to the medication's Patient Package Insert (PPI). Yet Janssen's argument is a non sequitur.

The PPI provides warnings to *the patient*. The medication's warning label published in the Physician's Desk Reference is directed to *the prescriber*, a trained medical professional who must determine whether a prescription drug's potential benefits outweigh its potential risks. The falsity of the central premise of Janssen's preemption argument is revealed by the fact that the PPI does not and never was intended to contain all of the warnings, or all of the details, contained in the medication's warning label directed to the physician. Indeed, the vast bulk of the warnings contained in the warning label directed to physicians are not contained in the PPI, nor would the FDA permit them to be contained in the PPI. Thus, the mere fact that the FDA did not allow a particular warning to be added to the PPI fails to establish that the FDA would not have permitted Janssen

to include that warning in the label directed to physicians. Indeed, in this case, the jury specifically found that Janssen could have and should have added the warning plaintiffs advocated to the label directed to physicians, which would have avoided plaintiff's injuries.

Second, Janssen's Brief for Appellant quarrels with the jury's finding that an adequate warning of Topamax's actual human birth defect risks would have caused Ms. Powell's own prescribing physician not to have prescribed that medication. Janssen begins its argument with an irrelevancy, contending that because Ms. Powell ingested some Topamax prescribed to Ms. Powell's mother, the warning given to Ms. Powell's own prescribing physician would not have mattered. This bizarre argument, for which Janssen can cite no authority, did not distract the jury, which found as a fact that Ms. Powell at all times complied with her own physician's instructions concerning frequency and dosage.

The jury heard all of the relevant evidence on this point and returned a finding for plaintiffs on this issue. The evidence at trial, viewed in the light most favorable to plaintiffs, more than suffices to uphold this finding. The physician who prescribed Topamax to Ms. Powell testified both that he avoided prescribing to Haley another medication with a known risk of

birth defects and Topamax's birth defect risks, had the physician known of them, "would have had a major impact" on his decision whether or not to prescribe Topamax. This evidence more than sufficed to allow the jury to find, as the jury did find, that the physician would not have prescribed Topamax to Ms. Powell if the label had contained the warnings about human birth defects that plaintiffs established the label could have and should have contained.

Finally, Janssen argues that the trial court abused its discretion in failing to order a remittitur. Janssen's brief repeatedly characterizes Brayden's deformity of consisting only of a faint scar that might go unnoticed, following an initial round of surgery to correct this child's deformities. Yet Janssen's brief improperly downplays not only Brayden's actual current condition but also the additional risky medical procedures, including additional surgeries, that Brayden still must undergo, as well as the developmental disabilities in speech and personality that have plagued and may continue to permanently plague this child as a result of his injuries stemming from his mother's use of defendant's medication. The test for remittitur is extraordinarily stringent. Here, the jury had no choice but to consider the future course of Brayden's surgeries, medical treatment,

and lasting physical and emotional damage. Based on all the evidence, the trial court did not abuse its discretion in holding that the jury's award of damages was not plainly excessive or exorbitant and did not indicate that the jury was influenced by partiality, prejudice, mistake, or corruption.

IV. ARGUMENT

A. The Trial Court Correctly Ruled That Federal Law Does Not Preempt Plaintiff's Negligent Failure To Warn Claim Against The Manufacturer Of Brand–Name Topamax, And Janssen's Arguments To The Contrary Are Based On Irrelevancies And Misdirection

1. Plaintiff has prevailed on a traditional negligent failure to warn claim against the manufacturer of a brand–name prescription drug that the U.S. Supreme Court has held is not preempted by federal law

In *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the U.S. Supreme Court held, with regard to the manufacturer of a brand name prescription drug, that "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." *Id.* at 570–

71. The Supreme Court proceeded to explain that "[i]mpossibility preemption is a demanding defense." *Id.* at 573.

Thus, in *Levine*, the U.S. Supreme Court ruled that the FDA's approval of a drug's warning label does not insulate the manufacturer of an FDA–approved drug from liability on a state law failure to warn claim unless the FDA specifically precluded the manufacturer from giving the very warnings that the plaintiff claims should have been given. As the U.S. Supreme Court's opinion in *Levine* explains, "absent *clear evidence* that the FDA would not have approved a change to [a medication's] label, we will not conclude that it was impossible for [the drug's manufacturer] to comply with both federal and state requirements." *Id.* at 571 (emphasis added).

The U.S. Supreme Court recognized in *Levine* that whether the FDA would or would not reject the particular warning label that the plaintiff claims the medication should have contained constituted findings of fact based on the evidence before the jury at trial. *See id.* at 572. In this case, the trial court permitted the jury to hear all of the evidence that the parties wished to present on the issue of federal preemption, and the jury's verdict in plaintiff's favor represents the jury's rejection of Janssen's federal

preemption defense. This is because if the jury concluded that the FDA would have prohibited Janssen from including the warning that plaintiffs contend should have accompanied Topamax, the jury could not have found in favor of plaintiffs on their negligent failure to warn claim.

In this case, the record is replete with evidence that more than adequately supports the jury's findings in this regard. The evidence that plaintiff introduced at trial established that Janssen had actual knowledge that Topamax could cause birth defects in humans from at least 2000, and certainly by 2006, and that Janssen negligently chose to hide that relevant safety information from the prescribing healthcare providers. R.601a–04a, 606a–10a, 616a–17a, 628a–31a, 636a–39a, 640a–43a (Tr. 10/30/13 a.m. at 38–41, 43–47, 56–57, 83–86, 91–94, 95–98). Plaintiff's labeling and safety surveillance expert, Dr. Peggy Pence, testified that the label for Topamax was inadequate in 2007 in the follow respects:

> • Janssen's pre–clinical studies revealed incidences of cleft palate birth defects in different species — mice and rabbits — after exposure to Topamax. R.592a–96a (*Id.* at 29–33). These defects, in addition to other birth defects at increasing dosages, was a signal of teratogenicity and increases the likelihood that Topamax caused birth defects in humans. R.599a (*Id.* at 36). Janssen failed to specifically include the cleft palate animal findings in Topamax's label. (*Id.*).

- Janssen knew, by August 1998, that six humans had been born with birth defects after in utero exposure to Topamax. R.601a (*Id.* at 38). Four of those children were born with hypospadias. R.602a (*Id.* at 39). Janssen unilaterally changed its labeling to reflect these four occurrences because Janssen knew these constituted reasonable evidence of a potential association with Topamax. R.602a–03a (*Id.* at 39–40).

- Janssen's informed consent forms distributed to clinical research participants in and before 2001 conveyed that Topamax "has the potential to cause serious birth defects in children." R.606a–12a (Tr. 10/30/13 a.m. at 43–49). Janssen never included this risk in its label at any time through 2007. R.610a–13a (*Id.* at 47–50).

- In 2003, Janssen's "Safety Signal Assessment Report" identified four children who had been born with cleft lip or cleft lip with cleft palate. R.623a–25a (*Id.* at 63–65). In 2003, Janssen knew these reports reflected an important safety signal. R.1529a–30a (Plt. Exh. 37, Deposition of Dr. Lisa Ford, M.D. at 65); R.626a (Tr. 10/30/13 a.m. at 66). Despite this important safety signal in 2003, Janssen nevertheless failed to update its labeling to reflect its knowledge before 2011. R.625a (Tr. 10/30/13 a.m. at 65).

- In its 2005 pregnancy report, Janssen identified eight cases of cleft lip and/or palate that resulted following in utero exposure to Topamax. R.630a (*Id.* at 85). Although Janssen could have unilaterally changed its labeling to reflect the increased oral cleft cases, it did not do so. R.630a–31a (*Id.* at 85–86).

- In 2005, Janssen knew from the Morrow study that Topamax (monotherapy) had the highest malformation rate of any anti–epileptic drug in its class and that a fetus exposed to Topamax in utero was 2.75 times more likely to experience a birth defect than a fetus not exposed to Topamax. R.632a, 634a–

38a (*Id.* at 87, 89–93). Although Janssen knew this information was clinically significant, Janssen never updated its labeling through 2007 to reflect this known data. R.638a–39a (*Id.* at 93–94).

- Edward Osifchin, a Manager of Regulatory Medical Writing for J&J PRD, LLC (a sister company to Janssen), testified that the PDR sentence in the 2007 label that "[t]here are no studies using Topamax in pregnant women," "[a]s written, it's not completely correct. R.1535a (Plt. Exh. 19 at 57–60). That was so because Janssen had the Morrow study from 2005.

- In addition, the 2007 Topamax warnings and labels did not state the following that was known to Janssen by that time and that should have been included based on the evidence described above:

  - that "Topamax has the potential to cause serious birth defects in children."

  - and that "Topamax can cause cleft lip and/or palate."

Rather, the 2007 (R.3303a (Plt. Exh. 1208)) Topamax label in the Physician's Desk Reference ("PDR") stated only the following concerning pregnancy risks:

> Pregnancy: Pregnancy Category C
>
> Topiramate has demonstrated selective developmental toxicity, including teratogenicity, in experimental animal studies. . . .
>
> . . .

> There are no studies using TOPAMAX® in pregnant women. TOPAMAX® should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.
>
> In post–marketing experience, cases of hypospadias have been reported in male infants exposed in utero to topiramate, with or without other anticonvulsants; however, a causal relationship with topiramate has not been established.

Id.

The jury in this case heard that, under the "Changes Being Effected" regulation of the federal Food and Drug Administration, Janssen did not need prior FDA approval to add to its Topamax label directed to prescribers specific mention of the particular birth defect risks that the drug presented, as described above, that were known to Janssen in 2006 and 2007. R.589a–60a (Tr. 10/30/13 a.m. at 19–20). The U.S. Supreme Court discussed the "Changes Being Effected" regulation in *Levine*, 555 U.S. at 568–71.

As in *Levine*, here Janssen is unable to point to any "clear evidence that the FDA would not have approved a change" to the warning label for Topamax in 2006 or 2007 concerning the medication's actual known birth defect risks. Janssen's argument that simply because the FDA approved a particular warning label demonstrates the FDA would have rejected a

more informative and more accurate warning label was itself rejected by the U.S. Supreme Court under the similar circumstances presented in *Levine* and should likewise be rejected by this Court. *See Levine*, 555 U.S. at 558–59 ("The question we must decide is whether the FDA's approvals provide Wyeth with a complete defense to Levine's tort claims. We conclude that they do not.").

2. Janssen's argument concerning federal preemption and Topamax's pregnancy category is irrelevant and incorrect

The very first argument Janssen raises in its Brief for Appellant consists of nothing more than a completely irrelevant red herring. Plaintiffs did not ask the jury to hold Janssen liable because Janssen should have changed the pregnancy category for Topamax from C to D. Because the jury's finding against Janssen could not have rested on that basis, Janssen's preemption argument concerning this issue is irrelevant to this case.

As noted above in the Statement of the Case, in September 2013, Judge Arnold L. New entered an order stating that under FDA regulations Janssen did not have the ability to unilaterally change the pregnancy category applicable to Topamax from C to D. R.548 (Sept. 2013 order).

Later, Judge New issued a clarifying order stating that, although Janssen had the ability to request a change in the pregnancy category applicable to Topamax, the FDA's approval was necessary before Janssen could alter its warning label to identify Topamax as in pregnancy category D rather than in pregnancy category C. R.1422a–23a (clarifying order).

During the trial of this case, plaintiffs adhered completely to Judge New's ruling on the subject of pregnancy categories. Indeed, a review of plaintiffs' counsel's closing argument to the jury, and the trial court's instructions to the jury, reveals that neither plaintiffs' counsel nor the trial court even once suggested to the jury or asked the jury to find Janssen negligent because Janssen had failed to change Topamax's pregnancy category from C to D. R.1105a–48a, 1150a–66a (Tr. 11/15/13 a.m. at 11–54, 101–17) (closing argument of plaintiffs' counsel); R.1175a–230a (Tr. 11/15/13 p.m. at 6–61 (judge's charge to the jury).

Thus, Janssen's lengthy and convoluted argument about how the doctrine of "impossibility preemption" recognized in the U.S. Supreme Court's ruling in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011) — a decision that exclusively concerned federal preemption of warnings applicable to *generic* medications (a holding not applicable here, because Topamax is a

brand–name prescription drug governed by the U.S. Supreme Court's ruling in *Levine*) — should cause this Court to grant j.n.o.v. in favor of Janssen based on preemption due to Topamax's pregnancy category entirely misses the mark.

The jury in this case was not asked by plaintiff, nor permitted by the trial court, to find that Janssen should have labeled Topamax as a pregnancy category D drug, and thus Janssen's argument that federal law would preempt any such finding provides no basis whatsoever for the entry of j.n.o.v. in Janssen's favor.

3. Janssen cannot satisfy its heavy burden of establishing federal preemption under *Wyeth* v. *Levine* because the FDA never rejected any of plaintiff's proposed warnings from the label directed to prescribers

This Court should reject Janssen's attempt to fit within *Levine*'s extremely limited exception to establish preemption because Janssen mischaracterized its 2005 and 2006 submissions to the FDA and the agency's response to those submissions. Janssen can only prevail under the *Levine* "clear evidence" standard if it demonstrates that before Ms. Powell's date of conception, in October 2007 or through the first critical weeks of her

first trimester, Janssen "attempted to give" a warning that Topamax could cause cleft lip and/or palate, "but was prohibited from doing so by the FDA." *See Levine*, 555 U.S. at 572. Janssen comes nowhere near satisfying these requirements to prove preemption, because Janssen never attempted to warn prescribers that Topamax causes cleft lip and/or palate, nor did the FDA prohibit Janssen from doing so.

Janssen begins by asserting that "[i]n September 2005, Janssen submitted a revised version of the Topamax *patient packet insert* to FDA, incorporating new information and proposing new pregnancy language referencing reports of birth defects in humans." Brief for Appellant at 34. In asserting that "clear evidence" of federal preemption exists, Janssen relies exclusively on the FDA's response to Janssen's proposed changes to Topamax's Patient Package Insert (PPI) rather than focusing on the actual warning label directed to the prescriber of the medication.

This Court in *Coleman* v. *Wyeth Pharmaceuticals, Inc.*, 6 A.3d 502, 512 (Pa. Super. Ct. 2010), has already recognized the distinction between "the physician–labeling information published annually in the *Physicians' Desk Reference* ('PDR') and patient package inserts for the medications at issue." As its name indicates, the Patient Package Insert contains information

directed to the patient, not to the physician. Thus, the PPI contains only the most important and easy to understand risks of a medication, but the PPI is not intended by the FDA to provide the same comprehensive catalogue of all of a prescription medication's risks in the same way that the warning label directed to prescribers must. There are of course several reasons for this, including the fact that only the prescriber decides whether to give the patient a certain prescription drug, and only the prescriber is trained to understand all of the medical and scientific terminology contained in the warning label directed to prescribers.

Understood in this correct context, the FDA's May 2, 2006 response was not a "rejection" of any birth defect warning. R.3138a (Def. Exh. 1206). Rather, the FDA was responding to Janssen's September 29, 2005 submission of a revised draft PPI — information directed towards the patient, which is undeniably not a label — that contained inappropriate adverse event information. R.3118a (Def. Exh. 1196); R.1047a (Tr. 11/12/13 p.m. at 87). Janssen's proposed PPI contained language that "[b]irth defects have been reported, including a minor malformation of the penis called hypospadias." R.3118a (Def. Exh. 1196). On May 2, 2006 the FDA sent Janssen a proposed PPI that did not include the "birth defects" sentence

because "the PPI is not expected to contain all known possible side effects." R.3138a (Def. Tr. Exh. 1206); R.1047a (Tr. 11/12/13 p.m. at 87).

The FDA's May 2006 email further informed Janssen that if the information was "important for prescribers and patients, its prominence in the label should be elevated * * * to Warning or Precautions . . . ." R.3138a (Def. Exh. 1206). But, as the evidence at trial showed, Janssen did not take any action to include birth defect warnings, including a causation warning, in the label directed to the drug's prescribers. Dr. Pence's testimony illustrates the difference between a PPI and a drug's labeling, and that it was Janssen's responsibility to include the proposed warning in Topamax's labeling directed to prescribers:

> Q. You said if human data surfaces or poses or shows there's a potential risk to a fetus, is it required or is it just optional for the pharmaceutical company to then request a label change?
>
> A. It's required that the label be updated with clinically important information when there is reasonable evidence that there's an association of a birth defect. In this case with the drug, the company is required to update the label.
>
> * * *
>
> A. Can you clarify? You're looking for the ways that companies can update labels?
>
> Q. Correct.

A. There are two ways. The first way is what we call changes being effected, and that means that the company unilaterally, on its own, can update the label for safety when there's a safety update, and send that label, use that label immediately without getting FDA's approval.

They submit it to FDA at the time they begin to use it, but they don't have to wait for FDA's approval; and that's what we call a CBE, for short, where a change is being effected to the label.

* * *

In the case of safety information, again, I just want to reiterate, a company, the CBE, exists to enable you to update for safety reasons in particular.

Q. Why?

A. Because, again, the doctors are on the front line; they're seeing patients every day and making prescribing decisions, and if they don't up-to-date information, and in the example -- in this case, if the product -- if there's birth defect information and the doctor doesn't know about it, he may prescribe a product for someone that he would not otherwise prescribe the product for.

So if he has the up-to-date information, then potential birth defects can be prevented, if he knows if the product has the potential to cause birth defects.

Q. Are these rules voluntary, Dr. Pence?

A. No.

* * *

> Q Now, a patient package insert is something that goes directly to the patient, correct?
>
> A That's correct.
>
> Q What we have been talking about up until now is information that goes to the physician, correct?
>
> A Yes, the professional labeling.

R.588a–90a, 675a (Tr. 10/30/13 a.m. at 18–20; 10/30/13 p.m. at 57).

Janssen's own regulatory expert, Dr. Dena Hixon, agreed that the medication's warning label directed toward prescribers, rather than the PPI, was "pharmaceutical company's primary mechanism to communicate with physicians." R.1056a (Tr. 11/13/13 a.m. at 12). Dr. Hixon also acknowledged in her testimony that the PPI "is not expected to contain all known possible side effects. For this reason, information from the post-marketing section is not usually included in PPIs." R.1047a (Tr. 11/12/13 p.m. at 87).

If more evidence were needed that the exclusion of warning–related information from the PPI does not mandate the exclusion of the same warning–related information from the warning label directed to prescribers, Topamax's warning label directed to prescribers contains mention of far more risks, and in far greater detail, than are contained in

that medication's PPI. The same could be said of essentially all other prescription drugs. If in fact a prescription drug's warning label could only contain mention of those risks described in the PPI, then perhaps Janssen's unprecedented preemption argument might seem plausible. Unfortunately for Janssen, the record in this case clearly disproves the basis for Janssen's preemption argument arising from what the Topamax PPI was or was not allowed to contain.

The FDA's response to the PPI and Janssen's inaction in light of the FDA's suggestion to include birth defect warnings in the label does not constitute "clear evidence" that the FDA would have prohibited a stronger birth defect causation warning for Topamax contained in the medication's warning label directed to prescribers. Moreover, Janssen has failed to cite to any case law establishing that the FDA's rejection of a specific warning *to the patient* in the PPI establishes clear evidence that the warning could not have been included in the warning label directed *to the physician* so as to give rise to preemption for purposes of *Levine*. The non–existence of any such case law, and the fact specific to this case that the FDA's exclusion of the warning from the PPI *expressly instructed* Janssen to include the birth defect warning in the labeling directed to the prescriber, *which instructions*

Janssen ignored, demonstrate that the trial court properly rejected Janssen's motion for j.n.o.v. under *Levine*.

Lastly, Janssen criticizes the trial court for refusing to provide the jury with a special jury interrogatory on the subject of federal preemption. But the trial court's refusal to provide such a jury interrogatory was certainly not legally erroneous or an abuse of discretion, for two independent reasons. First, as explained above, Janssen's federal preemption argument based on Topamax's PPI is so clearly without merit that on this record no evidentiary basis existed for any reasonable jury to find in favor of Janssen on the issue of federal preemption.

And second, even in the absence of such a jury interrogatory, the jury's verdict demonstrates that the jury affirmatively rejected Janssen's federal preemption defense. If the jury agreed with Janssen that the FDA would not have permitted Janssen to include the sort of human birth defect warning that plaintiffs had argued in favor of in the warning label directed to prescribers, then the jury would have had no alternative other than to return a defense verdict, finding Janssen not negligent. Thus, the jury's verdict already provides the same definitive rejection of Janssen's

preemption defense that any separate jury interrogatory would have afforded.

* * * * *

As demonstrated above, Janssen's arguments for j.n.o.v. stemming from federal preemption are based on irrelevancies and misdirection. The trial court, for the reasons explained above, properly rejected Janssen's request for j.n.o.v. predicated on supposed federal preemption.

B. The Trial Court Properly Rejected Janssen's Request For J.N.O.V. On Inadequate Warning Causation, As Ms. Powell's Prescriber's Testimony Allowed The Jury To Find, And The Jury Did Find, That Warnings Of Topamax's Actual Birth Defect Risks Would Have Prevented The Drug's Being Prescribed To Ms. Powell

In this case, Dr. Warner, Ms. Powell's prescribing healthcare provider, testified at trial (by deposition) that he would not have prescribed Topamax to Ms. Powell if its warning label warned that Topamax carried a risk to an unborn fetus, and/or increased the risk of cleft lip and palate, and/or could cause cleft lip and palate. R.1428a–29a, 1431a–32a, 1439a, 1445a–46a (Ex. P–62, Dr. Warner Tr. at 13–14, 26–27, 49, 69–70, 72–73). The jury also heard Dr. Warner testify that in 2006 and 2007,

he relied on the Topamax information Janssen provided in the PDR to determine whether to prescribe Topamax. R.1428a–29a (*Id.* at 13–14).

To prove inadequate warning/learned intermediary causation, plaintiffs presented the following testimony from Dr. Warner to the jury for its consideration:

> Q. Do you expect that the information that is provided to you through the PDR 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?
>
> THE WITNESS: As thoroughly as possible.
>
> Q. Did you avoid using Depakote because of the high risk of birth defect?
>
> 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?
>
> THE WITNESS: No.
>
> Q. Did you warn Haley that Topamax had a teratogenic effect?
>
> THE WITNESS: Not specifically, no.

> Q. If you had been aware of a risk with Topamax and a risk of 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?
>
> THE WITNESS: It would have had a major impact, I think.

R.1428a–29a, 1432a, 1439a, 1445a (*Id.* at 13–14, 27, 49–50, 69–70).

As excerpted above, the jury also heard testimony from Dr. Warner that he had avoided prescribing to Ms. Powell other medication that in fact contained the very same sort of human birth defect warnings that plaintiffs herein established that the warning label for Topamax should have contained when Dr. Warner was considering whether to prescribe it to Ms. Powell. R.1431a–32a (*Id.* at 26–27).

Under Pennsylvania law and South Carolina law, which both recognize the learned intermediary doctrine, *see Odom* v. *G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law), the foregoing testimony from Dr. Warner is precisely the very type of testimony needed to establish warning causation — that due to the drug

manufacturer's negligent failure to warn of the medication's actual risk, the drug was prescribed to the patient, whereas it *would not* have been prescribed to the patient if the warning label contained an accurate and complete warning of the drug's known or knowable risks. *See*, *e.g.*, *Simon* v. *Wyeth Pharmaceuticals, Inc.*, 989 A.2d 356, 368 (Pa. Super. Ct. 2009); *Demmler* v. *SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996).

The evidence more than sufficed to allow the jury to find that the "major impact" that an adequate Topamax birth defect warning would have had on Dr. Warner was that he would have decided not to prescribe that drug to Haley Powell, just as he had previously decided not to prescribe another medication to Ms. Powell because that other medication had a known risk of human birth defects. The trial court thus was entirely correct in rejecting Janssen's motion for j.n.o.v. on the issue of learned intermediary causation with respect to Dr. Warner, Ms. Powell's prescribing physician.

Perhaps recognizing that sufficient evidence exists, when viewing the evidence in the light most favorable to plaintiffs, to establish proximate cause with respect to Dr. Warner, Janssen seizes on an unusual factual facet of this case to argue that because Haley Powell for a time was ingesting

Topamax obtained via her own mother's separate prescription, the mother's physician should be considered the pertinent prescriber for purposes of any learned intermediary analysis.

As a logical and a legal matter, Janssen's argument is bizarre and unprecedented. It is clear that the mother's prescribing physician never prescribed Topamax for Haley Powell. If Haley Powell's mother had simply obtained the exact same prescription medication, in the exact same dosage as had been prescribed to Haley, and then Haley took that medication based on the instructions that Haley received from Haley's own physician, under these facts surely the mother's doctor *would not* be considered the prescribing physician for Haley. Janssen has failed to cite to any authority, under either Pennsylvania or South Carolina law, that would make the mother's doctor the relevant prescriber for purposes of the learned intermediary inquiry under the facts of this case.

Moreover, once again the jury verdict in favor of plaintiffs confirms the utter lack of substance to Janssen's appellate arguments. In this instance, the jury had to find as a fact that Haley Powell was continuing to ingest Topamax with the same frequency and dosage that Dr. Warner had prescribed the medication in order for plaintiffs to prevail on their claims.

This particular unusual aspect of this case did not trouble the jury, which only could have found in favor of the plaintiffs if the jury first found that Haley Powell had continued to ingest Topamax in the exact dosage and frequency as Dr. Warner had prescribed.

Janssen surely tried its best before the jury to emphasize the unusual factual wrinkle that this case presents — sadly arising from a commonplace condition in society, financial vulnerability — and then exploit that wrinkle to evade liability for Brayden Gurley's severe injuries. The jury, after hearing all the evidence and all of the arguments of counsel, and after considering the judge's legal instructions, found in favor of plaintiffs despite the unusual factual wrinkle that this case presented.

As explained above, more than sufficient evidence exists to support the jury's finding of learned intermediary causation with respect to Dr. Warner, the one and only learned intermediary who prescribed Topamax to Haley Powell. Accordingly, for all of the foregoing reasons, the trial court did not err in denying Janssen's motion for j.n.o.v. on this issue of warning causation.

C. The Trial Court Did Not Abuse Its Discretion In Denying Janssen's Remittitur Request

As explained above in the "Standard of Review" section, this Court exercises a highly deferential abuse of discretion standard of review, viewing the evidence in the light most favorable to the verdict winner, in considering a remittitur request.

In *Gbur* v. *Golio*, 932 A.2d 203 (Pa. Super. Ct. 2007), this Court explained:

> The grant or refusal of a new trial because of the excessiveness of the verdict is within the discretion of the trial court. *Hall* v. *George*, 403 Pa. 563 170 A.2d 367 (1961). This court will not find a verdict excessive unless it is so grossly excessive as to shock our sense of justice. *Kravinsky* v. *Glover*, 263 Pa. Super. 8, 396 A.2d 1349 (1979). 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. *Mineo* v. *Tancini*, 349 Pa. Super. 115, 502 A.2d 1300 (1986).

Id. at 212.

Janssen's quest for appellate review runs ashore at the outset, failing to view the evidence in the light most favorable to the verdict winner. *See Smalls* v. *Pittsburgh–Corning Corp.*, 843 A.2d 410, 414 (Pa. Super. Ct. 2004) (when considering a remittitur request, the court must view the evidence in

the light most favorable to the verdict–winner). According to Janssen, the jury in this case awarded to Brayden Gurley and his parents more than $10 million when his injuries consist of nothing more than a fully repaired cleft lip whose only remaining consequence is a faint scar that might evade detection. And Janssen maintains that Brayden Gurley's speech defects and emotional injuries have already fully resolved themselves. Yet Janssen's view of the evidence improperly depicts the evidence in the light most favorable to Janssen, rather than in the light most favorable to plaintiffs. The latter is what Pennsylvania law requires. *See Smalls*, *supra*.

In this case, the jury heard that Brayden still must undergo additional reconstructive procedures, including additional surgeries, and that Brayden's speech and emotional development have been and remain negatively impacted in a significant way by the birth defects resulting from his mother's ingestion of Topamax. R.1476a–79a (Plt. Exh. 48, Deposition of Dr. Reid at 51–58); R.822a–24a, 826a (Tr. 11/7/13 a.m. at 127–29, 164). As the trial court's Rule 1925(a) opinion explains at pages 35–36:

> This Court 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 Plaintiff 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. The jury also heard testimony from Brayden Gurley's stay–at–home mother who is responsible for his care. Brayden Gurley's mother 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. Brayden Gurley's mother 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. Additionally, physicians' testimony as to Brayden 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. Given the injuries that will plague Brayden Gurley into adulthood, the award determined by the jury can hardly said to be excessive.

Rule 1925(a) opinion at 35–36.

The trial court correctly recognized that Brayden will likely require dental surgery, oral surgery, nasal surgery, plastic surgery, ongoing speech and psychological therapy. Moreover, the trial court correctly understood that these injuries "will plague Brayden Gurley into adulthood." *Id.* The trial court properly viewed the evidence in the light most favorable to plaintiffs in denying Janssen's remittitur request.

The jury in this case had one and only one opportunity to determine what amount of damages was necessary to adequately compensate

Brayden Gurley and his parents not only for all that he has already experienced as a result of these birth defects but all that he has yet to experience. No amount of money can ever make up for the physical and emotional abnormalities that are an everyday part of Brayden Gurley's existence, and that may remain that way permanently, as a result of defendant's negligent failure to warn of Topamax's birth defect risk. Thus, the trial court correctly concluded that the jury's verdict in this case "can hardly be said to be excessive."

In the *Czimmer* case now also pending on appeal before this Court, the jury returned a verdict of slightly more than $4 million, and Janssen did not argue in that case that the jury's verdict was excessive. Why $4 million is not excessive in that case but $10 million is in this case, Janssen's brief in this case fails to address. Plaintiffs respectfully submit that the verdict in this case is not that much larger than the verdict in *Czimmer* so as to make the verdict in this case conscience–shocking.

In fact, if the worst case scenarios come to pass on any of Brayden's upcoming surgeries or if Brayden's speech and emotional difficulties worsen rather than improve and remain permanent, then the jury's verdict in this case in retrospect could end up seeming far too small.

For all of these reasons, the trial court did not abuse its discretion in denying Janssen's remittitur request, and the judgment in plaintiffs' favor should be affirmed.

V. CONCLUSION

For all of the foregoing reasons, this Court should uphold the trial court's judgment and affirm the trial court's denial of Janssen's post–trial motion.

Respectfully submitted,

Dated: September 19, 2014

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This brief complies with the type–volume limitations of Pa. R. App. P. 2135(a)(1) because this brief contains 8,820 words excluding the parts of the brief exempted by Pa. R. App. P. 2135(b).

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CERTIFICATE OF SERVICE

I hereby certify that I am this day serving a true and correct copy of the foregoing document upon the persons and in the manner indicated below which service satisfies the requirements of Pa. R. App. P. 121:

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