IN THE SUPREME COURT OF PENNSYLVANIA

ALICIA E. MAYA, individually, and
BRIANNA MAYA, by and through her natural parent and guardian

Plaintiffs-Appellees-Respondents,

v.

MCNEIL-PPC, INC.,

Defendant-Appellant-Petitioner.

PETITION FOR ALLOWANCE OF APPEAL

Request for review of July 22, 2014 Order of the Superior Court at Nos. 3259 EDA 2011 and 471 EDA 2012 (consolidated) – as to which reconsideration was denied on September 25, 2014 – affirming the judgment entered January 6, 2012 following trial and post-trial motions by the Court of Common Pleas of Philadelphia County at February Term 2009 No. 2879 (Hon. N. Quinones-Alejandro, J.)

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The Superior Court opinion is reported at 97 A.3d 1203 (Pa. Super. 2014). The opinion of the Court of Common Pleas is available at 2012 WL 7657789, and the amended opinion is available at 2012 Phila. Ct. Com. Pl. LEXIS 449 and 2013 WL 663158 and is appended hereto as provided for in Pa.R.A.P. 1115(a)(6). All citations in the Petition are to the amended opinion.

II. TEXT OF THE ORDER IN QUESTION

The order and opinion are appended hereto as provided for in Pa.R.A.P. 1115(a)(2) and (a)(6).

III. QUESTIONS PRESENTED FOR REVIEW

Whether the Superior Court erred by excusing as "harmless" the trial court's plain error charging the jury, where the court omitted the word "not" when reading a jury charge and thereby wrongly told the jury it could consider (as opposed to could not consider) the "conduct of other pharmaceutical manufacturers" and "what happened with other drugs, such as other drugs being taken off the market," in assessing McNeil's conduct?

The Superior Court answered this question in the negative.

Whether the Superior Court erred by excusing the trial court's trial management error in misleading counsel by ruling that a conclusive "heeding presumption" charge would be given, causing McNeil to forego arguing warning causation in its closing?

The Superior Court answered this question in the negative.

Whether the Superior Court erred by upholding the trial court's decision to give a "concurring cause" jury instruction where no expert offered the opinion that two or more agents combined to cause the plaintiff's injuries?

The Superior Court answered this question in the negative.

Whether the Superior Court erred by sustaining a verdict against a manufacturer of over-the-counter Children's Motrin where the evidence established that the plaintiff's mother relied on the advice of her pediatrician rather than on anything contained in the medicine's label?

The Superior Court answered this question in the negative.

IV. CONCISE STATEMENT OF THE CASE

A. Form of the Action

This petition arises out of the Superior Court's affirmance of a $10 million jury verdict against McNeil-PPC, Inc. ("McNeil"), the manufacturer of Motrin and Children's Motrin, for failing to warn adequately about a rare and idiosyncratic disease, Toxic Epidermal Necrolysis, a variant of Stevens-Johnson Syndrome.

B. Chronological Narrative/Procedural History/Names of the Judges

Brianna Maya became ill when she was three years old. She first developed a cough and a fever, followed by a rash – all symptoms that she had experienced before. On this occasion, however, the rash turned into blisters and required treatment first at a local hospital, then a children's hospital in Memphis, and finally at Shriner's Burn Hospital in Texas. The cough and fever began on a weekend, and, based on the pediatrician's instructions, Brianna's parents alternated Children's Motrin and Tylenol to bring down the fever. When Brianna was no

better on Monday, the pediatrician saw her, diagnosed her with mycoplasma pneumonia, and prescribed a sulfa-containing antibiotic (Pediazole) while continuing to advise that she be given alternating doses of Children's Motrin and Tylenol. On Tuesday, the rash had spread and blisters had begun to form. The pediatrician saw her again and recommended that she be hospitalized, concluding that she had either Kawasaki's disease or Stevens-Johnson Syndrome. She spent approximately two weeks at the Shriner's Burn Hospital, and even after her release, she has required multiple surgeries and other treatment and has permanent injuries resulting from the disease.

Although the Mayas lived in Tennessee, they brought an action in the Philadelphia County Court of Common Pleas on February 19, 2009. The case was tried to a jury before Judge Nitza I. Quinones-Alejandro for over 35 court days, from March 23 until May 20, 2011, when the jury returned a verdict on the Mayas' negligent failure to warn claim (one of two counts remaining of the nine set forth in the Second Amended Complaint). The jury awarded $10 million against McNeil, the manufacturer of Children's Motrin. The jury did not award punitive damages and did not find that McNeil had negligently designed the medication.

After post-trial motions, McNeil appealed to the Superior Court. The case was argued before Judges Ford Elliott, Wecht, and Musmanno in November 2013, and the panel issued its opinion affirming the trial court, authored by Judge Ford

Elliott, on July 22, 2014. McNeil's motion for reconsideration was denied on September 25, 2014.

C. Brief Statement of the Determinations Under Review

On each of the questions raised in this petition, the trial court and the Superior Court reached the same result but rested their respective opinions on very different grounds.

First, McNeil had asked the trial court to instruct the jury that in assessing McNeil's conduct it could not consider the conduct of other manufacturers or what had happened with other drugs, including whether other drugs had been taken off the market. After argument, the trial judge agreed with McNeil that such an instruction was appropriate on the circumstances of this case. Nevertheless, when it came time to give the charge, Judge Quinones instead told the jury that it *could* take into account the conduct of other companies with respect to other drugs, omitting the word "not" from the charge that had been proposed (and accepted by the court). Although she recognized in the charging transcript that there was a word missing, she refused to revisit the charge – despite two objections. The explanation she gave in her opinion was that she merely read the charge that McNeil had given her and was "perplexed" that McNeil was complaining about that instruction, even though she had the transcript of the charge conference and the proffered instruction. 1925(a) Op. at 109; R.2221a; R.2172a.

The Superior Court declined to defend the mistake on this ground, concluding "[t]he trial court's insistence that it read the instruction exactly as submitted by McNeil makes no sense in light of defense counsel's objections and the fact that the instruction, as given, operates against McNeil." Superior Court Op. at 28. The panel decided, however, that "the issue does not compel a new trial because McNeil was not prejudiced by the trial court's alleged mistake" because "the instruction really only pertains to their claims for negligent design defect and punitive damages, both of which the jury resolved in favor of McNeil." *Id*. at 29 (internal citations omitted). In fact, the instruction was not so limited, and the Superior Court did not explain how an instruction that told the jurors to consider how some companies had withdrawn their drugs from the market could fail to influence a juror's consideration whether McNeil should have placed a stronger warning on the label.

Second, during the charge conference the trial judge decided, over McNeil's objection, to instruct the jury according to what was then SSJI (Civ) 8.03(b) (Heeding Presumption). 1925(a) Op. at 111-12. In what the trial court called "an unfortunate event," it then omitted that heeding presumption instruction (the Superior Court surmised that the judge forgot). 1925(a) Op. at 111; Superior Ct. Op. at 23-26.

Even though the jury was charged after closings were complete, and McNeil had lost the opportunity to make its argument, Judge Quinones opined that McNeil's argument "makes little sense" because, whether or not the charge was actually given, McNeil "could have made whatever remarks it wanted to on this issue since the court had indicated it would provide the charge after the closing arguments." 1925(a) Op. at 111.[1]

The Superior Court would not go as far as the trial judge had gone but did reason that, whether or not the charge was given, McNeil was "in no way precluded [ ] from arguing to the jury that plaintiffs failed to prove an adequate warning would have prevented Brianna from receiving additional doses of Children's Motrin after she developed a rash and blisters" – because, that court reasoned, the heeding presumption is rebuttable. Superior Ct. Op. at 25.

Third, McNeil challenged the trial court's decision to give a concurring cause instruction in the face of divergent expert testimony on causation – with the defense expert testifying that Brianna's TEN could have been caused either by a virus or the Pediazole that Brianna took and the plaintiffs' expert testifying that the sole cause was Children's Motrin. Citing the later reversed Superior Court opinion of *Shamnoski v. PG Energy*, 765 A.2d 297, 304 (Pa. Super. 2000), *rev'd on other*

[1] Both courts faulted McNeil for failing to object to the trial court's failure to give the previously objected-to charge. 1925(a) Op. at 111-12; Superior Ct. Op. at 25.

grounds, 858 A.2d 589 (Pa. 2004), Judge Quinones said that where the parties each attributed the injury to "conflicting" causes, a concurring cause instruction was appropriate. 1925(a) Op. at 110-11. In deciding to give the charge, Judge Quinones rejected McNeil's argument that Pennsylvania law required Plaintiffs to provide evidence of concurring causes as a prerequisite to charging the jury on concurring causes. *Id.* at 110.

The Superior Court did not accept the trial court's interpretation of Pennsylvania law, instead recognizing that a concurring cause instruction would be appropriate only if there was reason to believe that "OTC Children's Motrin and some other agent, ***e.g.***, the antibiotic Pediazole, *combined* to cause Brianna's illness." Superior Court Op. at 27 (second emphasis added). Even so, it held that the instruction was proper here, reasoning that because the defense expert "could not exclude the possibility that Children's Motrin and Pediazole both contributed to Brianna's TEN," there was a sufficient basis for a jury to find that the two drugs acted in combination. *Id*.

Finally, the two courts disagreed as to what, if any, impact changing the label could have had on Brianna Maya's injuries. This was in doubt for two reasons, the first having to do with the disease itself, and the second having to do with the way in which Mrs. Maya addressed Brianna's illness – by consulting with the pediatrician and relying on the pediatrician's advice. It is, of course, sensible

and laudable for a parent to follow the directions of a pediatrician, but no Pennsylvania court prior to this case has ruled that a manufacturer may be held liable for a failure to warn in a label directed at consumers when the parent gave the medicine in accordance with her doctor's advice.

In her opinion, the trial judge stated that "had the OTC Children's Motrin label included a warning of 'rash, skin reddening and blisters' in November 2000, Alicia Maya would not have purchased the drug, Brianna would not have ingested it, and she would not have suffered catastrophic injuries." 1925(a) Op. at 42. The trial court included an alternative as well: "had the warnings on the label included the language sought by Plaintiffs, Ms. Maya would not have bought the medication, and/or would have stopped giving her daughter the drug at the first signs of symptoms. The injuries Brianna suffered conceivably may not have been as devastating." *Id*. at 47.

The Superior Court settled on the second rationale. Acknowledging that Mrs. Maya's testimony was that she had relied on Dr. Brewer's advice in alternating doses of Tylenol and Children's Motrin, the panel nevertheless concluded that "there was testimony that an adequate warning would have prevented Brianna from receiving the last four or five doses of Children's Motrin." Superior Ct. Op. at 18.

V. REASONS FOR ALLOWANCE OF THE APPEAL

A. This Court Should Allow This Appeal Under Pa.R.A.P. 1114(a)(1), (a)(2), (a)(3), and (a)(6).

For the first three questions, the opinion of the Superior Court cannot be reconciled with well-settled principles of Pennsylvania law. The final question, however, warrants allowance of appeal not because it is contrary to settled law but because, as the trial court acknowledged, it concerns a question of first impression. The panel looked at each asserted error in isolation, *see* Superior Ct. Op. at 13-29, rather than in the context of the case, and it thus failed to appreciate that the errors were highly prejudicial because they affected the jury's determination of hotly disputed issues that were critical to deciding liability: whether McNeil was negligent, whether Plaintiffs' proposed warning would have avoided the injuries, and whether Brianna's TEN was caused by Motrin at all.

The trial court's rulings on three of these questions tainted the jury charge, and separately and together misled the jury in a manner that "may have contributed to the verdict . . . ." *Choma v. Iyer*, 871 A.2d 238, 243 (Pa. Super. 2005). In affirming those rulings, the Superior Court rendered a decision that is inconsistent with decisions including *Polett v. Public Communications, Inc*., 83 A.3d 205 (Pa. Super. 2013), a case on which this Court recently heard argument; *Schaefer v. Stewartstown Development Co.*, 647 A.2d 945 (Pa. Super. 1994); *Angelo v. Diamontoni*, 871 A.2d 1276, 1279 (Pa. Super. 2005) (recognizing that a jury can

be instructed only on legal principles applicable to the facts specific to a case and a charge is erroneous if it probably misled the jury); and *Lilley v. Johns-Manville Corp.*, 596 A.2d 203, 209 (Pa. Super. 1991) (A new trial is proper because "the jury instruction might have prejudiced the appellant.").

In addition, these questions call for allowance of appeal because all four are instances where the Superior Court – explicitly or implicitly – recognized that the trial court had erred but then effectively swept the errors under the rug, in one case excusing it as "harmless" and in another attributing it to the judge's forgetfulness. In the process, the panel rewrote the facts that the trial court had found to fit what the Superior Court deemed a more palatable statement of Pennsylvania law. That is not the function of the Superior Court: it is there to correct errors, not to rescue a trial court by glossing over its legal errors by rewriting the facts.

This Court just recently had to address the same reluctance to correct error on the part of the Superior Court.

> We note that we are no more pleased to disturb a compensatory jury award than the intermediate court. In the present circumstances, however, the governing law should have been applied by the trial court at the summary judgment stage, before the case ever reached trial, and certainly our error-correcting court should have recognized and vindicated this law on appeal. Since this did not happen, it has been left for us to do so at this late juncture, four years after trial.

Patton v. Worthington Assocs., 89 A.3d 643, 650 (Pa. 2014). In *Patton*, this Court "allowed appeal to address the noted difficulties with the trial court's approach,

perpetuated in the published opinion of the Superior Court. Our review is plenary." *Id*. at 647. The Court should do the same here.

One aspect of the Court's role is "charting a definite course of action for the judiciary, and [ ] select[ing] our method of action from various alternatives at hand and in light of these conditions to guide and determine the present and future course of this branch of government." *In re Stout*, 559 A.2d 489, 497 (Pa. 1989). This is inherent in the grant to the Supreme Court of general supervisory and administrative authority over all the courts, found in Article V, Section 10 of the Pennsylvania Constitution, and works itself out both through the promulgation of rules of procedure and through exercising a "rulemaking quality" in decisional law. *Id*. Because the questions in this Petition go to the ways in which a jury should answer the questions raised by a negligent failure-to-warn claim – and the standards of expert and other evidence required – they likewise call for the "rulemaking quality" of the Court.

B. Each of the Questions Raised Warrants Allowance of Appeal.

1. Dismissing an admittedly erroneous jury instruction as meaningless discredits the system and its presumption that a jury follows the instructions given it by the trial court.

At trial, the Plaintiffs told the trial court that the jury should be permitted to consider the conduct of other companies with respect to other drugs, and that an instruction limiting consideration to McNeil and to Motrin should not be given

because the conduct of those other companies "goes to every question out there. It's not limited or focused on one particular claim." R.2221a; *see also* R.2172a (McNeil's proposed preclusive charge). The trial court rejected Plaintiffs' argument, R.2221a, instead deciding, in accordance with Pennsylvania law, to charge as McNeil had requested. *See* Pa.R.E. 401, 403; *cf. Commonwealth v. TAP Pharm. Prods.*, 36 A.3d 1197, 1284 (Pa. Cmwlth. 2011) (Under Pa.R.E. 403, the trial judge "properly shielded the jury from such inflammatory evidence as guilty pleas and Fifth Amendment invocations by other drug companies (not BMS) and their employees."), *rev'd on other grounds*, 94 A.3d 350 (Pa. 2014).

When the judge actually delivered the instruction, however, she told the jury it *could* take into account, in evaluating McNeil's conduct, what other companies had done with respect to other drugs – thus authorizing it to do what Plaintiffs had asked for, but the trial court had rejected, at the charging conference. She told the jury this despite the fact that the jury had no evidence as to the relative risks or benefits of Motrin and other drugs that had been withdrawn from the market, or about the similarities or differences among Motrin and those other drugs – and despite the fact that other drugs being taken off the market had no bearing on the adequacy of McNeil's warnings.

Defendants' Instruction No. 41 – accepted by the Court – read:

> You may have heard references to drugs other than ibuprofen[2] that may have been removed from the market; to the conduct of companies other than McNeil relating to their drugs; or to information that may have been reported to companies other than McNeil. *You may not* base your verdict on the conduct of other pharmaceutical manufacturers or on what happened with other drugs, such as other drugs being taken off the market.

R.2172a (emphasis added). The charge as given read as follows:

> You heard reference to drugs other than ibuprofen that were removed from the market. There is a word missing. I'm trying to figure out what the word is here. Okay. You may have heard reference to drugs other than ibuprofen that were removed from the market, or information that may have been reported to companies other than McNeil. *You may consider* the conduct of other pharmaceutical manufacturers, or what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct.

R.2469a (emphasis added). After the charge was given, McNeil objected. R.2476a.

Rather than attempt to defend the instruction, Judge Quinones insisted that she had actually given verbatim the charge that McNeil had requested. 1925(a) Op. at 109; R.2476a. The transcript and the docketed version of McNeil's proposed instructions said otherwise, and the Superior Court recognized that her explanation made no sense. Superior Court Op. at 28-29. Despite that recognition, and even though the integrity of the jury system relies on the presumption that

[2] Plaintiffs had repeatedly sought to elicit such testimony – to which McNeil persistently objected, although its objections were not consistently sustained. R.1832a; R.1842a-1843a; R.1926a; R.1991a, 1993a-1996a, 1998a-1999a; R.2004a-2005a; R.2018a-2019a, 2021a; R.2419a.

jurors will listen to and follow the instructions they are given, *see, e.g.*, *Commonwealth v. Fortenbaugh*, 69 A.3d 191, 195 & n.2 (Pa. 2013), the Superior Court treated the error as "harmless." Superior Ct. Op. at 29. But surely telling the jury the exact opposite of what it should have been told cannot be harmless error.

In so holding, the panel reasoned that inasmuch as the jury had returned a verdict in favor of the plaintiff only on the failure to warn claim, it did not matter that the jury was instructed to consider the conduct of other companies vis-à-vis other drugs, because that testimony was relevant only to punitive damages or the design defect claim. *Id*. But that simply is not true. At trial, Plaintiffs acknowledged that the disputed testimony went to every claim. The plain language of the charge as given was not limited, and the trial judge certainly never gave any limiting instruction to confine it to one claim and exclude it from another. R.2221a; R.2469a. Indeed, the instruction was plainly relevant to the failure to warn claim, because it told the jury to take into account what other companies had done when they had learned about risks their drugs carried. Given that some drugs were pulled from the market, asking jurors to compare that obligation to requiring a company to put a stronger warning on a label surely would have made the label change seem a comparatively small request.

The Superior Court ruled that it was harmless to instruct the jury affirmatively that it could consider specific matters that the trial court itself had determined, after argument, were not relevant to the pleadings or proof. That ruling is contrary to the Superior Court's own analysis in *Angelo*, 871 A.2d at 1279, and this Court's observations in *Price v. Guy*, 735 A.2d 668, 671-72 (Pa. 1999) (concluding that the "extraneous facts" that were drawn to the jury's attention by a jury instruction were prejudicial and recognizing that the "purpose of jury instructions is to keep jurors focused on resolving factual disputes based on the governing law rather than on their own ideas of how best to balance the equities").

2. By misapprehending the procedure contemplated for the heeding presumption and by improperly discounting the obligations of counsel, the Superior Court generated both legal and ethical confusion.

Pennsylvania has three suggested standard jury instructions relating to what has been termed a heeding presumption – a presumption that has been applied only "in cases involving workplace exposure to asbestos." *Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534, 537 (Pa. Super. 2003), *aff'd*, 881 A.2d 1262 (Pa. 2005).[3] To determine which instruction is appropriate, the trial court makes a legal determination whether the defendant has produced some evidence that the warning

[3] Indeed, in *Viguers*, the Superior Court refused to extend the presumption to tobacco, reasoning that the heeding presumption was appropriate only when plaintiffs "were exposed in the course of their employment under circumstances that provided them no meaningful choice" of avoiding exposure. 837 A.2d at 537 (citation omitted).

would not have been heeded. SSJI (Civ.) § 16.50, formerly § 803B. If there is such evidence, the presumption "disappears from the case" and the instruction is not given. *See* SSJI (Civ.) § 16.50, Subcommittee Note (leaving it to the jury whether the plaintiff would have avoided the hazard with a different label and explaining that, if so, SSJI (Civ.) § 16.60, formerly § 8.03C, is given instead).

In this case Plaintiffs contended they would have heeded an adequate warning by not giving or by stopping the Children's Motrin, avoiding all or at least several doses and preventing or lessening the injury. But Mrs. Maya gave Motrin in reliance on her doctor's advice. Superior Ct. Op. at 16. Her proposed warning would have said "[s]top use and call your doctor if" signs of an allergic reaction (including rash) appeared. *Id.* It is undisputed that Mrs. Maya saw the rash on Sunday, Brianna saw the doctor on Monday, the doctor advised continued use of Motrin at that time, and Ms. Maya followed that advice by giving the final doses. Superior Ct. Op. at 3; R.2041a-2043a, 2045a; R.3505a-3506a.

> [T]he thing I primarily relied on was Dr. Brewer and the fact that Dr. Brewer, the pediatrician who had treated her since ten days after she was born, told me that she wanted her to be treated with this medication. I would say that I relied on those advertisements to the extent that those advertisements didn't raise red flags for me. . . . If those advertisements would have said, you know, parents, you need to watch for a rash, you need to watch for blisters, you need to watch for her – their eyes, or eye involvement or problems with their eyes, then that would have definitely raised red flags where I would have called Dr. Brewer and asked those questions.

R.2068a. Based on this evidence, defense counsel should have been allowed to argue that the warning Plaintiff sought would not have avoided the last several doses or prevented the injury, contrary to Plaintiffs' claim.

Nevertheless, the trial judge accepted plaintiffs' argument that the heeding presumption had not been rejected in an over-the-counter medication case, 1925(a) Op. at 111 (citing 5/17/2011 AM at 23:21-28:8). As a result, the judge decided to instruct the jury that it "*may not find* for the defendant . . . that, even if there had been adequate warnings or instructions, the plaintiff would not have read or heeded them. Instead, the law presumes, and *you must presume*, that if there had been adequate warnings or instructions, the plaintiff would have followed them." SSJI (Civ.) § 16.50, formerly § 8.03B (emphasis added). When Instruction § 16.50 is given, the jury "may not find" that the plaintiff "would not have acted differently . . . ." *Id.* The alternative, § 16.60, permits the jury to make the finding "whether the plaintiff would have been harmed if the needed warning had been provided." SSJI (Civ.) § 16.60, formerly § 8.03C.

Given Judge Quinones's ruling on what her charge would be, McNeil's counsel shifted her emphasis during closing, focusing on the implausibility of Children's Motrin as the medical cause of TEN instead. Indeed, the only references to the label were to remind the jury that the label warned of an allergic reaction that could be fatal and to acknowledge that Ms. Maya had said that the

words "[s]kin reddening, blisters, and rash" would have made a difference, but that this did not mean the label was inadequate. R.2443a-2444a. Defense counsel did not argue, however, that the jury should reject Ms. Maya's testimony about what she would have done if the warning had been different or that it should find that a different warning would have made no difference, because such an argument would have been inconsistent with the trial judge's ruling. The only inference the jury could have drawn from the constrained closing is that McNeil did not ascribe any significance to the Mayas' reliance upon Dr. Brewer – and that the jurors should not either.

But as it happened, the trial court failed to give the heeding presumption instruction it said that it was going to give – and also did not give the alternative instruction. This omission left the jury without any guidance or signal that the testimony the jury had heard critically undermined Plaintiffs' claims. This error accordingly severely prejudiced McNeil.

The trial court, however, was incredulous that McNeil complained about an instruction that was not given, couching the error as "unfortunate" but "waived" because McNeil did not object to the omission of the harmful instruction (an objection that would have made no sense given that the instruction was – and McNeil had argued that it was – improper). The trial judge further reasoned that, because the jury was not instructed until after counsel had delivered closing

arguments, "Defendant McNeil could have made whatever remarks it wanted to on this issue." 1925(a) Op. at 111.

The Superior Court suggested that the issue could be deemed waived and agreed that McNeil could have continued to argue that a different warning would not have mattered – although it based its conclusion on its assessment that the presumption was rebuttable. Superior Ct. Op. at 25. The court also suggested that the heeding presumption is "most relevant" in cases where the plaintiff is dead or incapacitated and thus cannot testify as to what he would have done if an adequate warning had been given, making the heeding presumption "not particularly relevant" in this case. *Id.*[4]

This is not the law that had developed in the Superior Court. That court had clearly limited the applicability of the heeding presumption to those situations where the plaintiff is "forced by employment to be exposed to the product causing harm" because of the policy rationale for an evidentiary advantage in such situations. *Viguers*, 837 A.2d at 538.

More troubling even than the rewriting of the role of the heeding presumption, however, are the procedural and ethical consequences of the Superior

[4] The Superior Court took this from Plaintiffs' argument – for which neither Plaintiffs nor the court provided any citation – that the heeding presumption was "particularly important" where a purchaser or prescriber is not available to testify to what would have happened if an adequate warning had been provided, because "the death or incapacitation of the prescribing physician may preclude any recovery by the plaintiff." Opp. Br. at 38.

Court's holding. Although the Subcommittee Note explains clearly that the court must rule as a matter of law whether there is evidence in the case to rebut the heeding presumption – and that ruling determines which instruction is given – the Superior Court (in reaching to affirm a part of the trial court's conclusion) has undone the previously well-established rules: instead of taking a trial court's rulings at a charge conference as a directive and conforming their behavior accordingly, counsel are now told they must disregard the fact that the instruction requires the jury to find one way, and argue to the jury that it should instead find the opposite. Indeed, according to the Superior Court's ruling, obeying the trial court's rulings and instructions at the charging conference, rather than defying them, constitutes a waiver of the objection.

This is contrary not only to counsel's ethical obligations but to other Superior Court case law making clear that a party cannot disregard a court's rulings and argue whatever it concludes is strategically advantageous. *See Poust v. Hylton*, 940 A.2d 380, 385 (Pa. Super. 2007). Moreover, reading the Superior Court literally, it appears that going forward it is the argument of counsel – and not the previously-admitted evidence – that rebuts a now-widely-applicable heeding presumption. This is a complete transformation of Pennsylvania law on this subject.

It has only been a month since Chief Justice Castille (in a single-judge opinion on a post-decisional motion) was compelled to remind the bar that all lawyers "are obligated to obey court rules and orders, and to conform their strategies and agendas to that ethical reality." *Commonwealth v. Spotz*, No. 576 CAP, 2014 Pa. LEXIS 2340, at *120 (Pa. Sept. 3, 2014). The rulings of a court create a two-way obligation: they must be honored by litigants, and they must be able to be relied on by litigants – and not to their prejudice. *Id*.; *Jackson v. Hendrick*, 746 A.2d 574, 577 (Pa. 2000). The Superior Court's attempt to rescue the trial court has wreaked havoc with the law and unsettled the well-established mechanism that is clearly set forth in the jury instructions themselves and that was until now a narrow and well-defined exception to the burden every plaintiff otherwise bears of proving that a different warning would have prevented the injury. *See Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. 2010). That, coupled with the overt message to counsel to disregard the rulings of a trial court, cries for this Court's supervisory hand.

3. Correcting a trial judge's improper construction of controlling law on concurring causation – and then revising the facts found by the trial court to fit the revised construction – does not fulfill the "error-correcting" role of the Superior Court.

There are cases in which a plaintiff's claim is that two or more forces combined to cause harm to the plaintiff. In those cases, a concurring cause

instruction may be proper. But this was not such a case. Instead, there was conflicting expert testimony as to the sole cause of Brianna's injuries.

Throughout trial, Plaintiffs' experts "steadfastly maintained that Children's Motrin was the sole cause" of Brianna's injuries. 1925(a) Op. at 110. The defense expert, Dr. Stern, testified to a reasonable degree of medical certainty that the sole cause was either Pediazole or a virus, depending whether one accepted the chronology in the medical records or Plaintiffs' testimony. R.2119a, 2121a. Indeed, significant scientific data establish that, with a 95 percent confidence level, persons taking antibiotics such as Pediazole were between 75 and 396 times more likely to contract TEN than those not taking the drugs. *E.g.*, R.2116a; R.2243a. This powerful association stood in stark contrast to the statistically insignificant association of Children's Motrin and TEN. R.2244a.

In response, the Plaintiffs requested a concurring cause charge, explaining that "we say it's one thing, they say it's another. The law says it's possible that it could be both. I don't have to have an opinion that says it's both." R.2216a. The trial judge asked for further briefing and ultimately agreed with the Plaintiffs, although she modified the instruction:

> You will be asked to determine whether the defendant's negligence was a factual cause of the plaintiff's injuries. Plaintiff may recover for all the injuries the defendant's conduct was a factual cause in producing. The defendant's conduct need not be the sole cause. Other causes may have also contributed. However, where the defendant's negligence combines with other circumstances to cause

> plaintiff's harm, the defendant is responsible if the defendant's negligence was a factual cause, even if the harm would have occurred without it.

R.2469a. *Compare with* SSJI (Civ.) § 3.17 (3d ed.) ("other circumstances *and other forces*" (emphasis added)).

Post-trial, the trial judge looked to the subcommittee note for the pattern civil jury instruction for § 3.17 (the substance of which has now been made a part of the subcommittee note for § 13.150), and reasoned that because it cited to a case in which a flood breached a dam, leading the defendant to blame an Act of God while the plaintiff blamed the defendant, there was no need for evidence that two possible causes combined, even though in that case both events needed to occur for the harm to result. 1925(a) Op. at 110-11. But Pennsylvania law is clear that a jury cannot simply speculate that two different sole causes identified by experts actually combined to cause an injury. *See Lee v. Pittsburgh Corning Corp.*, 616 A.2d 1045, 1048-49 (Pa. Super. 1992) (where opposing experts testified to sole causes jury could not speculate that each was substantial cause; new trial was required because without erroneous instruction jury might have found no liability). It is equally clear that a jury is charged in error when it is charged on legal principles that are not "issues which are relevant to pleadings and proof." *Angelo*, 871 A.2d at 1279 (quoting *Carpinet v. Mitchell*, 853 A.2d 366, 371 (Pa. Super. 2004)).

The law limits concurring cause instructions to circumstances when a single harm is brought about when *the acts of multiple actors combine* for a reason. Here, the statement that it does not matter whether Plaintiffs' injuries were all caused by something other than Children's Motrin had the effect of requiring the *defendants* to prove that a virus or Pediazole was the *only* possible cause of Brianna's injuries, when, in fact, Pennsylvania law places the burden upon the Plaintiffs to prove that Children's Motrin caused Brianna's injuries.[5] And the necessary predicate for such a finding has to be established by expert testimony.[6]

The Superior Court recognized precisely this principle of law *sub silentio*. *See* Superior Ct. Op. at 26-27 (setting forth the circumstances in which a concurring cause instruction may be given). It nevertheless excused what the trial court did by citing to an earlier draft of a *different* jury instruction, the 1978 Subcommittee Draft of SSJI (Civil) § 3.26, which asks a jury to consider something very different from what the trial court asked this jury to consider:

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[5] The error was exacerbated by the omission of "and forces" from the instruction, telling the jury instead that it could find that the harm occurred if there was negligence and "circumstances" – and then going on to say that it could find that the harm occurred because of "circumstances" but still impose liability on McNeil "even if" Brianna's injuries would have occurred without any negligence by McNeil.

[6] Thus in *Young v. Commonwealth, Department of Transportation*, 744 A.2d 1276 (Pa. 2000), this Court explained that "[t]he mere happening of an accident is not evidence of negligence. Plaintiff must prove by a fair preponderance of the evidence that the defendant was negligent and that his negligence was the proximate cause of the accident." *Id.* at 1277. To do so, expert testimony was necessary to "impart sufficient knowledge to jurors regarding the many variables which are required to establish the existence of a legal duty to place signs over three miles away from a construction zone." *Id.* at 1278.

> When negligent conduct of two or more persons contributes concurrently to an occurrence or incident, each of these persons is fully responsible for the harm suffered by the plaintiff regardless of the relative extent to which each contributed to the harm. A cause is concurrent if it was operative at the moment of the incident, and acted with another cause as a substantial contributive factor in bringing about the harm.

SSJI Civ. § 3.26 Concurring Causes (Subcommittee Draft 1978).

In other words, instead of accepting the recognition by the trial judge – who, after all, lived through the trial – that the trial had consisted of a battle of experts over what the *sole* cause of Brianna's illness was, the Superior Court culled the transcript for any phrase that, in isolation, referred to the possibility of more than one cause.

It found one, a snippet of cross-examination of Dr. Stern, a defense expert who had testified, to a reasonable degree of medical certainty, that Children's Motrin was not the cause of Brianna's illness. R.2118a-2119a, 2121a-2122a. On cross, Dr. Stern was asked if he disagreed with the conclusion of Plaintiffs' expert that "Motrin was the 99.9 percent cause of Brianna Maya's TEN." R.2249a. Of course he did, and he was then asked if he could exclude the *possibility* that Motrin – and then that Motrin and Pediazole – could have caused the disease. *Id*. To both questions, he conceded he could not say it was impossible: "I can only tell you what I think is most likely." *Id*. Plaintiffs' counsel then repeated "The bottom

line is, you disagree with Dr. Schulz's conclusion that 99.9 percent likelihood Motrin was the sole cause." To which Dr. Stern answered "[y]es."

Even on the bare page, this testimony does not set forth an affirmative expert opinion that there were multiple causes that combined to make Brianna ill. No witness – neither Dr. Stern nor Plaintiffs' experts – opined that Pediazole and Motrin combined to cause Brianna's injuries. It was either Pediazole (McNeil's position) or Motrin (Plaintiffs'). Dr. Stern's testimony does no more than acknowledge that medical science does not allow an expert to say that either is impossible – which is why testimony is to be to a "reasonable degree of" rather than "absolute" medical certainty. As the Superior Court has previously held, it is not appropriate to find causation based on an opinion that a product "could have" caused an injury; there has to be a "reasonable degree of medical certainty." *McCann v. Amy Joy Donut Shops, Div. of Am. Snacks, Inc.*, 472 A.2d 1149, 1150 (Pa. Super. 1984).

The holding here contradicts *McCann* and misstates the law. That Dr. Stern could not eliminate the possibility of concurring causes was not a sufficient basis under Pennsylvania law for the jury to find them – or to be charged as to them. This Court should grant allowance of appeal both to clarify the circumstances in which a concurring cause instruction is appropriate and to affirm the need for the Superior Court to apply the correct law to a trial court's factual findings.

4. When the Superior Court acknowledged that Mrs. Maya chose to administer Children's Motrin based upon and in the manner prescribed by the pediatrician – thus demonstrating that it was not the label that led her to purchase or administer Children's Motrin – that court should not have tried to rescue the verdict by finding that the trial record established that fewer doses would have avoided Brianna's injuries in whole or in part.

The trial court opened its opinion with a statement that this case was one of first impression in Pennsylvania.[7] While Children's Motrin is an over-the-counter drug, and thus does not implicate Pennsylvania's learned intermediary doctrine, the causation claim in this case is animated by similar policy considerations. The decision to administer Children's Motrin and Children's Tylenol in alternating doses was the pediatrician's;[8] the Mayas trusted her judgment; and indeed, the label advised patients *not* to do what the Mayas did unless a doctor told them to do so. R.2759a. The Mayas' reliance on their physician thus separates this from a

[7] A federal court recently granted judgment as a matter of law in a similar Children's Motrin case, where Plaintiff followed her doctor's recommendation and plaintiff's testimony did not establish that "a different warning label would have changed her decisions to administer Children's Motrin. . . ." *Hunt v. McNeil Consumer Healthcare*, No. 11-457, 2014 U.S. Dist. LEXIS 61955, at *8-9 & n.5 (E.D. La. May 5, 2014) (recognizing the Plaintiff had not presented evidence that "a different warning would have caused her to administer Children's Motrin in a way that would have avoided M.H's injuries" and recognizing that "it would have been impossible to present such evidence. Assuming Children's Motrin caused M.H.'s injuries, there is no way the drug could have been safely administered. The evidence presented at trial established that by the time the prodromal symptoms of SJS/TEN manifested, *e.g.*, rashes and blistering, the disease was already underway. Thus, the dispositive inquiry is whether a different label would have caused Plaintiff not to administer Children's Motrin to M.H. in the first place.")

[8] Dr. Brewer continues to give this advice. R.3557a.

case concerning a typical retail product in which the label is the basis for a consumer's decision-making.

The law cares about why the Mayas made the decisions they did; indeed, reliance plays a critical role in everything from equitable estoppel to common law negligent misrepresentation[9] and is inherent in Pennsylvania's negligence analysis. *See Cochran*, 3 A.3d at 676 ("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.'"); *Young*, 744 A.2d at 1277 ("The mere happening of an accident is not evidence of negligence. Plaintiff must prove by a fair preponderance of the evidence that the defendant was negligent and that his negligence was the proximate cause of the accident.").

As discussed above, the Superior Court did not attempt to salvage the trial court's contention that the Mayas would never have purchased Children's Motrin had the warning been different. R.2078a. Instead, the Superior Court concluded that because Ms. Maya had testified that if the label had said "stop use and call your doctor if . . ." she would have stopped giving the medicine at the first

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[9] *Compare, e.g.*, *Commonwealth ex rel. Corbett v. Griffin*, 946 A.2d 668, 678 n.12 (Pa. 2008) (requiring, *inter alia*, unambiguous proof of reasonable reliance upon the misrepresentation by the party asserting estoppel), *with Milliken v. Jacono*, 96 A.3d 997, 1003 (Pa. 2014) (Todd, J., concurring) (recognizing that negligent misrepresentation requires, *inter alia*, an "injury to a party acting in justifiable reliance on the misrepresentation").

appearance of a rash (although she did not say what would have happened if she had called Dr. Brewer – which she in fact did – and Dr. Brewer had advised her to continue the medication – which she in fact did), and Brianna would accordingly have received four or five fewer doses of the Children's Motrin. Superior Ct. Op. at 16-18.

But, as *Cochran* affirms, a change in behavior must also lead to proof that the *injury* would have been avoided. *Cochran*, 3 A.3d at 676. As discussed above, Plaintiffs had chosen to sue McNeil, a manufacturer of a drug with a statistically insignificant association with TEN, rather than the manufacturer of the much more strongly causative Pediazole. To avoid the logical inference that the more likely cause was in fact the cause of Brianna's illness, Plaintiffs employed two tactics: they asked the Court (successfully) to instruct the jury on concurring causes; and they elicited expert testimony that there was no way to change the course of the disease once it had begun (arguing that the rash was the sign it had begun). R.1873a (Plaintiffs' expert testifying that because she took Pediazole after the rash appeared, "the horse is already out of the barn" and thus Pediazole could not be a cause).

The Superior Court, however, again disregarded the affirmative expert opinion and looked instead to two isolated fragments from two witnesses – neither of which expressed any opinion to any degree of medical certainty. Dr. Schulz, the

same expert who said that there was no way to change the course of the disease to counter the fact Brianna was taking Pediazole, also said that "getting rid of the causative agent as fast as possible might kind of decrease the severity of the syndrome once it starts" and that "the only thing that we have to offer, besides critical care, is try to stop the offending medication; and the evidence was that people in whom it was stopped faster, or in whom it was stopped and were on very short half-life drugs but washed out of their system fast tended to do better" (a reference to a study of the relative survival rate of the disease).[10] Superior Ct. Op. at 19-20 (citing R.1888a). Based on the same study, Dr. Tackett made a general observation that, as with anything that causes a side effect, "the sooner you stop it, then the side effect is going to be abated or go away." Superior Ct. Op. at 18 (citing R.1851a).

In order for the jury to assess whether Brianna's injuries would have been avoided or lessened, the Plaintiffs needed to produce "competent, relevant, expert" testimony "to inform the jurors' essential understanding" whether any and, if so,

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[10] Intentionally or not, the word "prognosis" was used advisedly, because the sole study relied on by both experts was examining only whether the timing of the withdrawal of causative drugs before or at the onset of a definite sign of TEN (early) compared to any point thereafter (late) affected the *mortality* rate from the disease, not whether there was any difference in the extent of injury to surviving patients. Garcia Doval et al., Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome: Does Early Withdrawal of Causative Drugs Decrease the Risk of Death, 136 ARCH. DERMATOL. 323, ("Main Outcome Measure: Death before hospital discharge"), 324 (defining early and late), 325 ("[o]ur aim was to determine whether the timing of causative drug withdrawal was related to mortality in patients with SJS or TEN") (2000).

which of Brianna's injuries could be attributed to the final 4-5 doses of Children's Motrin. *Pa. Dep't of Gen. Servs. v. U.S. Mineral Prods. Co.*, 898 A.2d 590, 607 (Pa. 2006) (requiring expert testimony on the extent of remediation needed after chemical contamination).[11] Plaintiffs did not do that. The thrust of their case was that if Brianna had not taken Children's Motrin, she would not have been injured. But Brianna took Children's Motrin because of the pediatrician's advice – advice that the Mayas alternate medications so as to provide fever reduction medication every three hours rather than every six. In shifting to the fallback position – that Brianna would have received fewer doses – Plaintiffs needed to prove that Brianna would likewise not have been injured, or, at least, the extent to which her injuries would have been avoided, and it needed to do so by competent expert testimony. The removal of that burden of proof from the Plaintiffs by the Superior Court cannot be squared with this Court's opinion in *U.S. Mineral Products*. This Court should grant allowance of appeal to resolve the question of first impression on warning causation in such circumstances.

[11] Indeed, the Superior Court has held that even where there is agreement that *some* injury was caused by a defendant's negligence – which was clearly not the case here – expert testimony is still required as to the extent of the injuries, if they are less than all. *E.g.*, *Kennedy v. Sell*, 816 A.2d 1153, 1157-58 (Pa. Super. 2003); *see also* 40 P.S. § 1303.512(b) (MCARE Act) (setting forth qualifications for experts in medical malpractice cases "testifying on a medical matter, including the standard of care, risks and alternatives, causation and the *nature and extent of the injury*" (emphasis added).)

Date: October 24, 2014

Respectfully Submitted,

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PROOF OF SERVICE

I hereby certify that I am this day serving the foregoing Petition for Allowance of Appeal upon the persons identified below by first class and electronic mail, which service satisfies the requirements of Pa.R.A.P. 121:

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IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

ALICIA E. MAYA, Individually, and BRIANNA MAYA, by and through her Natural Parent and Guardian	:	**FEBRUARY TERM, 2009**
Plaintiffs/Appellees	:	**No. 2879**
vs.	:	
BENEFIT RISK MANAGEMENT, JOHNSON & JOHNSON CONSUMER COMPANIES, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH, JANSSEN PHARMACEUTICA, INC., JANSSEN PHARMACEUTIC PRODUCTS, LP, JANSSEN PHARMACEUTICA NV, JANSSEN-CILAG a/k/a JANSSEN-CILAG, LTD., JANSSEN, LP, JANSSEN RESEARCH FOUNDATION, McNEIL-PPC, INC., McNEIL CONSUMER HEALTHCARE, McNEIL CONSUMER PRODUCTS COMPANY, McNEIL CONSUMER SPECIALTY PHARMACEUTICALS, PHARMACIA & UPJOHN COMPANY, LLC, PHARMACIA & UPJOHN, INC., and PHARMACIA & UPJOHN COMPANY	:	**SUPERIOR COURT DOCKETS**
Defendants/Appellants	:	**3259 EDA 2011** **471 EDA 2012**

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QUIÑONES ALEJANDRO, J. **DATE: January 7, 2013**

AMENDED OPINION

INTRODUCTION

This opinion addresses what may be a case of first impression in the Commonwealth involving a claim of injury resulting from the use of *over-the-counter* Children's Motrin. Alicia E. Maya, individually, and as the natural parent and guardian of Brianna Maya, a minor (Plaintiffs), sued numerous pharmaceutical companies, subsidiaries, and their successors, essentially alleging that Brianna Maya (Brianna) developed Stevens Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis ("TEN") in November 2000 after ingesting over-the-counter ("OTC") Children's Motrin and Children's Tylenol. Their initial complaint, premised on allegations of negligence and a defective product failure to warn claim, named the following defendants: Benefit Risk Management, Johnson & Johnson Consumer Companies, Inc., Johnson & Johnson Services, Inc., Janssen Pharmaceutica, Inc., Janssen Pharmaceutic Products, LP, Janssen Pharmaceutica NV, Janssen, LP, Janssen Research Foundation, Janssen-Cilag, Pharmacia & Upjohn Company, LLC, Pharmacia & Upjohn, Inc., Johnson & Johnson, McNeil-PPC, Inc., McNeil Consumer Products Company, McNeil Consumer Healthcare, McNeil Consumer & Specialty Pharmaceuticals, Johnson & Johnson-McNeil Consumer Pharmaceuticals Co., and Johnson & Johnson Pharmaceutical Research & Development, LLC.[1]

Subsequently, Plaintiffs filed an amended complaint. Discovery ensued and was completed. On May 24, 2011, after 46 days of testimony, the jury found in favor of Brianna and against Defendant McNeil-PPC, Inc., *only,* as successor in interest to Defendant McNeil

[1] On August 18, 2009, Plaintiffs filed a second amended complaint. By Orders dated June 18, 2010, the Honorable Patricia A. McInerney sustained Defendants' preliminary objections and dismissed as party defendants Janssen-Cilag and Janssen-Cilag, Ltd., as divisions of Janssen Pharmaceutica, Inc., Janssen Pharmaceutica, N.V., and Janssen Pharmaceutica, N.V., for lack of personal jurisdiction, and Johnson & Johnson Pharmaceutical Research & Development, LLC, Benefit Risk Management, a division of Johnson & Johnson Pharmaceutical Research & Development, LLC, Pharmacia & Upjohn Company, Pharmacia & Upjohn Company, LLC, and Pharmacia & Upjohn, Inc., for legal insufficiency.

Consumer Products Company (Defendant McNeil),[2] and awarded her $10 million in compensatory damages.

Defendant McNeil filed a post-trial motion which was heard and denied. Thereafter, on November 16, 2011, Defendant McNeil filed a notice of appeal of the jury's verdict officially recorded on May 24, 2011, and of the Order dated October 17, 2011, which denied its motion for post-trial relief. This appeal was docketed as 3259 EDA 2011.

On January 17, 2012, Defendant McNeil filed a second notice of appeal, this time of the Order dated January 4, 2012, which entered final judgment in favor of Plaintiffs for $10 million plus post-judgment interest.[3] This appeal was docketed as 471 EDA 2012.

On December 7, 2011, Defendant McNeil submitted its statement of errors complained of on appeal consisting of 23 paragraphs (many with multiple subparagraphs) exposing legal arguments that this trial judge erred in denying its numerous motions, *inter alia*, for summary judgment, *in limine,* compulsory nonsuit, directed verdict, judgment notwithstanding the verdict or, in the alternative, its motion for new trial. Defendant McNeil further contends that this trial judge made numerous evidentiary and charging errors which were prejudicial and tainted the jury's verdict. This trial judge disagrees and for the reasons stated herein, respectfully recommends that Defendant McNeil's appeals either be quashed for failure to conform to the Pennsylvania Appellate Rules of Procedure (Pa. R.A.P.) or, alternatively, denied for lack of merit.

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[2] Also referred to in pleadings as "McNeil Consumer Products Company," and as "McNeil Consumer Healthcare Division of McNeil".

[3] A settlement conference was held on February 14, 2012, in the Superior Court Appellate Mediation Program. The parties failed to reach a settlement.

RELEVANT FACTUAL AND PROCEDURAL HISTORY

The salient facts which occurred within a week's span of time and the procedural history, as defined by the pleadings, memoranda, trial testimony and exhibits, can be summarized as follows:

> On Saturday, November 25, 2000, Brianna Maya (Brianna) was a three-year old girl residing with her parentes in Martin, Tennessee. That evening, she attended a play with her grandmother, Marilyn Crist, who testified that during the intermission, she called her daughter, Alicia E. Maya (Brianna's mother/Ms. Maya), inquiring whether she should take Brianna home since the child was coughing and felt slightly warm. To not disappoint her daughter, Ms. Maya advised her mother to stay and watch the rest of the play. When she arrived home around 10:30 p.m., Ms. Maya gave Brianna a dose of over-the-counter (OTC) Children's Motrin, a medication manufactured by Defendant McNeil,[4] for the fever that had developed.[5]
>
> Early Sunday morning, November 26, 2000, Ms. Maya was awoken by Brianna, who was still feverish. She gave Brianna a second dose of OTC Children's Motrin.[6] Around 4:00 p.m., Ms. Maya noticed a rash on Brianna's neck near the top of her chest. She did not perceive this rash to be a life-threatening allergic reaction since Brianna had experienced a similar rash sometime in February 1999. This time, however, Brianna's eyes were pinkish. A third dose of OTC Children's Motrin was given to Brianna[7] after Ms. Maya spoke with Susan Brewer, M.D., Brianna's pediatrician, who instructed her to alternate OTC Children's Motrin with OTC Children's Tylenol.[8] Throughout the day, Brianna was given two additional doses of OTC Children's Motrin, alternated with OTC Children's Tylenol for her fever.[9]
>
> Ms. Maya testified that prior to administering the OTC Children's Motrin to Brianna, she read the label and dose instructions.[10] She recalled that the warnings on the label indicated that "hives, wheezing, facial swelling, or shock" could result from consuming OTC Children's Motrin, and to "call your doctor" if symptoms persisted.[11]
>
> Due to Brianna's persistent fever, Ms. Maya decided Brianna should be examined by Dr. Brewer. On Monday, November 27, 2000, Sean Maya,

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[4] N.T. 3/23/2011 p.m. at 66:22.
[5] N.T. 4/21/2011 a.m. at 73:23.
[6] *Id.* at 99:20.
[7] *Id.* at 76:23-79:12.
[8] *Id.* at 87:20.
[9] *Id.* at 100:4-101:4.
[10] *Id.* at 84:8.
[11] *Id.* at 85:20.

Brianna's father, took his daughter to Dr. Brewer, who examined and diagnosed Brianna with mycoplasma pneumonia, and prescribed Pediazole.[12] Ms. Maya picked up the prescription later that day and when she arrived home around 6:00 p.m., she found Brianna screaming, crying, and complaining that her "pee pee hurt."[13] Ms. Maya observed that Brianna's eyes were red with a runny discharge and that she had a fever, red lips, and a collar of red rash on her chest.[14] After carefully reading the dosing instructions, Ms. Maya gave Brianna a dose of the Pediazole antibiotic,[15] and continued alternating OTC Children's Motrin and OTC Children's Tylenol throughout the evening.[16] Ms. Maya testified that if the warnings on the Children's Motrin label had advised to "stop use" upon presentation of certain symptoms, she would have done so.[17]

On Tuesday morning, November 28, 2000, Brianna was rushed to Volunteer Hospital in Martin, Tennessee,[18] with a rapidly spreading rash over her entire body, her eyes red with discharge, and blisters on her mouth, chest and vaginal area.[19] On Dr. Brewer's recommendation based upon the severity of her worsening condition, Brianna was emergently transferred to Lebonheur's Children's Hospital in Memphis, Tennessee, later that same day.[20]

By the early morning hours of Wednesday, November 29, 2000, Brianna's rash had developed into blisters that rapidly spread and erupted all over her body and her eyes had swollen shut.[21] Because of the increased risk of infection from so many open blisters and wounds, Brianna underwent several debridements (forcefully sloughing off the skin using a highly abrasive material), requiring skin grafts of either pigskin or cadaver skin to protect the exposed underlying skin.[22] Brianna quickly deteriorated and was monitored in the intensive care unit for rapidly decreasing blood oxygen levels.[23]

On Friday, December 1, 2000, a medical decision was made to transfer Brianna to Shriner's Burn Hospital in Texas, which occurred around midnight via a private jet plane.[24] Upon arrival at Shriner's Hospital, approximately 84.5% of Brianna's total body surface was covered with open, burn-like wounds.[25] (In the presentation of the evidence, the jury was shown numerous photos of Brianna taken contemporaneously with the treatment rendered).

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[12] N.T. 3/23/2011 p.m. at 81:13-20.
[13] N.T. 4/21/2011 a.m. at 109:8.
[14] *Id.* at 111:2.
[15] *Id.* at 113:24; id. at 121:2.
[16] *Id.* at 118:3-120:19.
[17] *Id.* at 117:7.
[18] N.T. 4/14/2011 p.m. at 44:7.
[19] *Id.* at 43:18-44:20.
[20] N.T. 4/21/2011 a.m. at 127:13-21.
[21] *Id.* at 133:4-136:13.
[22] N.T. 4/07/2011 p.m. at 108:16-109:3.
[23] N.T. 4/14/2011 p.m. at 56:21-22.
[24] *Id* at 64:8-65:23.
[25] N.T. 4/05/2011 a.m. at 72:6-7; 4/07/2011 a.m. at 109:18-21.

For several days, Brianna's symptoms continued to worsen and she experienced a drop in blood pressure, hypoxia (decreasing oxygen),[26] fluid in her lungs, which had to be continually suctioned out, and internal bleeding, which required multiple blood transfusions.[27] Her open wounds covered the majority of her body to such an extent that family members could only touch the tip of one unaffected toe. Brianna was sedated to help the healing process and relieve the excruciating pain.[28]

Arthur Peter Sanford, M.D., the primary treating burn surgeon at Shriner's Burn Hospital,[29] testified that approximately nine days after the first onset of symptoms, the medical staff determined that the possible cause of Brianna's condition was the ingestion of OTC Children's Motrin (pediatric ibuprofen).[30] Dr. Sanford testified that Brianna's condition was diagnosed as toxic epidermal necrolysis (TEN),[31] described as an especially severe form of Stevens Johnson Syndrome (SJS), a rare but life-threatening disease that causes severe blistering and sloughing off of skin, together with serious damage to the mouth, eyes, throat, and esophagus.[32] Treatment for the disease is similar to that given burn victims, as the separation of the top layer of skin from the deeper layers of skin, is akin to a second-degree or partial-thickness burn.[33]

Brianna remained hospitalized at Shriner's Burn Hospital until December 16, 2000.[34] Thereafter, she was discharged to the Ronald McDonald House adjacent to the hospital where she remained until December 19, 2000, at which time she and her family returned to Martin, Tennessee. However, because TEN affected the mucus membranes of Brianna's eyes requiring specialized treatment, the family relocated to Clearlake, Texas.[35]

Scheffer Tseng, M.D., Brianna's treating ophthalmologist since 2002,[36] opined that Brianna suffered severe eye damage as a result of the TEN reaction as early as December 3, 2009.[37] Dr. Tseng described part of the eye injuries as adhesion and scar tissue on and between the eyelid and the eyeball, which

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[26] N.T. 4/07/2011 a.m. at 95:6-18.
[27] N.T. 4/15/2011 p.m. at 19:23-20:2.
[28] *Id.* at 16:23-17:4.
[29] N.T. 4/07/2011 a.m. at 69:13-22; 70:24-71:5.
[30] N.T. 4/05/2011 a.m. at 141:12-14; 4/07/2011 a.m. at 68:13-25.
[31] N.T. 4/07/2011 a.m. at 86:3-11.
[32] *See* ***Robinson v. McNeil Consumer Healthcare***, 615 F.3d 861, 864; 2010 U.S. App. LEXIS 17027, ** (citing Jean-Claude Roujeau, Robert S. Stern & Bruce U. Wintroub, "Cutaneous Drug Reactions," Harrison's Principles of Internal Medicine 343, 346 (Anthony S. Fauci et al. eds., 17th ed. 2008); Pierre-Dominique Ghislain & Jean-Claude Roujeau, "Treatment of Severe Drug Reactions—Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis," www.sjsupport.org/pdf/tsdr.pdf.
[33] *Id.*; N.T. 4/07/2011 a.m. at 34:20-35:4.
[34] N.T. 4/15/2011 p.m. at 20:21-23.
[35] *Id.* at 24:2-18.
[36] N.T. 4/13/2011 a.m. at 40:12-15.
[37] *Id.* at 98:4-5.

occurred after the skin sloughed off,[38] causing difficulty with blinking and fully closing the eyelids.[39] Dr. Tseng stated that because of the constantly changing nature of the eyes, a TEN reaction is ongoing and that there is no cure for Brianna's ocular damage or blindness.[40]

Brianna has undergone 16 eye surgeries,[41] all reportedly necessitated because of complications of the TEN reaction.[42] These surgeries were performed at Shriner's Burn Hospital by lead eye surgeon, Brian Wong, M.D., primarily to address the eyelid adhesions and to correct a condition where the eye lashes were growing inward.[43] Eventually, the eyelash follicles were removed via electrolysis to prevent the lashes' inward growth and the constant scratching to the surface of the eye balls which was causing eye irritation and damage.[44]

Ms. Maya testified that due to Brianna's TEN complications, Brianna has had to make lifestyle changes which include, *inter alia*, avoiding exposure to sunlight that can be damaging to her eyes; and strenuous activity in high, humid temperatures due to her inability to perspire normally,[45] pulmonary fibrosis, and the scarring in the lungs which makes respiration difficult and increases the risk of asthmatic attacks and upper respiratory infections.[46]

Steven Pliskow, M.D., an expert obstetrician gynecologist, testified that Brianna suffered gynecological complications due to TEN, which became more evident as Brianna matured into a young lady. He described the fact that Brianna suffered a complete fusion of both sides of the vaginal wall, which resulted in hematometra and retrograde menstruation, as confirmed by a MRI and ultrasound. Both conditions involved blocked blood in Brianna's uterus, which because of scarring caused the menses to back up through the Fallopian tubes into the abdominal cavity instead of discharging as normal menstruation.[47] Dr. Pliskow testified that the danger of menstrual blood backing up into the abdominal cavity is that it can lead to infection and/or endometriosis, where the lining of the uterus grows inside the abdominal cavity, creating further scarring, abdominal pain, and future complications.[48] While several surgical procedures performed by Dr. Pliskow successfully enabled Brianna to have normal menstruation,[49] Dr. Pliskow opined that the extent of damage to her reproductive system caused by TEN will bar her from having normal intercourse and childbirth. He opined that she would

[38] N.T. 4/13/2011 a.m. at 100:9-102:8.
[39] *Id.* at 104:14-18.
[40] *Id.* at 108:14-17; 109:25-110:11; 116:4-14.
[41] *Id.* at 121:7-122:12.
[42] *Id.* at 123:17-124:7.
[43] *Id.* at 118:5-21.
[44] *Id.* at 122:5-12.
[45] N.T. 4/15/2011 p.m. at 34:8-22.
[46] N.T. 4/05/2011 a.m. at 123:21-24.
[47] *Id.* at 93:2-8.
[48] *Id.* at 97:4-9.
[49] *Id.* at 119:24-120:10.

be able to produce a child through in-vitro fertilization carried by a surrogate.[50]

> Ms. Maya testified that she would *not* have used OTC Children's Motrin if she had seen the word "blisters" on the package because a medicine should not cause blisters.[51] Ms. Maya also testified that she does not believe, based on the 13½ years of administering OTC Children's Tylenol to her daughter, that Brianna has ever had a reaction to OTC Children's Tylenol.[52]
>
> At trial, both parties presented numerous experts who offered opinions addressing causation, what warnings were and should be on the OTC Children's Motrin label, and the relevant scientific studies that had been conducted. To avoid repetition, portions of the pertinent opinion testimony will be considered where appropriate in the discussion section of this opinion.

Procedurally, on February 19, 2009, Plaintiffs filed their initial complaint, which was amended on November 22, 2010. The amended complaint contained counts of: (1) negligent labeling of OTC Children's Motrin; (2) negligent design of ibuprofen; (3) strict liability; (4) breach of express and/or implied warranty, (5) violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"); (6) fraudulent misrepresentation and concealment; (7) reckless and/or negligent misrepresentation and concealment; (8) joint and several liability; (9) Plaintiff's damages; and (10) punitive damages.

Prior to the commencement of trial, approximately 50 motions *in limine* were filed by the parties and decided over a span of two days. Also, decided by an Order dated March 22, 2011, was Defendants'[53] motion for summary judgment, which was granted *in part*, dismissing, by agreement, all claims regarding OTC Children's Tylenol, the UTPCPL, consumer protection law, and breach of express and/or implied warranty. The order also provided that Pennsylvania law applied to the facts in this case.

On March 23, 2011, trial testimony commenced on the remaining counts; to *wit*: (1) strict

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[50] N.T. 4/05/2011 a.m. at 133:8-136:3.
[51] N.T. 4/26/2011 a.m. at 45:9-46:3.
[52] N.T. 4/27/2011 a.m. at 104:21-105:17.
[53] Johnson and Johnson, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. f/k/a/ McNeil Consumer Specialty & Pharmaceuticals, a division of McNEIL-PPC, Inc. and McNEIL-PPC, Inc.

products liability – defective design; (2) strict products liability – failure to warn; (3) negligent products liability – defective design; (4) negligent products liability – failure to warn; (5) negligence; (6) fraudulent misrepresentation; and (7) punitive damages.

At the conclusion of the presentation of evidence, Defendants on May 16, 2011, filed a motion for directed verdict as to all counts. By Order dated May 17, 2011, said motion was granted, *in part*, and Defendant Johnson & Johnson and Plaintiff Alicia Maya were dismissed as parties (Ms. Maya remained as Plaintiff in a representative capacity); and the claims of strict liability, defective design, and the existence of an alternative design, *i.e.*, dexibuprofen and Tylenol, were dismissed.[54] Thereafter, Plaintiffs voluntarily withdrew the claim of fraudulent misrepresentation. Thus, for the jury's consideration were Plaintiffs' contentions of negligent failure to warn, negligent design, and the request for punitive damages.

On May 24, 2011, the jury returned a verdict in favor of Brianna Maya and against Defendant McNeil, *only,* in the amount of $10 million. By way of the verdict slip, the jury specifically found that:

1) Defendant McNeil negligently failed to warn of risks associated with OTC[55] Children's Motrin.

2) This negligent failure to warn was a factual cause of minor Plaintiff's injuries;

3) Defendant McNeil did not negligently design OTC Children's Motrin; and

4) Defendant McNeil's conduct was not outrageous.[56]

On May 31, 2011, Defendant McNeil filed a lengthy post-trial motion requesting either judgment notwithstanding the verdict (n.o.v.) or, in the alternative, a new trial on the negligent failure to warn claim and on damages. Oral argument on this motion was scheduled and heard,

[54] N.T. 5/17/2011 a.m. at 8:16-21.
[55] *See* N.T. 5/17/2011 p.m. at 9:12-13.
[56] *See* verdict slip.

and by Order dated October 17, 2011, the motion was denied. Thereafter, Defendant McNeil filed appeals identified as Superior Court docket numbers 3259 EDA 2011, and 471 EDA 2012.

ISSUES

In response to an Order issued in accordance with Pennsylvania Rule of Appellate Procedure (Pa. R.A.P.) 1925(b), Defendant McNeil on December 7, 2011, filed of record the following verbatim statement of errors complained of on appeal:

Federal Preemption

1. this Court erred in failing to hold that federal law preempts Plaintiff Brianna Maya's ("Plaintiff") negligent failure-to-warn claim in two separate ways. First, federal law preempts Plaintiff's principal argument, which is that the labeling for over-the-counter Children's Motrin should have included warnings about the risk of SJS/TEN, life-threatening diseases or reactions, or blindness or injuries to genitalia. Second, federal law preempts Plaintiff's only other argument, that the labeling for over-the-counter Children's Motrin should have included warnings about rashes, skin reddening, and blisters. The Court therefore also erred by admitting evidence in support of the preempted claims, and by denying Defendant's Motion *in Limine* given that the claims were preempted, the Court erred in denying Defendant's motions for compulsory nonsuit, directed verdict, or judgment notwithstanding the verdict. In the alternative, even if it were concluded that only some of Plaintiff's theories were preempted, the Court erred in denying Defendant's motion for a new trial, because preempted theories and evidence supporting those theories were presented and argued to the jury;

Choice of Law

2. the Court erred in failing to hold that Tennessee law governed, and precluded Plaintiff's negligent failure-to-warn claim. There was a true conflict between the laws of Pennsylvania and Tennessee; Tennessee was indisputably the state of injury and the center of the parties' relationship; and Tennessee is the state with the most significant interest in having its laws applied to these claims. The Court, therefore, erred when it applied Pennsylvania law to the claims, when it granted Plaintiff's Motion *in Limine* No. 22, and when it refused to grant Defendant's motions for summary judgment, compulsory nonsuit, directed verdict, and judgment notwithstanding the verdict. In the alternative, the Court erred by failing to

instruct the jury on pertinent elements of Tennessee law, and, having erroneously instructed the jury on Pennsylvania law, in failing to grant Defendant's motion for a new trial;

Legal Insufficiency of the Evidence to Support Plaintiffs' Claims

3. Plaintiff failed to present evidence sufficient to carry her burden of proving that a negligent failure to warn was the factual and proximate cause of her injuries. In light of the insufficiency of Plaintiffs' evidence, the Court erred in denying Defendant's motions for compulsory nonsuit, directed verdict and judgment notwithstanding the verdict, or in the alternative, Defendant's motion for a new trial;

4. Plaintiffs failed to present sufficient evidence:

   (a) to establish the standard of care that Defendant was required to meet in the development of warnings on Children's Motrin;

   (b) to carry her burden of proving that Defendant had a duty to warn of the specific idiosyncratic reaction that Brianna Maya suffered; or

   (c) to prove that Defendant negligently breached any duty to warn, particularly given that the warnings that appeared on Children's Motrin's over-the-counter label adequately warned of the potential for a severe allergic reaction.

   The Court therefore erred in denying Defendant's motions for compulsory nonsuit, directed verdict and judgment notwithstanding the verdict, or in the alternative, Defendant's motion for a new trial;

5. Plaintiffs failed to present sufficient evidence to carry her burden of proving that ibuprofen is a medical cause of Stevens Johnson Syndrome ("SJS") or Toxic Epidermal Necrolysis ("TEN"), and that it was the specific cause of Brianna Maya's injuries. Their experts' testimony was inadmissible and should have been excluded. None of the remaining evidence was sufficient to support a finding of general or specific medical causation. The Court, therefore, erred in failing to grant Defendant's motions for compulsory nonsuit, directed verdict and judgment notwithstanding the verdict, or in the alternative, Defendant's motion for a new trial;

Prejudicial Misconduct by Plaintiffs' Counsel at Trial

6. Plaintiffs' counsel disregarded this Court's rulings and engaged in constant, pervasive and egregious misconduct at trial, which caused undue

prejudice to Defendant, tainted the verdict, and deprived Defendant of a fair trial. The Court failed to recognize that the extent and degree of prejudice caused by this misconduct far exceeded anything that could be cured by sustaining objections or by giving curative instructions to the jury, and the Court, therefore, erred in denying Defendant's motions for a mistrial or new trial. Defendant's mistrial motions and motion for post-trial relief detailed numerous instances of Plaintiff's counsel's misconduct throughout the trial, including:

(a) introducing non-record facts in his cross-examinations, presenting argumentative preambles to his questions, intentionally asking questions that counsel knew were outside the scope of the witnesses' knowledge and expertise so that he could present argumentative summaries of his own, and misstating facts in his questions, all of which allowed Plaintiffs' counsel to offer the jury facts and opinions outside the record that Defendant could not cross-examine;

(b) presenting information and evidence the Court had excluded in rulings prior to and during trial, ignoring the Court's contemporaneous rulings, and repeatedly making speaking objections contrary to the Court's order;

(c) making *ad hominem* attacks on defense witnesses and engaging in abusive cross-examination practices, such as quoting language out of context and attempting to examine witnesses about documents while preventing them from seeing or reviewing the documents;

(d) attempting to turn the case into a referendum on the drug industry rather than a trial of the facts relating to Plaintiff, and making repeated improper statements about the size of Defendant's legal team in order to induce prejudice against Defendant based on its size and wealth and to encourage the jury to impose the burden of proof on Defendant when under the law Plaintiff bore the burden of proof;

(e) leading his witnesses on direct to the point of testifying, and coaching his witnesses during their testimony;

(f) presenting false, irrelevant, and inappropriate evidence to the jury, such as his improper suggestion that he personally played a critical role in forcing an allegedly

defective and dangerous drug (Fen-Phen) off the market, and his improper criticism of Defendant and its witnesses for failing to reach out to the Maya family, conduct which he continued even after the Court sustained an objection; and

(g) presenting cumulative and repetitive testimony, and manipulating the scheduling of witnesses in order to delay cross-examination of Plaintiff's experts, and placing Defendant in the highly prejudicial position of having to present its defense long after the time the jurors had been told they would be discharged. Defendant's motion for post-trial relief also explained that after having engaged in extensive misconduct throughout the trial, Plaintiffs' counsel continued his misconduct during his closing argument by making false statements about Defendant and Defendant's conduct; by making false statements about the medical testimony; and by inviting the jury to decide the case based not on the evidence but instead based on the jury's sympathy for Plaintiff and/or prejudice against Defendant as a large corporation with large law firms representing it. The Court further erred by denying Defendant's request for remittitur of the damages award based on Plaintiff's counsel's egregious misconduct at trial, given that it tainted the verdict and thus supports the conclusion that the jury was guided by partiality or prejudice;

Erroneous Evidentiary Rulings

7. the Court erred by admitting irrelevant and hearsay evidence presented for the purpose of showing that Tylenol was a safer drug than Children's Motrin, and by allowing evidence and argument that Plaintiff would not have contracted SJS or TEN if her mother had been aware of these alleged "facts." That evidence, presented over objection, included:

(a) discussing the relative risk of gastrointestinal bleeds and liver failure;

(b) testimony that Defendant failed to warn users of Children's Motrin that Tylenol was safer than Children's Motrin;

(c) testimony by Alicia Maya about Tylenol advertisements that she did not see, despite the Court's ruling on a motion *in limine* that such questions would not be permitted, and

despite Alicia Maya's failure to identify in discovery any of the advertisements that allegedly influenced her decision to use Children's Motrin with Brianna Maya; and

(d) questioning of Alicia Maya about what decisions she would have made had she "known that Tylenol had a superior safety profile."

The admission of this evidence was prejudicial and requires a new trial;

8. the Court erred by admitting evidence relating to alleged risks or adverse effects of Children's Motrin other than the risk that allegedly resulted in injury in Plaintiff's case, specifically that she developed SJS and TEN. That error prejudiced the Defendant and requires a new trial;

9. the Court erred by not enforcing at trial its rulings on motions *in limine* about other incidents and determinations about Children's Motrin in other countries. The admission of this evidence was prejudicial and requires a new trial;

10. the Court erred by allowing testimony at trial about other drugs and the withdrawal of other drugs. The admission of this evidence was prejudicial and requires a new trial;

11. the Court erred by allowing Plaintiff to present information and evidence from time periods after Plaintiff's use of Children's Motrin as though it were current or known at the time of Plaintiff's SJS/TEN, thereby falsely suggesting that such later information and evidence was relevant to whether Defendant was negligent in the warnings given with Children's Motrin when Plaintiffs used the medication. The admission of this evidence was prejudicial and requires a new trial;

12. the Court erred by allowing incompetent, irrelevant and hearsay reports of specific incidents, including case reports and adverse event reports, to be presented as proof that ibuprofen causes SJS or TEN or that it caused Brianna Maya to develop SJS or TEN. The admission of this evidence was prejudicial and requires a new trial.

13. the Court erred by admitting Plaintiffs' experts' testimony because:

(a) they were not qualified to provide the testimony they did, including for reasons set forth in Defendant's Motions *in Limine* Nos. 15 (Hyland and Bunin allowed to testify using unsound methodology), 16 (Schulz, allowed to testify as to matters outside his area of expertise), 17 (Tseng, same), Tackett (*ipse dixit* opinions that do not satisfy *Frye*), 19 (Goldberg and

Bix, same), 20 (Dillman allowed to testify using unsound methodology), 21 (Pliskow and Walker allowed to testify as to matters outside their area of expertise), and 22 (Sanford allowed to give expert testimony despite being merely a fact witness), which motions were denied erroneously by the Court;

(b) they were allowed to testify to causation based upon individual adverse event or case reports which were not admissible and not a proper basis for determinations as to causation;

(c) they were permitted to testify beyond the scope of their reports;

(d) their testimony was improper and cumulative, in that multiple experts gave opinions relating to causation of SJS or TEN by ibuprofen generally and in Brianna Maya's case specifically;

(e) Dr. Goldberg was permitted to testify that the Motrin label was inadequate for reasons unrelated to SJS and TEN, which was irrelevant to the failure to warn claim;

(f) certain of them testified to opinions which depended upon "facts" not proven by competent evidence at trial, including "facts" supported only by hearsay statements by Sean Maya, Brianna Maya's father, who did not testify at trial;

(g) Dr. Tackett was permitted to testify to opinions that McNEIL-PPC, Inc., hid information from the FDA and that the FDA would not have approved Children's Motrin for OTC sale had it been given complete information, which opinions were irrelevant, speculative and beyond the scope of his expertise;

(h) Dr. Tackett was allowed to testify that the "distribution" of rashes proves that drugs were the cause of Plaintiff's SJS/TEN despite the lack of any reliable basis for that testimony; and

(i) various of Plaintiff's experts were permitted to bolster their opinions with references to opinions testified to by other experts in the trial.

The admission of this evidence was prejudicial and requires a new trial;

14. the Court erred by allowing Plaintiff's counsel to comment on the number of experts he presented in comparison to the number of experts the Defendant presented, and about the size of the Defendant and its "army" of lawyers, which comments were intended to and did have the effect of inducing prejudice against the Defendant and of shifting the burden of proof improperly from Plaintiffs to Defendant. Permitting these comments was prejudicial and requires a new trial;

15. the Court erred by excluding evidence concerning Dr. Brewer's personal experience with and knowledge of SJS, which was properly offered to rebut assertions by Plaintiffs that Dr. Brewer lacked knowledge concerning SJS which caused her to recommend the use of Children's Motrin to Alicia Maya. That error prejudiced the Defendant and requires a new trial;

16. the Court erred by allowing evidence of the contents of prescription ibuprofen labels to be used by Plaintiffs for the purpose of arguing that the prescription label failed adequately to advise Brianna Maya's pediatrician of the risk of SJS or TEN, when the relevant issue was the adequacy of the OTC label to warn the consumer, not the adequacy of the prescription label to warn a physician. That error prejudiced the Defendant and requires a new trial;

17. the Court erred by admitting evidence of the contents of the 2005 Citizen's Petition, which was irrelevant, hearsay and unduly prejudicial. That error prejudiced the Defendant and requires a new trial;

18. the Court erred by admitting evidence of the contents of McNEIL-PPC, Inc.'s 1984 Citizen's Petition and related litigation, which was irrelevant and unduly prejudicial, and which Plaintiff should not have been allowed to use as a basis for tort liability in light of Defendant's First Amendment right to petition the government under the *Noerr-Pennington* doctrine. That error prejudiced the Defendant and requires a new trial;

19. the Court erred by admitting evidence of the supposed inadequacy of the FDA, which was inadmissible hearsay, irrelevant, and unduly prejudicial. That error prejudiced the Defendant and requires a new trial;

Errors in the Charge Conference and Jury Instructions

20. the Court erred by instructing the jury that Defendant was subject to a "high degree" of care standard, rather than the normal standard of care that applies under the Pennsylvania law of negligence. This instruction prejudiced the Defendant, and requires a new trial;

21. the Court erred by instructing the jury that it could consider "what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct." This compounded the evidentiary error discussed in paragraph 8, above, prejudiced the Defendant, and requires a new trial;

22. the Court erred by instructing the jury on "concurring causes" even though there was no competent evidence that would permit any rational finder of fact to conclude that ibuprofen combined with some other cause to produce Plaintiff's injury. This instruction prejudiced the Defendant and requires a new trial; and

23. the Court erred by informing counsel that it would give the standard instruction on the "heeding presumption" in Pa. SSCJI (Civ) 8.03(b), which would have been error under Pennsylvania law. Although the Court ultimately did not give that instruction, Defendant's counsel was required to limit her closing argument to conform to the Court's ruling on this instruction, and, therefore, did not argue, as she should have been permitted to do, that the evidence showed that Alicia Maya would not have acted differently even if the label had contained the additional language urged by Plaintiffs. The evidence supported a finding that Plaintiffs would have used the product even if that additional language had been on the label at the relevant time. Had the jury so found the Defendant could not have been found liable. The Court's erroneous ruling on this instruction, therefore, prejudiced the Defendant and requires a new trial.

LAW AND DISCUSSION

Recommendation that the appeal be quashed for failure to conform to Pa. R.A.P. 1925(b).

It is unusual for this trial judge to comment on the conduct of trial counsel. However, an exception is herein made since this trial judge was overly challenged by the combative nature and unpleasant disposition exhibited by all counsel to each other during the course of the nine week trial. A reading of the trial transcript reveals the constant morning *and* evening cries of unfair play and improper tactics counsel lodged against each other. Based upon the trial experience, it does not surprise this trial judge that Defendant McNeil ushers forth an armada of every conceivable issue available to object to rather than present for appellate review a concise argument of meritorious issues. Clearly, Pa. R.A.P. 1925(b) is not satisfied by simply filing a

statement of errors however convoluted it may be. Rather, the rule requires that the statement be "concise" and coherent as to permit the trial court to understand the specific issues being raised on appeal. ***Tucker v. R.M. Tours***, 939 A.2d 343, 346 (Pa. Super. 2007), *aff'd*, 977 A.2d 1170 (Pa. 2009). The rule also requires that the statement be detailed enough so that the judge can write a Rule 1925(a) opinion, but not so lengthy that it does not meet the goal of narrowing down the issues previously raised to the few that are likely to be presented to the appellate court without giving the trial judge volumes to plow through. ***Arnoldy v. Forklift, L.P.***, 927 A.2d 257, 261 (Pa. Super. 2007), *appeal denied*, 939 A.2d 889 (Pa. 2007) (citing ***Commonwealth v. Reeves***, 907 A.2d 1, 3 (Pa. Super. 2006) (citation omitted)). Such is not the case here. With its statement of errors, Defendant McNeil has failed to conform to this mandate.

Case law has held that when appellants raise an "outrageous" number of issues in their 1925(b) statement, appellants have "deliberately circumvented the meaning and purpose of Rule 1925(b) and ha[ve] thereby effectively precluded appellate review of the issues [they] now seek to raise." *See* ***Tucker***, *supra*, 939 A.2d at 346 (citing ***Kanter v. Epstein***, 866 A.2d 394, 401 (Pa. Super. 2004), *appeal denied*, 880 A.2d 1239 (Pa. 2005)). When considering the two-page briefing limitations in Pa. R.A.P. 2116(a),[57] "voluminous" statements of error do not identify the issues that appellants actually intend to raise on appeal and, thus, hinder a meaningful review, ***Kanter***, *supra*, 866 A.2d at 401, and make it all but impossible for the trial court to provide a comprehensive analysis of the issues. ***Tucker***, *supra*, 939 A.2d at 346 (citing ***Jones v. Jones***, 878 A.2d 86, 90 (Pa. Super. 2005)). Further, appellants engage in misconduct when they attempt

[57] "Rule 2116. Statement of Questions Involved
(a) General rule. The statement of the questions involved must state *concisely* the issues to be resolved, expressed in the terms and circumstances of the case but without unnecessary detail. The statement shall be *no more than two pages* and will be deemed to include every subsidiary question fairly comprised therein . . . ." Pa. R.A.P. 2116(a) (emphasis added).

to overwhelm the trial court by filing a Rule 1925(b) statement that contains a multitude of issues that [appellants] do not intend to raise and/or cannot raise before the appellate court. ***Id.*** (citing ***Kanter***, *supra*, 866 A.2d at 402).

When recommending that this appeal be quashed, this trial judge relies in part on the holding of ***Tucker***, *supra.* Therein, appellants' initial court-ordered Pa. R.A.P. 1925(b) statement consisted of 16 pages with 76 issue-paragraphs and exhibits. The appellate court found that the statement raised a voluminous number of lengthy issues which created confusion for the trial court. It further deemed the statement of errors to be a breach of appellants' duty of good faith and fair dealing with the Court which constituted a course of misconduct designed to "undermine the Rules of Appellate Procedure." The appellants' issues therein were found to have been waived. ***Id.***, *supra*, 939 A.2d at 347 (citations omitted).

In the case sub judice, Defendant McNeil's Rule 1925(b) statement clearly demonstrates a desire to preserve every unfavorable ruling and contested issue, including, *inter alia*, rulings made on the numerous motions *in limine,* motion for summary judgment, motion for directed verdict, post-trial motion, and on alleged misconduct of counsel that occurred during the contentious nine-week trial. Defendant McNeil's Rule 1925(b) "concise" statement of errors consists of 11 pages outlining 23 numbered paragraphs/issues, several of these paragraphs contain numerous sub-issues while others make specific references to its 50-page post-trial motion, which consists of 55 paragraphs with 96 subparagraphs, and/or to the motions *in limine*, and/or the oral motion for mistrial, and/or the supplemental motion for mistrial. As an example of these complex references or "roadmap", this trial judge highlights the appellate issue charging the alleged prejudicial misconduct by Plaintiffs' counsel (herein issue number six in the statement of errors). Therein, Defendant McNeil makes reference to its motions for mistrial,

new trial, and remittitur of the damage award, as well as to seven sub-sections which in turn include references to several sub-sub-sections. This illustration of cross references to several arguments, reiterated numerous times in other errors claimed, is hardly, in this trial judge's estimation, "concise".

Another example of Defendant McNeil's assertions:

> "(b) presenting information and evidence the Court had excluded in rulings prior to and during trial, ignoring the Court's contemporaneous rulings, and repeatedly making speaking objections contrary to the Court's order."

To fully explore this sub-issue alone, one must refer to Defendant McNeil's motion for post-trial relief, Paragraph 40, sub-paragraph h., at page 17, which cites three specific instances which, in turn, refer to Defendant McNeil's supplemental motion for mistrial, Section H, sub-paragraphs 1-4 (each paragraph citing several quotations from the notes of testimony), and Section I, which cites five other specific instances.

How Defendant McNeil intends to condense its current statement of errors into *two* pages to conform to Pa. R.A.P. 2116, while characterizing each alleged error in its Rule 1925(b) statement as "non-redundant, non-frivolous" to conform with Pa. R.A.P. 1925(b)(4)(iv), will be a feat of its own. Accordingly, this trial judge respectfully opines that Defendant McNeil's Pa. R.A.P. 1925(b) statement of errors is clearly a violation of the rules of appellate procedure and a waiver of all issues. It is respectfully recommended that the appeal be quashed since the statement of errors is anything *but* concise.

Appeal should be dismissed for lack of merit.

In the event the appellate court *does* find that Defendant McNeil's statement of errors comports with proper legal procedure, in the interest of judicial economy, this trial judge will attempt to address the issues presented. The standard of review is clearly established with respect to the various post-trial relief requests and errors argued by Defendant McNeil; to *wit*:

errors committed in denying the motions for compulsory nonsuit, directed verdict, judgment n.o.v., new trial, and directed verdict.

Briefly, a *motion for compulsory nonsuit* allows a defendant to test the sufficiency of a plaintiff's evidence, and may be entered only in cases where it is clear that the plaintiff has not adduced sufficient evidence to establish all of the elements necessary to maintain a cause of action. When considering a motion for nonsuit, a trial court must give the plaintiff the benefit of all reasonable inferences arising from the evidence presented and must resolve any conflict in favor of the plaintiff. Pennsylvania Rule of Civil Procedure (Pa. R.C.P) 230.1; ***Bugosh v. Allen Refractories Co.***, 932 A.2d 901, 913 (Pa. Super. 2007) (citing ***Rachlin v. Edmison***, 813 A.2d 862, 868 (Pa. Super. 2002) (en banc) (quoting ***Parker v. Freilich***, 803 A.2d 738, 744 9Pa. Super. 2002), *appeal denied*, 820 A.2d 162 (Pa. 2003)). "However, if the trial court denies the motion for compulsory nonsuit and the moving defendant proceeds with his/her defense, then the court's ruling is not appealable and the issue must be renewed during the post-trial phase as a request for judgment n.o.v.". *See* ***Northeast Fence & Iron Works, Inc. v. Murphy Quigley Co.***, 933 A.2d 664, 668 (Pa. Super. 2007), *appeal denied*, 947 A.2d 737 (Pa. 2008). Relying on this case law, this trial judge opines that any complaint Defendant McNeil may have regarding the ruling on the compulsory motion for nonsuit is not appealable since it presented a defense.

When reviewing a *motion for a directed verdict*, the appellate court's scope of review is limited to determining whether the trial court abused its discretion or committed an error of law that controlled the outcome of the case. ***Lear, Inc. v. Eddy***, 749 A.2d 971 (Pa. Super. 2000) (internal citations omitted). A motion for directed verdict may be granted only where the facts are clear and there is no room for doubt. ***Geschwindt v. Wagner***, 1 A.3d 970, 973 (Pa. Cmwlth.

2010), *appeal denied*, 19 A.3d 1502 (Pa. 2011) (citing ***Lear***, *supra*)). In ruling on a motion for directed verdict, the trial court must consider the facts in the light most favorable to the non-moving party and must accept as true all evidence which supports that party's contention and reject all adverse testimony. ***Id.***

Similarly, in reviewing a *motion for judgment n.o.v.*, the evidence must be considered in the light most favorable to the verdict winner, who must be given the benefit of every reasonable inference of fact arising therefrom, and any conflict in the evidence must be resolved in the victor's favor. ***Fletcher-Harlee Corp. v. Szymanski***, 936 A.2d 87, 93 (Pa. Super. 2007), *allocatur denied*, 956 A.2d 435 (Pa. 2008). The judge's appraisement of evidence is not to be based on how the judge would have voted if a member of the jury, but on the facts as they come through the sieve of the jury's deliberations. ***Id.*** A judgment n.o.v. may be entered when the movant is entitled to judgment as a matter of law and/or, when the evidence is such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant. ***Id.*** 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 the movant's 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. ***Id.***; *see also,* ***Simon v. Wyeth Pharms., Inc.***, 989 A.2d 356, 365 (Pa. Super. 2009).

With respect to *motion for a new trial*, a trial court has broad discretion to grant or deny a new trial. ***Harman ex rel. Harman v. Borah***, 756 A.2d 1116, 1121 (Pa. 2000), *appeal denied*, 790 A.2d 1017 (Pa. 2001) (citing ***Martin v. Evans***, 711 A.2d 458, 461 (Pa. 1998), *reargument denied*, (Jun. 3, 1998)); ***Morrison v. Commonwealth, Dept. of Public Welfare***, 646 A.2d 565, 570 (Pa. 1994); ***Coker v. S.M. Flickinger Co., Inc.***, 625 A.2d 1181, 1184 (Pa. 1993). A trial

court must follow a two-step process when responding to a request for a new trial. ***Harman***, *supra*, 756 A.2d at 1122; ***Morrison***, *supra*, 646 at 571; *see* ***Riccio v. American Republic Insur. Co.***, 705 A.2d 422, 426 (Pa. 1997). First, the trial court must decide whether one or more mistakes occurred at trial. These mistakes might involve factual, legal, or discretionary matters. Second, if the trial court concludes that a mistake (or mistakes) occurred, it must determine whether the mistake is a sufficient basis for granting a new trial. ***Harman***, *supra*, 756 A.2d at 1122; *see* ***Spang & Co. v. U.S. Steel Corp.***, 545 A.2d 861, 868 (Pa. 1988), *appeal denied*, 611 A.2d 712 (Pa. 1992).

Consideration of all new trial claims is grounded firmly in the *harmless error doctrine* which underlies every decision to grant or deny a new trial. A new trial is not warranted merely because some irregularity occurred during the trial or another trial judge would have ruled differently; the moving party must demonstrate to the trial court that he or she has suffered prejudice from the mistake. ***Passarello v. Grumbine***, 29 A.3d 1158, 1162 (Pa. Super. 2011), *appeal granted*, 44 A.3d 656 (Pa. 20120) (citing ***Harman***, *supra*, 756 A.2d at 1122)). Once the trial court passes on the moving party's claim, the scope and standard of appellate review coalesce in relation to the reasons the trial court stated for the action it took. *See* ***Harman***, *supra*, 756 A.2d at 1122. Where the court is presented with a finite set of reasons for supporting or opposing its disposition and the court limits its ruling by reference to those same reasons, the appellate court's scope of review is similarly limited. ***Passarello***, *supra*, 29 A.3d at 1162; ***Harman***, *supra*, 756 A.2d at 1123. Thus, where the trial court articulates a single mistake (or a finite set of mistakes), the appellate court's review is limited in scope to the stated reason, and the appellate court must review that reason under the appropriate standard. ***Harman***, *supra*, 756 A.2d at 1123 (quoting ***Morrison***, *supra*, 646 A.2d at 571).

The particular standard of review prescribes the degree of scrutiny applied to the trial court's decision and the manner in which its conclusions are evaluated. ***Passarello***, *supra*, 29 A.3d at 1162; ***Harman***, *supra*, 756 A.2d at 1123. If the trial court's challenged ruling was one of law, the appellate court reviews its grant or denial of a new trial on that point to discern if the court committed legal error. ***Id.*** Similarly, if the challenged ruling involved a discretionary act, the disposition of the new trial is reviewed relative to that act for abuse of discretion. ***Id.*** As such, discretion must be exercised on the foundation of reason. ***Id.*** Accordingly, an abuse of discretion exists when the trial court has rendered a judgment that is manifestly unreasonable, arbitrary, or capricious, has failed to apply the law, or was motivated by partiality, prejudice, bias, or ill will. A finding by an appellate court that it would have reached a different result than the trial court does not constitute a finding of an abuse of discretion. ***Id.*** Where the record adequately supports the trial court's reasons and factual basis, the court cannot be found to have abused its discretion. ***Passarello***, *supra*, 29 A.3d at 1162 (citing ***Rettger v. UPMC Shadyside***, 991 A.2d 915, 923-924 (Pa. Super. 2010), *appeal denied*, 15 A.3d 491 (Pa. 2011)).

Finally, as to the standard of review for remittitur, a trial court's decision to deny a request for remittitur is reviewed for an abuse of discretion or an error of law. ***Smalls v. Pittsburgh-Corning Corp.***, 843 A.2d 410, 414 (Pa. Super. 2004), *appeal denied*, 857 A.2d 680 (Pa. 2004) (citing ***Bindschuz v. Phillips***, 771 A.2d 803 (Pa. Super. 2001)). Remittitur is justified only in limited instances where the verdict plainly is excessive, exorbitant, and beyond what the evidence warrants, ***Murray v. Philadelphia Asbestos Corp.***, 640 A.2d 446 (Pa. Super. 1004), *aff'd sub nom*, or where the verdict resulted from partiality, prejudice, mistake, or corruption, ***Rafter v. Raymark Ind.***, 632 A.2d 897 (Pa. Super. 1993), or whether the jury verdict so shocks the sense of justice such that the trial court should have granted remittitur as a matter of law,

Smalls, *supra*, 843 A.2d at 414 (citing ***Bey v. Sacks***, 789 A.2d 232 (Pa. Super. 2001). 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. ***Id.*** (citing ***Ferrer v. Trustees of University of Pennsylvania***, 825 A.2d 591, 611 (Pa. 2002) (quoting ***Delahanty v. First Pennsylvania Bank***, 464 A.2d 1243, 1257 (Pa. Super. 1983)).

Federal Preemption

Defendant McNeil argues that all of Plaintiffs' claims are federally preempted and should be dismissed. Defendant McNeil bases this argument on the fact that the Federal Drug Administration (FDA) approved for use OTC Children's Motrin after carefully reviewing the known pertinent data and expressly finding that the manufacturers had not withheld safety information. It further argued that it had no duty to change the warnings on the label since the FDA had rejected some of the warnings Plaintiffs now argues should have been provided on the label; to *wit*: the risk of SJS/TEN, life-threatening diseases or reactions, blindness, and/or injuries to the genitalia. In addition, Defendant McNeil contends that by permitting evidence that the label should have included warnings regarding rash, skin reddening, and blisters, this trial judge erred when denying its numerous motions (*in limine,* for compulsory nonsuit, directed verdict, and judgment n.o.v.). Defendant McNeil argues, in the alternative, that even if only some of Plaintiffs' claims are preempted, error occurred in denying its motion for a new trial because the jury was tainted by having heard the preempted theories and supporting evidence.

Without guidance as to which particular claim or claims Defendant McNeil concedes *may* not be federally preempted, this trial judge cannot perform an analysis based upon a presumption of what may not be preempted. Defendant McNeil must frame its *own* proper issues. ***Commonwealth v. Lemon,*** 804 A.2d 39 (Pa. Super. 2002). Under the circumstances, this trial

judge opines that this alternative argument is waived. Notwithstanding this opinion, this trial judge will address the concept of preemption as to *all* of Plaintiffs' claims.

Federal preemption is a jurisdictional concern for a state court since it challenges subject matter jurisdiction and the competence of the court to reach the merits of the claims raised. ***Kiak v. Crown Equip. Corp.***, 989 A.2d 385, 390 (Pa. Super. 2010) (citing ***Werner v. Plater-Zyberk***, 799 A.2d 776, 787 (Pa. Super. 2002), *appeal denied*, 806 A.2d 862 (Pa. 2002)). The principle of federal preemption is derived from Article VI, clause 2, of the United State Constitution's Supremacy Clause, which provides, in part, that the "This Constitution and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Constitution, Art. VI, cl. 2. Thus, laws that are in conflict with federal law are "without effect." ***Id.*** (citing ***Maryland v. Louisiana***, 451 U.S. 725, 746, 101 S. Ct. 2114, 68 L. Ed. 2d 576 (1981)).

Congress has the undisputed power to preempt state law in areas of federal concern. ***Id.*** (citing ***Stone Crushed P'ship v. Jackson***, 908 A.2d 875, 880 (Pa. 2006)). In determining the breadth of a federal statute's preemptive effect on state law, courts are guided by the tenet that "the purpose of Congress is the ultimate touchstone in every preemption case." ***Wyeth v. Levine***, U.S., 129 S. Ct. 1187, 1194, 173 L. Ed. 2d 51 (2009) (quoting ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)). However, because States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action. ***Medtronic***, *supra*, 518 U.S. at 485. The courts have relied upon an "assumption that the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." ***Rice v. Santa Fe***

Elevator Corp., 331 U.S. 218, 230, 67 S. Ct. 1146, 91 L. Ed. 1447 (1947). Consequently, preemption may be expressed in any of three ways:

1. an "express preemption" meaning that a state law may be preempted when Congress enacts a provision which expressly preempts the state enactment;

2. an "implied preemption" meaning that preemption may be found where Congress has legislated in a field so comprehensively that it has implicitly expressed an intention to occupy the given field to the exclusion of state law; and,

3. an "implied conflict preemption" meaning that a state enactment will be preempted where a state law conflicts with a federal law. Such a conflict may be found when it is impossible to comply with either federal and state law, or where the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. ***Kiak***, *supra*, 989 A.2d at 391 (citing ***In re Estate of Sauers***, 971 A.2d 1265, 1269 (Pa. Super. 2009), *appeal granted*, 981 A.2d 1279 (Pa. 2009), *rev'd, remanded*, 32 A.3d 1241 (Pa. 2011) (internal citations omitted)).

See also, ***Dooner v. DiDonato***, 971 A.2d 1187, 1193-1194 (Pa 2009), *on remand*, 991 A.2d 365 (Pa. Super. 2010). When deciding whether state "requirements" are preempted by federal legislation, the court's focus is on the specific language of the preemption statute in question. ***Romah v. Hygienic Sanitation Co.***, 705 A.2d 841, 852 (Pa. Super. 1997), *aff'd*, 737 A.2d 249 (Pa. 1999) (citing ***O'Donnell v. Big Yank, Inc.***, 696 A.2d 846, 852 (Pa. Super. 1997), *appeal denied*, 725 A.2d 182 (Pa. 1998)).

Here, Defendant McNeil's assertions of federal preemption are pivotal determinations, that if accepted, would bar Plaintiffs' averments that the label for OTC Children's Motrin should have included warnings of: (1) the risk of SJS/TEN, life-threatening diseases or reactions, blindness, and/ or injuries to genitalia; and (2) of rashes, skin reddening, and blisters. When deciding the numerous motions claiming preemption, this trial judge was guided by the holding in ***Wyeth v. Levine***, *supra*, which established that federal law did *not* pre-empt state law and that Congress did not intend FDA oversight to be the *exclusive* means of ensuring drug safety and effectiveness. The ***Wyeth*** court reiterated that federal regulations support the premise that drug

manufacturers bear the responsibility for the content of labeling at all times and that 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. ***Wyeth***, *supra*, 129 S. Ct. at 1198. *See also*, 21 Code of Federal Regulations (CFR) § 201.80(e), which requires a manufacturer to 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) which places responsibility for post-marketing surveillance on the manufacturer; and 73 Federal Regulation 49603 which provides that a supplemental application is appropriate to amend the labeling for an approved product to reflect newly acquired information and to add or strengthen a contraindication, warning, precaution, or adverse reaction if there is sufficient evidence of a causal association with the drug.

In light of the case law and federal regulations, this trial judge opines that Plaintiffs' contentions are *not* preempted by federal law. This opinion is consistent with other federal and state court opinions in other Children's Motrin cases which have found that preemption does not apply and have denied similar arguments from Defendant McNeil. *See, e.g.,* ***Wolfe v. McNeil-PPC, Inc.***, 773 F. Supp.2d 561, 568 (E.D. PA. 2011).

Choice of Law

In its choice of law argument, Defendant McNeil essentially contends that this trial judge erred in granting Plaintiffs' motion *in limine* No. 22[58] and in ruling that Pennsylvania law, and not Tennessee law, applied to the facts in this case. Defendant McNeil insists that a true conflict exists between the laws of both states and proffers that Tennessee is the state with the most significant interest in having its laws applied. Defendant McNeil further argues that this erroneous ruling adversely impacted its other numerous motions. This trial judge disagrees.

To decide which state's substantive law controls, we look to the choice of law rules of the

[58] N.T. 3/22/2011 a.m. at 105:7-9.

forum state where the complaint was filed, Pennsylvania. ***Bearden v. Wyeth***, 482 F. Supp. 2d 614, 617; 2006 U.S. Dist. LEXIS 96010 (citation omitted). In Pennsylvania, the choice of law analysis first entails a determination of whether the laws of the competing states actually differ. If there is no conflict, no further analysis is necessary. However, if an actual conflict is present, the court must analyze the governmental interests underlying the issue and determine which state has the greater interest in the application of its law. ***Wilson v. Transp. Ins. Co.***, 889 A.2d 563, 571 (Pa. Super. 2005) (citing ***Ratti v. Wheeling Pittsburgh Steel Corp.***, 758 A.2d 695, 702 (Pa. Super. 2000), *appeal denied*, 785 A.2d 90 (Pa. 2001) (internal citations omitted)). If there is a conflict between the states' laws, the court must engage in "an 'interest analysis' of the policies of all interested states and based on the result of that analysis, characterize the case as having a true conflict, a false conflict, or as an unprovided-for case." ***Bearden***, *supra*, 482 F. Supp. 2d at 617 (citing ***Budget Rent-A-Car System, Inc. v. Chappell***, 407 F.3d 166, 170 (3d Cir. 2005)); *see also* ***Lacey v. Cessna Aircraft Co.***, 932 F.2d 170, 187 n.15 (3d Cir. 1991); ***Lejeune v. Bliss-Salem, Inc.***, 85 F.3d 1069, 1071 (3d Cir. 1996)).

A false conflict exists "if only one jurisdiction's governmental interests would be impaired by the application of the other jurisdiction's law." ***Lacey***, 932 F.2d at 187. In false conflicts situations, only the law of the interested jurisdiction is applied. ***Id.*** (citing ***Kuchinic v. McCrory***, 222 A.2d 897, 899-900 (Pa. 1966)).

A true conflict exists "when the governmental interests of both jurisdictions would be impaired if their law were not applied. ***Lacey***, *supra*, 932 F.2d at 187 n.15. In these situations, a more detailed analysis is required. ***Id.*** In Pennsylvania *choice of law* rules "call for the application of the law of the state having the most significant contacts or relationships with the particular issue." ***Bearden***, *supra*, 482 F.Supp. 2d at 619. This has been described as a "hybrid

approach that 'combines the approaches of both the Restatement (Second) (contacts establishing significant relationships) and the interest analysis (qualitative appraisal of the relevant States' policies with respect to the controversy).'" ***Lacy***, *supra*, 932 F.2d at 187, quoting ***Melville v. Am. Home Ass. Co.***, 584 F.2d 1306, 1311 (3d Cir. 1978)). Under ***Griffith v. United Air Lines***, 203 A.2d 796 (Pa. 1964), the choice of law determination looks to the law of the jurisdiction with the most significant relationship to the occurrence and the parties, and places importance on the analysis of the policies underlying the conflicting laws and the relationship of the particular contacts to those places. *See also* ***Ario v. Underwriting Members of Lloyd's of London Syndicates***, 996 A.2d 588, 593 (Pa. Commw. 2010) (citing ***Griffith***, *supra*, 203 A.2d at 802). Proper application of the analysis depends not on a mere counting of contacts with the respective jurisdictions; the contacts must be measured on a qualitative rather than a quantitative scale. ***Ario***, 996 A.2d at 593 (citing ***Caputo v. Allstate Ins. Co.***, 495 A.2d 959, 961 (Pa. Super. 1985)). *See also* ***In re Estate of Agostini***, 457 A.2d 861, 871 (Pa. Super. 1983); ***Cipolla v. Shaposka***, 267 A.2d 854, 856 (Pa. 1970). That is, the relevant inquiry is "the extent to which one state rather than another has demonstrated, by reason of its policies and their connection and relevance to the matter in dispute, a priority of interest in the application of its rule of law." ***Bearden***, *supra*, 482 F.Supp. 2d at 619 (citing ***Troxel v. A.I. duPont Institute***, 636 A.2d 1179, 1181 (Pa. Super. 1994) (citation omitted)).

> When applying the hybrid approach, relevant government considerations include:
>
> > (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied.

Restatement (Second) of Conflict of Laws § 6(2) (1971).

The "[c]ontacts to be taken into account in applying [these] principles" include:

> (a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered.

Id. at § 145 92).

Here, this trial judge reviewed the respective laws of Pennsylvania and Tennessee as these related to Plaintiffs' different causes of action to determine whether an actual conflict exits. However, greater consideration was given to Plaintiffs' primary claims; to *wit*: the failure to warn claims and the punitive damages claim, since these appeared to be Defendant McNeil's major preoccupation.

As to Plaintiffs' failure to warn (product liability action) of specific risks related to the use of OTC Children's Motrin claim, both Tennessee and Pennsylvania have adopted the Restatement (Second) of Torts, Sections 388 and 402A, which govern product liability claims. Specifically, Section 402A(1) essentially allows recovery where a product causes harm and contains "a defective condition unreasonably dangerous to the consumer or user". *See also* ***Whitehead v. Toyota Motor Corp.***, 897 S.W.2d 684, 688 (Tenn. 1995); ***Lance v. Wyeth***, 4 A.3d 160, 164 (Pa. Super. 2010) (citing ***Webb v. Zern***, 220 A.2d 853 (Pa. 1966)). This trial judge found no significant difference between the states.

Section 388 ascribes liability when one who supplies directly or through a third person a chattel for another:

> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Overbeck v. Cates, 700 A.2d 970, 972 (Pa. Super. 1997), *appeal denied*, 717 A.2d 534 (Pa. 1998).

A product is defective due to a failure-to-warn where the product was distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product. ***Donoughe v. Lincoln Elec. Co.***, 936 A.2d 52, 61-62 (Pa. Super. 2007), *reargument denied*, 2007 Pa. Super. LEXIS 6044 (Pa. Super. Ct. Dec. 13, 2007) (citing ***Phillips v. A-Best Products Co.***, 665 A.2d 1167, 1171 (Pa. 1995) (quoting ***Mackowick v. Westinghouse Electric Corp.***, 575 A.2d 100, 102 (Pa. 1990)).

In addition to the Restatement (Second), Tennessee also enacted the *Products Liability Act of 1978*, Tenn. Code. Ann. (T.C.A.) § 29-28-101, *et seq.* ("TPLA"), which essentially provides that to impose liability on a manufacturer, it must be shown that the product was in a defective condition or an unreasonably dangerous condition, at the time it left the manufacturer's control. T.C.A. § 29-28-105(a); ***Goode v. Tamko Asphalt Products, Inc.***, 783 S.W.2d 184, 187 (Tenn. 1989). Unreasonably dangerous is defined to mean that a product is dangerous to an extent beyond which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. T.C.A. § 29-28-102(8).

In Pennsylvania, due to the inherent risks and dangers associated with *prescription* drugs, the Supreme Court has limited the potential causes of action available to a plaintiff who alleges a strict liability claim against a drug manufacturer to either (1) a manufacturing defect claim or (2) a failure to warn claim. ***Lance***, *supra* (citing ***Baldino v. Castagna***, 478 A.2d 807, 810 (Pa. 1984)). In the matter of ***Incollingo v. Ewing***, 282 A.2d 206, 221 (Pa. 1971), the Court held that "assuming proper preparation and warnings, a manufacturer of drugs is not strictly liable for

unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk." If a plaintiff asserts a failure to warn claim under Section 402A, strict liability will not be imposed upon the drug manufacturer. Rather, pursuant to ***Hahn***, *supra*, the failure to warn claim will be analyzed and adjudicated in accordance with the negligence standard contained in the Restatement (Second) of Torts § 388. ***Hahn***, *supra*, 673 A.2d at 890-891. Although we have not found a case on point, this trial judge opines that the same principals apply to over-the-counter drug/medication.

As for the punitive damages claim, Tennessee and Pennsylvania allow punitive damages as a means to punish and/or deter reckless behavior. *See* ***McLemore v. Elizabethton Med. Investors, Ltd. P'ship***, 2012 Tenn. App. LEXIS 415, *19; ***Hutchison v. Luddy***, 870 A.2d 766, 770 (Pa. 2005). In Pennsylvania, punitive damages may be awarded for conduct that is outrageous, because of the defendant's evil motive or reckless indifference to the rights of others. A plaintiff must prove the claim by the preponderance of evidence. As the name suggests, punitive damages are penal in nature and are proper only in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct. When assessing the propriety of the imposition of punitive damages, "[t]he state of mind of the actor is vital. The act, or the failure to act, must be intentional, reckless or malicious." ***Daniel v. Wyeth Pharms., Inc.***, 15 A.3d 909, 929 (Pa. Super. 2011), *appeal granted, in part, denied, in part*, 32 A.3d 1260 (Pa. 2011).

In Tennessee, to be entitled to an award of punitive damages, a plaintiff must prove by *clear and convincing* evidence that a defendant acted either (1) intentionally, (2) fraudulently, (3) maliciously, or (4) recklessly. ***Meals v. Ford Motor Co.***, 2012 Tenn. App. LEXIS 234, *23, *app. granted*, 2012 Tenn. LEXIS 544 (Tenn. Aug. 15, 2012) (citing ***Sanford v. Waugh & Co.***, 328

S.W.3d 836, 848 (quoting ***Hodges v. S.C. Toof & Co.***, 833 S.W.2d 896, 901 (Tenn. 1992), *rehear'g denied*, 1992 Tenn. LEXIS 362 (Tenn. May 26, 1992)). The purpose of punitive damages is "to punish a defendant, to deter him from committing acts of a similar nature, and to make a public example of him." ***Sanford***, *supra*, 328 S.W.3d at 849 (quoting ***Goff v. Elmo Greer & Sons Constr. Co.***, 297 S.W.3d 175, 187 (Tenn. 2009), *certiorari denied*, 130 S. Ct. 1910 (U.S. 2010) (quoting ***Huckeby v. Spangler***, 563 S.W.2d 555, 558-59 (Tenn. 1978)). Therefore, punitive damages "are available in 'cases involving only the most egregious of wrongs.'" ***Id.*** (quoting ***Hodges***, *supra*, 833 S.W.2d at 901). Punitive damages are reserved for conduct that was so reprehensible that it must be both punished and deterred. ***Meals***, *supra* (citation omitted).

As is evident, the states' product liability and punitive damages laws are substantially similar. The states differ with respect to the burden of proof when it comes to punitive damages. Tennessee requires "clear and convincing evidence", while Pennsylvania requires "preponderance of the evidence." As will be noted, *infra*, this difference is moot since the jury found that under the lesser burden of proof, punitive damages were not warranted. Clearly, Defendant McNeil suffered no prejudice in having Pennsylvania law on punitive damages apply.

Briefly, with respect to fraudulent misrepresentation and concealment claim, Tennessee and Pennsylvania adhere to similar standards. *See* ***Homestead Group, LLC v. Bank of Tenn.***, 307 S.W.3d 746, 751 (Tenn. Ct. App. 2009), *appeal denied*, 2009 Tenn. LEXIS 626 (Tenn. Sept. 28, 2009); ***Heritage Surveyors & Eng'rs, Inc. v. Nat'l Penn Bank***, 801 A.2d 1248, 1250 (Pa. Super. 2002). Also similar are the two states' laws that protect consumers from unfair and deceptive practices in the conduct of any trade or commerce: Tennessee's Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq.* and Pennsylvania's Unfair Trade Practices and

Consumer Protection Law, 73 P.S. § 201, *et seq.* *See* ***Fayne v. Vincent***, 301 S.W.3d 162, 172 (Tenn. 2009); ***Bennett v. A.T. Masterpiece Homes at Broadsprings, LLC***, 40 A.3d 145, 151 (Pa. Super. 2012). Both states recognize products liability actions for breach of express or implied warranty. *See* ***Body Invest, LLC v. Cone Solvents, Inc.***, 2007 Tenn. App. LEXIS 480, *17 (Tenn. Ct. App. July 26, 2007); ***French v. Commonwealth Assocs.***, 980 A.2d 623, 633 (Pa. Super. 2009), *reargument denied*, 2009 Pa. Super. LEXIS 4437 (Pa. Super. Oct. 6, 2009).

Tennessee and Pennsylvania laws address and permit defective design theories but are, however, measured by different standards. Tennessee's § 29-28-101, *et seq.*, cover Pennsylvania's corollary to "negligent design" in that "the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable. Consideration is given also to the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products." T.C.A. § 29-28-105(b); *see* ***Potter v. Ford Motor Co.***, 213 S.W.3d 264, 270 (Tenn. Ct. App. 2006), *appeal denied*, 2006 Tenn. LEXIS 1071 (Tenn. Nov. 13, 2006). A "defective condition" is defined as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." T.C.A. § 29-28-102(2); ***Potter***, *supra*, 213 S.W.3d at 270.

Pennsylvania, on the other hand, does not permit negligence concepts in a strict liability defective design claim pursuant to the Restatement (Second) of Torts, Section 402A. A product need be made safe only for its intended user. ***Phillips v. Cricket Lighters***, 841 A.2d 1000, 1005 (Pa. 2003) (citing ***Mackowick v. Westinghouse Electric Corp.***, *supra*). The court explicitly stated that a manufacturer will not be held strictly liable for failing to design a product that was safe for use by any reasonably foreseeable user as such a standard would improperly import

negligence concepts into strict liability law. ***Id.***

As to Plaintiffs' joint and several liability claim, there is a variance between Tennessee and Pennsylvania. In Tennessee, joint and several liability is no longer applicable in circumstances "where the separate, independent negligent acts of more than one tortfeasor combine to cause a single, indivisible injury." ***Banks v. Elks Club Pride of Tenn. 1102***, 301 S.W.3d 214, 224 (Tenn. 2010) (citations omitted). Pennsylvania permits joint and several liability in "enabl[ing] the injured party to satisfy an entire judgment against any one of the tort-feasors, even if the wrong-doing of that tort-feasor contributed only a small part to the harm inflicted." Notwithstanding this difference, if the defendants are held jointly and severally liable, they may have contribution rights between them, but this does not affect the plaintiff's right to collect his judgment from either. ***Sehl v. Neff***, 26 A.3d 1130, 1133 (Pa. Super. 2011) (citing ***Hileman v. Morelli***, 605 A.2d 377, 384-385 (Pa. Super. 1992)).

Having reviewed Tennessee and Pennsylvania's pertinent statutes governing the different causes of action, this trial judge is of the opinion that a true conflict does not exist between the two states' laws. Thus, no further analysis is needed.

Notwithstanding this opinion, in the event the appellate court disagrees, this trial judge also opines that the analysis of governmental interests and relevant qualitative contacts supports this trial judge's finding that Pennsylvania has more interest in having its laws applied.

Briefly, when analyzing the governmental interests underlying the issue and determining the contacts involved, this trial judge acknowledges that Tennessee is where Brianna resided at the time of her injuries, where the Children's Motrin bottle was purchased, and where Brianna's injuries and initial treatment occurred. Brianna has also received specialized treatment in other states, such as Texas and Florida, and for a significant length of time has resided outside of

Tennessee. In contrast, Pennsylvania is where Children's Motrin was manufactured, where the decisions surrounding the language of warnings on the label were made, where the research on the product was conducted, and where the principal personnel involved either resided or worked; to *wit*: (1) Dr. Carrie Corboy, Johnson & Johnson senior scientist accountable for writing the periodic safety update reports for Motrin and submitting them to regulatory agencies, testified that Defendant McNeil's pharmaco-vigilance and its Benefit Risk Management component are located in Horsham, Pennsylvania;[59] (2) Paula J. Oliver, the former Senior Director of Regulatory Compliance for Defendant McNeil who handled Motrin pre-New Drug Application ("NDA")[60] inspections by the FDA, worked and lived in Pennsylvania;[61] (3) Mary Joan Denisco, Director of Medical Affairs and later the Director of Clinical Affairs at McNeil Consumer Healthcare, who testified that Defendant McNeil had the obligation to "report all data from the spontaneous reporting system related to ibuprofen when [McNeil] submitted [the] N[DA]", worked on the label for Children's Motrin, lived and was employed in Pennsylvania;[62] (4) Robert Christiansen, Associate General Counsel of Johnson & Johnson, who served on the Copy Label Committee for McNeil Consumer, was located in Pennsylvania;[63] (5) Dr. Eileen Helzner, the Director of Clinical Research or Development when Pediaprofen (ibuprofen) was being developed by Defendant McNeil, testified that she reported to the vice present of research and development, worked and lived in Pennsylvania;[64] (6) Dr. Tony Temple, Defendant McNeil's Medical Director and the individual in charge of all drug labeling decisions, as well as the most knowledgeable person at McNeil about the relationship between Children's Motrin (ibuprofen)

[59] Corboy Dep., 11/21/2007 at 9:5-18; 19:17-20:4.
[60] *See* N.T. 3/24/2011 p.m. at 90:10.
[61] Oliver Dep., 4/28/2004 at 17:1-18:11; 45:15-22; 49:4.
[62] Denisco Dep., 4/24/2004 at 16:6-17:14; 250:14-251:23; 265:7-266:17.
[63] Christiansen Dep., 5/20/2004 at 12:5-23; 31:11-16; 38:15-23.
[64] Helzner Dep., 4/27/2004 at 20:9-20; 32:12-24.

and SJS/TEN, was medically licensed in Pennsylvania, lived in Wayne, Pennsylvania, and was employed at the McNeil campus on Camp Hill Road in Fort Washington, Pennsylvania;[65] (7) Kenneth Kwong, Defendant McNeil's Executive Director of Pharmacovigilance, whose function changed to safety surveillance for Motrin under Defendant Benefit Risk Management, testified that the "pharmaco-vigilance department receives a list of scientific and medical journal abstracts from the Pharmaceutical Resource Center on a regular basis [and that Center is] a McNeil department located in Fort Washington, Pennsylvania";[66] (8) Lynn Pawelski, Defendant McNeil's Vice President of Regulatory Affairs, testified that she lives and works in Pennsylvania;[67] (9) Adrian Thomas, Johnson & Johnson Pharmaceutical Services LLC Vice President of Operations, who handled adverse event reports (or periodic safety update reports) for Motrin, testified that these were generated in Belgium and Horsham, Pennsylvania;[68] (10) Laura Reel Plantz, McNeil Medical Information Specialist, testified that her pharmacy license is in Pennsylvania and that she lives and works in Pennsylvania;[69] and (11) Sandra Schoenwald, McNeil's Manager of Safety and Risk Management, testified that her pharmacy license is from Pennsylvania and that she lives and works in Pennsylvania.[70]

In light of the totality of these significant qualitative *and* quantitative contacts, this trial judge opines that its ruling that Pennsylvania law applies in this case is correct. Clearly, Pennsylvania has the most significant relationship between the occurrence and the parties. It has an undisputed responsibility to ensure that manufacturers provide safe products for the consumer and comply with state laws. Equally relevant is the citizenships' expectation that products will

[65] Temple Dep., 5/19/2004 at 25:6-26:24; 27:9-12; 16:9-11; 7/25/2007 at 27:9-12.
[66] Kwong Dep., 9/24/2008 at 16:22, 21:21-25; 83:5-84:6.
[67] Pawelski Dep., 12/17/2008 at 8:18-24; 6:3-4.
[68] Thomas Dep., date unavailable, 32:18-33:24; 80:23-81:3; 121:20-21.
[69] Plantz Dep., 6/15/2004 at 7:14-15; 12:21-25; 74:6-8.
[70] Schoenwald Dep., 9/23/2008 at 5:19-22; 9:8-22; 14:3-15.

be safe for consumption. Defendant McNeil chose Pennsylvania as a major hub in its operations. Based upon this analysis, this trial judge opines that Defendant McNeil's choice of law argument is without merit.

Additionally, this trial judge also found persuasive Plaintiffs' argument that Defendant McNeil's intention to seek the application of Tennessee law should be rejected for failure to follow the requirements of 42 Pa.C.S. § 5327. In its pertinent part, Section 5327 entitled "Determination of foreign law" provides:

> NOTICE.—A party who intends to raise an issue concerning the law of any jurisdiction or governmental unit thereof outside this Commonwealth shall give notice in his pleadings or other reasonable written notice.

When a party fails to satisfy the requirements of Section 5327, its attempted use of foreign law must be rejected. *See* ***Commonwealth v. Manley***, 985 A.2d 256, 271 (Pa. Super. 2009), *appeal denied,* 996 A.2d 491 (Pa. 2010). There, the court held that a party's failure to provide timely notice of non-Commonwealth law prevented use of that law.

Here, Defendant McNeil rebuts Plaintiffs' assertions and offers that it fulfilled this statutory obligation of "notice" to the choice of law issue in a responsive pleading's paragraph which contains a broad reference to several states' constitutions; to *wit*: "*Defendant preserves any and all defenses to Plaintiffs' claims for punitive damages, including all defenses arising under the Tennessee Constitution, Texas Constitution, the Pennsylvania Constitution, and the Constitution of the United States.*"[71] In light of this overly broad and vague reference to any and all defenses, this trial judge opines that Defendant McNeil failed to conform to the requisite notice requirement of Section 5327. In light of this argument, Defendant McNeil's choice of law argument should be deemed waived. Clearly, Section 5327(c) provides the "court, not jury, shall

[71] Joint Answer and New Matter of McNeil Defendants to Plaintiffs' Second Amended Complaint (As to Remaining Defendants), ¶ 234.

determine the law of any governmental unit outside this Commonwealth. The determination of the tribunal is subject to review on appeal as a ruling on a question of law." 42 Pa.C.S. § 5327.

As a final comment, Defendant McNeil's choice of law argument appeared to be more concerned with the applicable law on punitive damages. Since the jury found that punitive damages were not warranted, this preoccupation of the choice of law would make this concern a non-issue.[72] There is no dispute that the intent and import of both states' punitive damages provisions are not at variance. What differs is the burden of proof required. Since there was a jury finding that punitive damages were not warranted, Defendant McNeil's argument is without merit.

Legal Insufficiency of the Evidence to Support Plaintiffs' Claims

In this subsection, Defendant McNeil contends that this trial judge erred in denying its motion for judgment n.o.v. since the evidence was insufficient to prove Plaintiffs' contentions that its negligent failure to warn was the factual cause of the injuries suffered by Brianna. Defendant McNeil further claims that the evidence was insufficient to prove the standard of care required for developing warnings on Children's Motrin label; that it had a duty to warn of the specific idiosyncratic reactions that Brianna actually suffered; and that it negligently breached any duty to warn arguing that the warnings on the OTC Children's Motrin's label adequately advised of the potential for severe allergic reaction. This trial judge disagrees.

As stated, a motion requesting judgment n.o.v. is the proper remedy where the evidence presented at trial is insufficient to sustain the verdict. ***Rohm & Haas Co. v. Continental Cas. Co.***, 732 A.2d 1236, 1248 (Pa. Super. 1999), *appeal denied*, 849 A.2d 1205 (Pa. 2004); ***Butler v. Flo-Ron Vending Co.***, 557 A.2d 730, 735 n.6 (Pa. Super. 1989), *appeal denied*, 567 A.2d 650

[72] As stated, all strict product liability claims were dismissed by Order dated May 17, 2011, upon Defendant McNeil's motion for a directed verdict; Plaintiffs withdrew their cause of action under Pennsylvania consumer law.

(Pa. 1989). Nonetheless, entry of judgment n.o.v. on the basis of evidentiary insufficiency is an extreme remedy, appropriate only in a clear case, where the facts are such that no two reasonable minds could fail to agree that the verdict, as rendered by the jury, was improper. ***Coward v. Owens-Corning Fiberglas, Corp.***, 729 A.2d 614, 622 (Pa. Super. 1999). Any appellate review is limited to whether competent evidence of record supports the elements of the underlying cause of action, viewing the evidence in the light most favorable to the verdict winner and granting that party the benefit of all reasonable inferences and rejecting all unfavorable testimony. ***Id.*** The trial court's order will be reversed only where the record demonstrates that its decision resulted from an abuse of discretion in assessing the evidence or an error of law in adjudging the cause of action. ***Id.*** However, a judgment n.o.v. may not be employed to invade the province of the jury. ***Id.*** When there is a question of fact to be resolved, it is within the sole purview of the jury. ***Id.*** Without dispute, it is the jury's prerogative to assess credibility. Lastly, a judgment n.o.v. should not be entered where evidence is conflicting upon a material fact. ***Id.***

Proximate cause is an essential element in a failure to warn case. ***Owens v. Wyeth***, 2010 Pa. Super. LEXIS 2095 (citing ***Simon v. Wyeth Pharms., Inc.***, 989 A.2d 356, 368 (Pa. Super. 2009)). A proximate or legal cause is defined as a substantial contributing factor in bringing about the harm in question. ***Id.*** at *5 (citing ***Whitner v. Von Hintz***, 263 A.2d 889, 893-94 (Pa. 1970)). Assuming that a plaintiff has established both the elements of duty and a failure to warn, a plaintiff "must further establish proximate causation by showing that had the defendant issued a proper warning . . . he [plaintiff] would have altered his behavior and the injury would have been avoided. ***Id.*** at *6 (citing ***Demmler v. SmithKline Beecham Corp.***, 671 A.2d 1151, 1155 (Pa. Super. 1996), *appeal denied*, 684 A.2d 557 (Pa. 1996) (citation omitted)). "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." ***Demmler***, *supra*, 671 A.2d at 1156.

As to the first part of Defendant McNeil's complex argument (that Plaintiffs' evidence was insufficient to prove that its negligent failure to warn was the factual cause of Brianna's injuries), it is apparent that Plaintiffs convinced the jury that had the OTC Children's Motrin label included a warning of "rash, skin reddening and blisters" in November 2000, Alicia Maya would not have purchased the drug, Brianna would not have ingested it, and she would not have suffered catastrophic injuries. Ms. Maya credibly testified that had those warnings been on the OTC Children's Motrin label, she would *not* have purchased the over-the-counter medication and/or she would have immediately stopped giving her daughter additional dosages of the medication at the first sign of a rash. The jury heard Ms. Maya testify as follows:

> Q. And how, if at all, would it have affected your thought process if you looked at the labels for Tylenol and Motrin and you saw nothing about skin reddening, rash, or blisters on the Tylenol label and you saw that it had that in the Motrin label, and throw in if you had known that Tylenol had a superior safety profile to Motrin, how, if at all, would that have affected your purchasing decision . . . .
>
> A. It would have been a no-brainer which medication to purchase, and it would have been Tylenol.
>
> Q. Same question for life-threatening skin reactions. Had that been on the Motrin label, but not on the Tylenol label without Dr. Brewer involved, how would that have affected your purchasing decision, if at all?
>
> A. Same thing, the Motrin wouldn't have been purchased.
>
> Q. Is there any relationship between what your thought process would have been in 2000 in making these purchasing decisions and what you told us about on last Thursday, your choice to endure 36 hours of labor pain for a minuscule risk that may last a couple days, like drowsiness?
>
> MS. JONES: Objection.
>
> THE WITNESS: Yes, absolutely.

Q. How so?

A. I went through 36 and-a-half labors [sic] did not get an epidural or any kind of pain medication simply because I did not want my child to have a minimal or small chance of being groggy after being born. And it's that same mindset that, you know, that I tell you that if I would have known that Motrin could cause all of the things that it has caused my daughter, including nearly taking her life, there is no way that I would have purchased it.[73]

Plaintiffs also presented evidence that the "stop use" warning language would have prevented Ms. Maya from giving Brianna additional doses of Children's Motrin. Her testimony offered the following evidence:

Q. Do you recall I asked you questions about how many additional doses of Motrin you would not have given Brianna if the label that you had hypothetically stated something it did not state, which is, the hypothetical that it would have stated, "Stop use and call your doctor if," as opposed to the label that you got, just said "Call your doctor if," contrary to what the FDA said should be the case; do you recall that?

A. Yes.

Q. So -- and do you recall when I asked you that, you said had the label said something it did not state, "Stop use and call your doctor if," that you gave the answer that she would have not have been given four to five additional doses; do you recall that?

A. Yes, that's correct.

Q. And I want to see whether or not we can clear that up. Were you estimating how many she would not have been given had the label said "Stop use," which it didn't say, or please explain?

A. I said she would not have gotten four to five additional doses simply because of when the rash presented, and the fact that she was given Motrin right around the time that the rash presented, so I said four or five.

Q. So do I have it right that you intentionally said four or five because it happened at the same time?

A. Correct.

[73] N.T. 4/26/2011 a.m. at 45:9-46:24.

Q. Okay. And let me reorient the jury. First of all, this is the label I'm now showing, the one that you had -- you believe you had in your possession. It doesn't say "Stop use," it just says "Call your doctor if"?

A. That's correct.

Q. And the jury saw your timeline, and I'm going to go to what you're referring to; and do you understand that this would be your timeline on Sunday at 4:00 p.m.?

A. That is correct.

Q. And tell us what it says here, please, and how it relates to what you just told us that you intentionally said she wouldn't have gotten four or five additional doses, please?

A. At 4 o'clock it says Brianna had red rash on upper chest and lower neck and that she was given a dose of Motrin by me. So that is why I said four or five, because if I would have seen the rash or if it would have said "Rash" she never would have gotten that dose of medication or any of the subsequent doses of medication.[74]

In addition, Plaintiffs offered numerous expert opinions to establish the fact that once symptoms appeared it is imperative to cease the administration of the medication to reduce the possibility of extensive injuries. Specifically, Doctors Randall Tackett and John Schulz opined that an earlier cessation of OTC Children's Motrin would have impacted Brianna's prognosis. Dr. Tackett opined that stopping the use of the drug at the first signs of specific symptoms of SJS/TEN would help abate the side effects but that such advice was not on the label in November 2000. His testimony on this issue was as follows:

Q. What else is important about this -- well, is there any information in this medication guide that pertains to when you might want to stop taking ibuprofen, Dr. Tackett?

A. Yes, there is, and that's a very important issue.

Q. Is that down here at the bottom, now this 2 or 3-page document, if you include the list?

[74] N.T. 4/26/2011 a.m. at 87:11-89:15.

A. Yes, it is.

Q. And can you tell us what's relevant there, please?

A. We know from the literature that has been --it's like with every drug, is that if the drug is causing something, then the sooner you stop it, then the side effect is going to be abated or go away. And so it's very important that it tells consumers that to -- they need -- if any of these symptoms occur, that they need to stop the drug because these symptoms may be associated with very serious consequences that if you continue to take the drug can develop.

Q. And here it says, "Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:" And one of the bullet points is skin rash or blisters with fever. Do you see that, Dr. Tackett?

A. I do.

Q. Was that information, or any information like it, available on the label in 2000 over the counter when Miss Alicia Maya purchased the Children's Motrin for her daughter, Brianna Maya?

A. No.

Q. Should it have been, in your opinion?

A. Yes, it's very important.

Q. Why?

A. Because those are the early signs of SJS and TEN.[75]

And:

Q. Why, in your opinion, is it important that this new information is in the warning section of the label, Dr. Tackett?

MS. JONES: Objection.

THE COURT: Overruled.

THE WITNESS: What's very important is we know that if you continue taking the drug, that it can continue to get worse; and so it's important to stop it at the very early signs. And we know that the prognosis or the ability to recover from it is much improved the sooner you stop the drug.[76]

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[75] N.T. 3/25/2011 a.m. at 56:21-58:9.
[76] N.T. 4/4/2011 a.m. at 77:18-78:6.

Likewise, Dr. Schulz offered a medical opinion that the continuation of ingesting OTC Children's Motrin after the rash began was relevant to causation and the severity of Brianna's resulting TEN reaction; to *wit*:

> Q. . . . And why is it relevant to your conclusion, Dr. Schulz, that she kept taking Motrin?
>
> A. Well, I mean, it's relevant to the conclusion only insofar as because we know that the causative agent -- getting rid of the causative agent as fast as possible might kind of decrease the severity of the syndrome once it starts. It's relevant that she was still getting it as she's getting very ill.
>
> Q. And do you know of evidence or studies that pertain to that very testimony you just gave, that --
>
> A. Yes, there are.
>
> Q. And what is it?
>
> A. Well, the evidence, Garcia-Doval was the principal author on that paper.
>
> Q. And what's the evidence that's provided by that?
>
> A. The evidence is -- and it's really the only thing that we have to offer, besides critical care, is try to stop the offending medication; and the evidence was that people in whom it was stopped faster, or in whom it was stopped and were on very short half-life drugs but washed out of their system fast tended to do better.[77]
>
> * * *
>
> Q. And how relevant is it that she's still on Motrin, she's got her 7th dose at 9:00 p.m. Monday night, her 8th dose at, if I can move this and find out, 3:00 a.m. early Tuesday morning, how relevant are these matters to your opinion that she had this -- she was getting worse?
>
> A. It matters because she's descending into in this firestorm of a disease, and the causative agent is still being given. That's why it matters.[78]

It is apparent that the jury carefully weighed the voluminous amount of evidence and assessed credibility in favor of Plaintiffs' witnesses. Based upon the totality of the evidence with

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[77] N.T. 3/30/2011 a.m. at 112:4-123:5.
[78] *Id.* at 123:20-124:4.

emphasis to the testimony of Alicia Maya and the opinions of Drs. Tackett and Schulz, this trial judge opines that the evidence of record supports the jury's findings that had the warnings on the label included the language sought by Plaintiffs, Ms. Maya would not have bought the medication, and/or would have stopped giving her daughter the drug at the first signs of symptoms. The injuries Brianna suffered conceivably may not have been as devastating.

As to Defendant McNeil's contentions that Plaintiffs failed to present sufficient evidence to establish the standard of care required in the development of the label warnings of OTC Children's Motrin, or to prove that it had a duty to warn of the specific idiosyncratic reactions that Brianna suffered, or that it negligently breached any duty to warn, suffice to state that sufficient evidence was presented regarding these issues and to rebut this argument.

While a manufacturer does not have a duty to warn of every conceivable danger, the mere fact that a condition is idiosyncratic or rare does not end the analysis of whether there is a legal duty to warn. A manufacturer of a product has a duty to provide those warnings or instructions necessary to make the product safe for its intended use. *See* ***Mackowick***, *supra*, 575 A.2d 100 at 102 (citing ***Sherk v. Daisy-Heddon***, 450 A.2d 615, 618 (Pa. 1982) (plurality); ***Berkebile v. Brantly Helicopter Corp.***, 337 A.2d 893, 902-3 (Pa. 1975)).

A failure to warn contention will be analyzed and adjudicated in accordance with the negligence standard provided in the Restatement (Second) of Torts, § 388. *See* ***Hahn***, *supra*, 673 A.2d at 890-91; ***Lance***, *supra*, 4 A.3d at 165. In its relevant part, Section 388 provides that a seller is subject to liability when the seller knows or has reason to know that its product is likely to be dangerous for the use for which it is supplied, has no reason to believe that the intended user will realize its dangerous condition, and fails to exercise reasonable care to inform users of the dangerous condition. The legal duty to warn is based on the magnitude of the risk

which includes an analysis of the likelihood of injury. ***Ebbert v. Philadelphia Electric Co.***, 198 A. 323, 328 (Pa. 1938). The care to be exercised in discharging the duty to warn is therefore measured by the dangerous potentialities of the commodity as well as the foreseeable use to which it might be put. *See* ***Dougherty v. Hooker Chem., Corp.***, 540 F.2d 174, 179 (3d Cir., 1976) (referencing comment n. § 388, Restatement (Second) of Torts).

As stated, Plaintiffs argue that the warning on the label of OTC Children's Motrin should have included the mention of SJS and TEN, and the symptoms of "rash, skin reddening, and blisters." To create a jury question on these issues, "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." ***Owens***, *supra*, 2010 Pa. Super. LEXIS 2095, *5. Clearly, Plaintiffs established through the above-cited testimony of Alicia Maya that the inclusion of this warning language would have prevented her from administering OTC Children's Motrin to Brianna. On this issue, the jury was instructed as follows:

> . . .Whenever I mention the word "Manufacturer of the product," I'm relating to the Defendant McNeil. A manufacturer of a product is not required to provide a warning or instruction concerning the possibility of a rare, idiosyncratic, or hypersensitive reaction to an otherwise safe and useful product. A manufacturer is only liable where the product was unsafe or likely to cause harm to a normal consumer -- I guess it's really an average consumer. In other words, a manufacturer is not liable merely because a consumer of a product had an allergic reaction to the product. For that reason, the manufacturer is only required to warn of such allergic reactions if a substantial number of people are likely to experience the reaction. In determining whether a number is a substantial number, you may consider the nature and severity of the risk involved.[79]

Based upon the evidence presented, it is apparent that the jury believed that Defendant McNeil should have provided more adequate warnings and by failing to do so, Defendant McNeil was negligent.

Defendant McNeil's final argument of legal insufficiency stems from its contention that

[79] N.T. 5/19/2011 a.m. at 41:12-42:9.

Plaintiffs did not present any evidence or presented inadequate evidence to prove that Children's Motrin (pediatric ibuprofen) is a medical cause of SJS or TEN and that it was the specific cause of Brianna's injuries. The cadre of Plaintiffs' experts and opinions as to medical causation, evidence believed by the jury, belie Defendant McNeil's arguments. Among the expert opinions offered by Plaintiffs were that of: (1) Arthur Peter Sanford, M.D., a burn surgeon and expert in the critical care and the treatment to patients suffering SJS and TEN[80] and Brianna's primary physician at Shriner's Hospital,[81] opined that OTC Children's Motrin and ibuprofen caused TEN;[82] Scheffer Tseng, M.D., an expert in ophthalmology, eye surgery and the treatment of TEN, testified that he has been Brianna Maya's treating eye surgeon and ophthalmologist since she was five years old,[83] and is "absolutely certain" that TEN caused all of Brianna's eye damage and is "100% certain" that her TEN was caused by ibuprofen/Children's Motrin;[84] (3) Steven Pliskow, M.D., a duly qualified obstetrician/gynecologist, Brianna Maya's treating gynecologist and gynecologic surgeon[85] with vast experience in the care and treatment of patients with SJS and TEN,[86] testified that pediatric ibuprofen, also known as Children's Motrin, caused Brianna Maya's TEN, and that nothing else, including the antibiotic Pediazole, could have contributed to or caused her TEN;[87] and (4) John Schulz, M.D., Ph.D., a burn surgeon currently at Yale University and previously associated with Shriner's Burn Hospital while at Harvard University,[88] testified with over "99% certainty" that Children's Motrin caused Brianna's TEN because it was

[80] N.T. 4/7/2011 a.m. at 62:7-11.
[81] *Id.* at 69:13-16.
[82] *Id.* at 68:11-21.
[83] N.T. 4/13/2011 a.m. at 4:21-24.
[84] *Id.* at 66:16-18.
[85] N.T. 4/5/2011 a.m. at 45:13-19.
[86] *Id.* at 62:21-63:3.
[87] *Id.* at 23:18-24:18.
[88] N.T. 4/7/2011 a.m. at 72:24-73:3.

the only medication she received that fit the sequence of symptoms.[89]

It appears that Defendant McNeil would have this trial judge reject the evidence and opinions offered by Plaintiffs' experts in favor of granting its request for judgment n.o.v. simply because Defendant McNeil deems its evidence to be "better."[90] It is often the case that jurors are required to choose between dueling testimony in a "battle of the experts" and when such a conflict in opinions is presented, the jury's verdict is not "properly subject to the grant of judgment n.o.v." *See* ***Estate of Hicks v. Dana Cos. LLC***, 984 A.2d 943, 957 (Pa. Super. 2009), *appeal denied*, 19 A.3d 1051, 2011 Pa. LEXIS 662 (2011). This trial judge will not act contrary to the jury's assessment of credibility, its decision, and the law of the land. Based upon the evidence and case law, this trial judge opines that no error was committed when deciding these issues and in denying Defendant McNeil's dispositive motions and request for post-trial relief.

Prejudicial Misconduct by Plaintiffs' Counsel at Trial

Defendant McNeil argues that this trial judge erred in denying its motions for a mistrial, new trial, and remittitur of the damages and failing to recognize that the full extent of the undue prejudice Plaintiffs' counsel's alleged misconduct caused; a prejudice not cured by the many sustained objections and/or the curative instructions given, and which tainted the verdict and deprived Defendant McNeil of a fair trial. This trial judge disagrees and is disconcerted by the lack of adequate explanation and proof of exactly what prejudice was suffered and/or how these alleged acts of misconduct actually tainted the jury's verdict. While this trial judge admits that an exorbitant amount of patience was required to control *all* counsel throughout the entire trial, this trial judge cannot find that the implied misconduct affected the jury's ability to sieve through the evidence objectively and return a verdict that is supported by and comports with the evidence

[89] N.T. 3/28/2011 a.m. at 102:24-103:11.
[90] *See* Defendant McNeil's motion for JNOV, pp. 9-11.

presented. Further, after being alerted in a motion *in limine* filed by Defendant McNeil of the possibility of Plaintiff's counsel engaging in unacceptable behavior, this trial judge made it clear from day one that any inappropriate conduct by any counsel would not be tolerated, lest the court find the offender in contempt, and advised that the court was "not to [be] test[ed]" in this regard.[91] When deemed necessary and without hesitation, this trial judge enforced the court's stated expectations.[92]

Notwithstanding, in its post-trial motion, Defendant McNeil enumerated 49 paragraphs with 64 additional sub-allegations outlining Plaintiffs' counsel's alleged wrongdoings. On appeal, Defendant McNeil pared down the list to allegations that can be summarized as: (a) improper examination tactics; (b) disregard for the trial court's rulings; (c) prejudicial comments about Defendant McNeil; (d) improper evidentiary inferences; (e) improper remarks during closing argument; and (f) error in denying remittitur based upon Plaintiffs' counsel's missteps.

The standard of review with respect to inappropriate counsel conduct is clear. A new trial is to be granted where the unavoidable effect of counsel's conduct or language was to prejudice the fact finder to the extent that the fact finder is rendered incapable of fairly weighing the evidence and entering an objective verdict. If counsel's misconduct contributed to the verdict, it will be deemed prejudicial and a new trial will be required. ***Poust v. Hylton***, 940 A.2d 380, 385 (Pa. Super. 2007), *appeal denied*, 959 A.2d 320 (Pa. 2008) (citing ***Commonwealth v. Francis***, 665 A.2d 821, 824 (Pa. Super. 1995)). Whether remarks by counsel warrant a new trial requires an assessment of the circumstances under which the statements were made, and the precaution taken by the court and counsel to prevent such remarks from having a prejudicial effect. It is the duty of the trial judge to take affirmative steps to attempt to cure any harm.

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[91] *See* N.T. 3/22/2011 p.m. at 54;16-55:14.
[92] *See, e.g.*, N.T. 4/26/2011 a.m. at 147:3-15.

There are certain instances where counsel's comments are so offensive or egregious that no curative instruction can adequately obliterate the taint. ***Poust***, *supra*, 940 A.2d at 386 (citing ***Siegal v. Stefanyszyn***, 718 A.2d 1274, 1277 (Pa. Super. 1998), *appeal denied*, 739 A.2d 1059 (Pa. 1999) (citations omitted)).

Improper conduct also occurs when an attorney presents facts to the jury which are not in evidence and are prejudicial to the opposing party; counsel may not comment on evidence to the effect that it removes an issue of credibility from the jury. ***Young v. Washington Hosp.***, 761 A.2d 559, 561 (Pa. Super. 2000), *appeal denied*, 782 A.2d 548 (Pa. 2001); ***Derry Township School Dist. v. Suburban Roofing Co.***, 517 A.2d 225, 229 (Pa. Cmwlth. 1986). Any statement by counsel not based on evidence and which tends to influence the jury in resolving the issues solely on an appeal to passion and prejudice is also improper and will not be countenanced. A verdict obtained by incorrect statements or unfair argument or by an appeal to passion or prejudice stands on but little higher ground than one obtained by false testimony. ***Young***, *supra*, 761 A.2d 559 at 564 (citations omitted).

However, not every unwise or irrelevant remark made in the course of a trial by a judge, witness, or counsel compels granting of a new trial. ***Commonwealth v. Goosby***, 301 A.2d 673, 674 (Pa. 1973). Rather, the award of a new trial is warranted only where the effect of the remark results in the deprivation of a fair and impartial trial. ***Id.*** Whether counsel's argument is appropriate is a matter primarily to be decided by the trial judge who is present and in the best position to assess the manner of presentation and the effect on the jury. *See, e.g.*, ***Purcell v. Westinghouse Broadcasting Co.***, 191 A.2d 662, 671 (Pa. 1963). As such, an appellate court, by its nature, stands on a different plane than a trial court. ***Thompson v. Philadelphia***, 493 A.2d 669, 672 (Pa. 1985). Whereas a trial court's decision to grant or deny a new trial is aided by an

on-the-scene evaluation of the evidence, an appellate court's review rests solely upon a cold record. ***Id.***, 493 A.2d at 672. Thus, appellate review of the trial court's decision to grant or deny a request for a new trial is to focus on whether the trial judge has palpably abused its discretion, as opposed to whether the appellate court can find support in the record for the jury's verdict. ***Id.*** (citing ***Austin v. Ridge***, 255 A.2d 123 (Pa. 1969); ***Anzelone v. Jesperson***, 258 A.2d 510 (Pa. 1969)); ***Baldino***, *supra*, 478 A.2d (emphasis omitted). With this standard in mind, Defendant Mc Neil's contentions will be discussed seriatim.

Alleged Improper Examination Tactics

Within the general allegations of counsel's improper conduct and examination tactics, Defendant McNeil highlights specific events, including: (a) introducing non-record facts during cross-examinations, presenting argumentative preambles to his questions, asking questions counsel knew were outside the scope of the witnesses' knowledge and expertise so that he could present argumentative summaries of his own, and misstating facts in his questions, all of which allowed Plaintiffs' counsel to offer to the jury facts and opinions outside the record that Defendant McNeil could not cross-examine; (b) making *ad hominem* attacks on defense witnesses and engaging in abusive cross-examination practices, such as quoting language out of context and attempting to examine witnesses with documents yet preventing them from seeing or reviewing the documents; (c) leading his witnesses on direct examination to the point of testifying, and coaching his witnesses during their testimony; and (d) manipulating the scheduling of witnesses in order to delay the cross-examination of Plaintiff's experts, and placing Defendant in a highly prejudicial position of having to present its case long after the time the jury had been told they would be discharged.

It is well-established that the scope and limits of cross-examination are within the trial

court's discretion and the court's ruling thereon will not be reversed absent a clear abuse of discretion or an error of law. ***Rafter***, *supra*, 632 A.2d 897, 900; ***Kemp v. Qualls***, 473 A.2d 1369, 1371 (Pa. Super. 1984) (citing ***Gatling v. Rothman***, 407 A.2d 387 (Pa. Super. 1979)). The right of cross-examination "includes the right to examine the witness on any facts tending to refute inferences or deductions arising from matters the witness testified to on direct examination. ***Kemp***, *supra*, 473 A.2d at 1371 (citing ***McGowan v. Devonshire Hall Apartments***, 420 A.2d 514 (Pa. Super. 1980)). Every circumstance relating to the direct testimony of an adverse witness or relating to anything within the witness' knowledge is a proper subject for cross-examination, including any matter which might qualify or diminish the impact of direct examination. ***Id.*** (citing ***Commonwealth v. Britton***, 380 A.2d 807 (Pa. Super. 1977)). Clearly, error in allowing improper questions can be cured by answers which contain only admissible information. *See* ***Maravich v. Aetna Life & Cas. Co.***, 504 A.2d 896 (Pa. Super. 1986); *see also*, ***Pulliam v. Fannie***, 850 A.2d 636, 642 (Pa. Super. 2004). Any weakness in the underlying evidence may, of course, be brought out on cross-examination, but this alleged weakness goes to the weight rather than the admissibility of the hypothetical question and the expert's response. ***McSparran v. Hanigan***, 225 F. Supp. 628 (E.D. Pa. 1963), *aff'd*, 356 F.2d 983 (3d. Cir. 1966).

As to its first point of contention, Defendant McNeil offers as examples of misconduct counsel's comments to opinions made by Dr. Maja Mockenhaupt in other similar cases; calling the ALDEN computer algorithm a "litigation defense tool"; and remarking that he (Plaintiffs' counsel) was integral in removing the diet drug Fen-Phen from the market.

Dr. Mockenhaupt was an expert witness identified by Defendant McNeil, who has testified on its behalf in other OTC Children's Motrin/Tylenol cases. She is reportedly a world-renowned expert in epidemiology studies related to serious cutaneous reactions, who in 2009 co-

authored the EUROSCAR Study, which concluded that there were no non-medication causes of TEN.[93] The study specifically found that TEN was a drug-induced reaction.

Plaintiffs used the findings of the study during the examinations of their expert witnesses. Specifically, during the examination of Plaintiffs' expert, Dr. Tackett testified that he had reviewed the literature, opined that the EUROSCAR Study was authoritative, and agreed with the study's conclusions. Defendant McNeil incorrectly argues that Dr. Tackett's reliance on the study was improper. There is no question that if published material is authoritative and is generally relied upon by experts in the field (in this case, the EUROSCAR Study relied upon by Dr. Tackett, a toxicologist and pharmacologist), although hearsay, an expert may rely upon the literature in formulating the opinion rendered; indeed, it would be unreasonable to suppose that an expert's opinion would not in some way depend upon the body of works preceding it. *See* Pa. R.E. 705; ***Hycrza v. West Penn Allegheny Health Sys.***, 978 A.2d 961, 976 (Pa. Super. 2009) (citing ***Aldridge v. Edmunds***, 750 A.2d 292, 332 (Pa. 2000)).

Pennsylvania courts have permitted, subject to appropriate restraint by the trial court, limited identification of textual materials (and in some circumstances their contents) on direct examination to permit an expert witness to fairly explain the basis for his reasoning. ***Aldridge***, *supra*, 750 A.2d at 332; *see also,* Pennsylvania Rule of Evidence (Pa. R.E.) 705 (an expert may testify in terms of opinion or inference and give reasons therefore); *see also,* ***In re. C.R.S.***, 696 A.2d 840, 845 n.7 (Pa. Super. 1997) (experts may refer to published works serving as the basis for their opinions); ***Cummings v. Nazareth Borough***, 242 A.2d 460, 466 (Pa. 1968) (it is entirely proper in examination and cross-examination for counsel to call the witness's attention to published works on the matter which is the subject of the witness's testimony). However, the purpose for which treatises may be referenced on direct examination is generally limited to

[93] *See* N.T. 3/24/2011 a.m. at 67:9-69:12.

explaining the reasons underlying the opinion and the trial court should exercise careful control over their use to prevent them from being made the focus of the examination. ***Aldridge***, *supra*, 750 A.2d at 332.

In this trial judge's opinion, in light of the case law and the evidence rule cited, Plaintiffs' reference to Dr. Mockenhaupt, as the author of a study, and the study itself that directly related to the issue of causation, was proper; Dr. Tackett's reliance on the study was proper; and no error occurred in allowing this testimony.

Defendant McNeil claims it suffered prejudice in having the ALDEN computer algorithm characterized as a "litigation defense tool". However, a careful review of the transcript reveals that throughout multiple references made, Defendant McNeil objected only twice; once on the grounds that it was beyond the witness's qualifications; the other objection did not provide a basis. Both of these objections were sustained.[94] Under the circumstances, this contention of misconduct is of little or no import and certainly does not warrant the granting of a new trial. Defendant McNeil has not convinced this trial judge that these comments in any way tainted the jury's evaluation of the evidence and its ultimate verdict.

As to Defendant McNeil's misconduct contention regarding the role Plaintiff's counsel played in the Fen-Phen litigation, this issue will be addressed in the discussion section under *Alleged Improper Evidentiary Inferences*, *infra*, p.69.

As to its argument regarding counsel's preambles and summaries, Defendant McNeil cites as examples of numerous infractions, the following exchange with its expert, Dr. Stern:

> Q. But—let's go back to my question. We're going to get to the list they used, at least what they put on the internet under the EuroSCAR website. You don't know—you're not an expert and to the best of your knowledge your colleagues are not experts, like Dr. Goldberg is, and what people remember – like Dr. Goldberg is an expert on whether an add [sic] sells a product. And I submit to

[94] *See* N.T. 5/3/2011 a.m. 87:6-90:17; 5/10/2011 p.m. at 101:20-106:15.

you that when you're assessing how a question handles this thing that's important to you, this recall bias, you're not talking about something that you're an expert at, like deciding whether a case is SJS or TEN; we're not talking about something that you're an expert at like figuring out what's the difference between psoriases and alopecia, that's what a dermatologist does, you're not an expert and your colleagues, to the best of your knowledge, are not experts at that marking question of what people will remember –

MS. JONES: Objection.

Q. – or not about brand name Ibuprofen products in those four foreign countries, right?

THE COURT: Overruled.[95]

Another example:

Q. Before I come back to the reports from McNeil about adverse reaction time, I would like to ask you about this: I will represent to you, Dr. Stern, that when Miss Jones was asking Alicia Maya, Brianna Maya's mom, questions, in fact at the very end of her questions she asked her questions, about what Miss Maya, of course, knew about her daughter's prior exposures to Motrin and whether or not there was any documentation, or what she knew about what things happened to her while she was on Motrin. Do you understand what I'm representing to you, sir?

A. I think so.

Q. Okay. And I will further represent to you that Mrs. Jones's last two questions she picked for Alicia Maya, she actually stood her [sic] and put her hands on the back of my chair like this, and when she did that, she asked Miss Maya whether or not it was true that I was the one, Keith Jensen, whether I was the one who thought of the concept, if you will, that Brianna had been on Motrin before this ever happened in November 2000 and may or did have a reaction like a cutaneous reaction, a skin reaction to Motrin in the prior times. Do you understand what I'm representing to you the questions were about, sir?

A. Yes.

Q. And if that's true that the very last question that Miss Jones asked Miss Maya was: So the suggestion was first made by your attorney, and she stood right here and she had her hands behind my chair, if it was true that she was suggesting that I, as opposed to some treating medical expert of Brianna Maya, came up with the notion that Brianna had past exposures to Motrin and had a reaction to them potentially before this happened in November 2000, if that's true, and I'm

[95] N.T. 5/10/2011 p.m. at 81:7-82:2.

> representing it was, you know that to be incorrect, don't you, sir? That it was not Keith Jensen who first had the idea or opinion or belief that she might have had a prior reaction to Motrin, you know a medical treating expert has discussed that, don't you?
>
> MS. JONES: Objection, Your Honor.
>
> THE COURT: Sustained.[96]

As the trial transcript reveals and as illustrated above, some of Defendant McNeil's objections to these preambles were overruled[97] and some were sustained.[98] There is no case law to support the proposition that "argumentative preambles" are reversible error, and Defendant McNeil has not presented a convincing argument as to what prejudice, if any, resulted from these so-called preambles. These preambles are similar to when facts are provided during hypothetical questions. Further, this trial judge instructed the jury *not* to consider counsel's questions or comments as evidence; to *wit*:

> Remember, the questions asked by the attorneys and the comments made by them are not evidence. Only the answers to the questions posed and the exhibits that were admitted into the record constitute the evidence in this case.[99]

On this point, this trial judge opines that a new trial is not warranted.

Defendant McNeil further contends that Plaintiffs' counsel made *ad hominem* attacks on defense witnesses and/or engaged in abusive cross-examination practices, including quoting language out of context or attempting to examine witnesses with a document which he withheld from their review. Before addressing one of Defendant McNeil's examples, it is important to note that the perspective from the bench substantially differs from Defendant McNeil's characterization of counsel's "abusive" cross-examination practices.

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[96] N.T. 5/10/2011 a.m. at 82:6-84:2.
[97] N.T. 5/10/2011 p.m. at 81:24-82:3.
[98] N.T. 5/10/2011 a.m. at 83:25-84:2.
[99] N.T. 5/19/2011 a.m. at 10:13-18.

Regarding the cross-examination of Ms. Lynn Pawelski, Vice President of Regulatory Affairs at McNeil Consumer Healthcare,[100] a review of the trial transcript confirms that Ms. Pawelski was at times unresponsive, requiring counsel to repeat the same question numerous times before obtaining an answer. To illustrate, this trial judge points to the exchange which occurred during the questioning regarding the estimated volume of documents that composed the New Drug Application ("NDA")[101] for Motrin.[102] This trial judge instructed Ms. Pawelski (numerous times) to "please answer only his questions" when she failed to respond to the question and, instead, offered a tangential response.[103] Frustrated, counsel moved to strike some of the responses offered by Ms. Pawelski. [104] In those instances, the motions were denied since this trial judge was satisfied that the witness had adequately answered the questions.[105] A similar analysis can be made regarding the cross-examination of other witnesses.

This trial judge opines that a careful review of the trial transcript does not support Defendant McNeil's *ad hominem* attack contentions. Undisputedly, Plaintiff's counsel is no shrinking violet, and can be aggressive and tenacious in his representation. However, his examination cannot be considered abusive. The issues before this court were serious and required a concerted time and effort to prove. This trial judge has not nor will it ever permit an abuse by any counsel to a witness, or any abusive behavior in the courtroom. There is always a fine line between advocacy and abuse, a line closely monitored by this trial judge, and which was not, in this trial judge's opinion, crossed by counsel. This trial judge opines that as to this allegation, no new trial is warranted.

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[100] N.T. 4/15/2011 p.m. at 51:3-5.
[101] *See* N.T. 4/19/2011 a.m. at 84:24.
[102] *See* N.T. 4/15/2011 p.m. at 57:17-25; 58:1-14; 59:7-14; 59:15-60:7.
[103] N.T. 4/15/2011 p.m. at 86:14-18.
[104] *Id.* at 82:16-18; 85:15-21.
[105] *Id.* at 81:23-24.

Next, Defendant McNeil argues that witnesses were not allowed to view documents being used during cross-examination. This trial judge disagrees and recalls ensuring that any document used was shown and/or provided to the witness. In addition, there are numerous occasions when Plaintiffs' counsel provided the witness with a notebook or a stack of labeled documents to refer to during the witness' testimony. As an example, the transcript reveals that when Ms. Pawelski was cross-examined:

> BY MR. JENSEN:
>
> Q. You have a copy in front of you, if you would like, Ms. Pawelski. In fact, almost everything I speak to you about you'll have right at your disposal there.
>
> A. Can you just help me where it might be?
>
> Q. You're asking me? I think it's in the stack with the labels in it, ma'am.
>
> A. Can you tell me -- it's an e-mail from Desire Ray Wells Morrison.
>
> Q. No, ma'am, from Vicky Wagner to you dated September '05. Do you have that in front of you?
>
> A. Okay. Yes, I do.[106]

The trial transcript also reveals a similar offer was made to Defendant McNeil's expert, Dr. Robert Stuart Stern.[107] This trial judge acknowledges that there were occasions when counsel waved a document during cross-examination, or made reference to a specific document located within a larger pile. However, on those occasions, this trial judge recalls instructing counsel to show the document to the witness and/or giving the witness time to be handed the specific document in question.[108]

As a final observation to the charge of counsel misconduct, this trial judge notes that the

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[106] N.T. 4/15/2011 p.m. at 77:8-20.
[107] *See* N.T. 5/3/2011 a.m. at 101:19-23.
[108] *See* N.T. 4/18/2011 a.m. at 123:4-124:17; N.T. 5/10/2011 a.m. at 64:6-66:10, 72:20; N.T. 5/10/2011 p.m. at 8:12-13, 92:12-17.

behavior of Defendant McNeil's counsel was not exactly pristine, and on one occasion admonished a defense counsel for the obdurate tone taken and directed him to apologize to Dr. Tseng in front of the jury; to *wit*:

> THE COURT: . . . Counsel, I personally did not appreciate that comment that you made to the Doctor.
>
> MR. ABERNETHY: I apologize, Your Honor. I wasn't trying to be rude.
>
> THE COURT: I would like you to apologize in front of the jury, because it did come across as very inappropriate.[109]

Next, Defendant McNeil accuses Plaintiffs' counsel of leading his witnesses during their direct examination to the point of appearing that counsel was testifying and/or coaching the witnesses during their testimony. While counsel did at times lead his witnesses, this trial judge opines that those occurrences, either singularly or collectively, do not warrant a new trial.

The law in the area of leading questions is clear. The allowance of leading questions lies within the discretion of the trial court and a court's tolerance or intolerance of leading questions will not be reversed absent an abuse of discretion. ***Katz v. St. Mary Hospital***, 816 A.2d 1125, 1128 (Pa.Super. 2003) (citing ***Commonwealth v. Johnson***, 541 A.2d 332 (Pa.Super. 1988), *appeal denied*, 552 A.2d 250 (Pa. 1988)). No abuse of discretion occurs on the part of the trial court for permitting some leading questions, due to the "length and complexity of the testimony." ***Katz***, *supra*, 816 A.2d at 1128. Further, any error committed is deemed harmless since none of the elicited responses were of such a character that the information would not have come into evidence but for the leading format.

As to specifics, in its motion for mistrial, Defendant McNeil highlighted the following instances where Plaintiffs' counsel led the witnesses:

- "In your opinion is it true that, quote, 'it is not sufficient to list certain of the

[109] N.T. 4/14/2011 a.m. at 82:14-21.

essential information for safe use in small print in the back panel of the package label'?" [110]

- "Q. Has SJS or TEN ever been in the warning section of the professional label for ibuprofen from 1989 all the way through 2000? / A. No. / Q. Does it, therefore, not comply with the regulation? / A. That's correct."[111]

- "Q. Does what is below contain a detailed analysis of all skin issues in BUFS? / A. It does not contain a detailed analysis of all skin issues, no. / Q. Is that because there is no analysis whatsoever in this document of the two SJS reports?"[112]

- "Are you telling the jury that these studies, therefore, would not apply to the analysis of Pediazole with Brianna Maya and TEN?"[113]

- "Is it true, if you know, that Dr. Schulz's sole involvement in this that [sic] case was not as an expert but as a treating Harvard Mass General burn surgeon of my client?"[114]

Of these cited instances, only one of Defendant McNeil's objections was overruled. As for the sustained objection(s), unless counsel is arguing that those rulings were incorrect, Defendant McNeil has failed to articulate what prejudice was actually suffered to warrant a new trial. To constitute reversible error, a ruling on evidence or an instruction to a jury must be shown not only to have been erroneous but harmful to the party complaining. ***Boyle v. Indep. Lift Truck, Inc.***, 6 A.3d 492, 496 (Pa. 2010). In light of the fact that no prejudice has been articulated (or error established), this trial judge opines that Defendant McNeil's argument lacks merit. No abuse of discretion occurred in denying the post-trial motion on these stated grounds.

As to the allegations of "coaching" witnesses, Defendant McNeil has not provided any specific occurrences. Notwithstanding, this trial judge does recall an instance involving a piece of paper found by the court crier which contained handwritten notes of what appeared to be the answers to Plaintiffs' counsel's questions to Dr. Tseng on redirect examination the morning of

[110] N.T. 3/24/2011 p.m. at 60:20-23.
[111] N.T. 3/25/2011 a.m. at 42:5-11.
[112] *Id.* at 133:11-18.
[113] N.T. 3/29/2011 a.m. at 28:12-14.
[114] N.T. 4/5/2011 p.m. at 52:2-4.

April 14, 2011. This trial judge brought this discovery to the attention of all parties and had the paper marked as Trial Court Exhibit 1.[115] This court's action on this piece of paper was deferred without resolution since Plaintiff's counsel offered an affidavit from the witness attesting that Plaintiff's counsel had no involvement with the note. Specifically, on April 16, 2011, Dr. Tseng swore to and signed an Affidavit which described the circumstances of the handwritten notes. Therein, Dr. Tseng attested to not discussing his testimony with anyone until his testimony was completed; that the notes were solely a reflection of the last topics Mr. Jensen and he [Dr. Tseng] discussed would be covered before testifying. According to the affidavit, the note contained numerical reminders regarding patents held for medical devices, surgical inventions, and peer-reviewed publications (there are about 280), which pertain to care and treatment of patients, which he had not committed to memory. To give accurate responses, he wrote the note to himself. Otherwise, there were no communications with anyone regarding his testimony after it began on April 13, 2011, until the "paper issue" was brought to his attention after he departed Philadelphia. In light of the sworn affidavit, this trial judge tacitly accepted the explanation provided by Dr. Tseng. If this instance is the example of "coaching" relied on by Defendant McNeil, then the argument is without merit. Defendant McNeil has failed to persuade this trial judge how this occurrence is prejudicial or was improper.[116] More so, when the discovery of the note and the discussions related to it were events that occurred without the jury's knowledge.

Defendant McNeil's so-called "manipulation" of the scheduling of witnesses is also without merit. Early in the trial proceedings, this trial judge noticed resistance by Plaintiffs' counsel to provide advance notice of who would be called as a witness on the following day.[117] To resolve the gridlock and lack of professionalism, this trial judge ordered counsel to advise

[115] *See* N.T. 4/14/2011 p.m. at 4:22-5:20.
[116] *See Defendants' Supplemental Motion for Mistrial*, p. 28, docketed under Control No. 11051934.
[117] N.T. 3/22/2011 p.m. at 3:1-5:2.

opposing counsel the name of the witness anticipated to be called the following day, no later than 3:00 p.m. of the previous day.[118] This order was directed to *all* parties. Unfortunately, not all witness' testimony concluded within the expected time. One instance of disagreement over the scheduling of a witness occurred on March 25, 2011, during the direct examination of Dr. Tackett. Defense counsel requested permission to interrupt that testimony to present out-of-turn the testimony of Mr. Willie Pagsuyuin, an employee of Defendant McNeil (or Johnson & Johnson),[119] because Mr. Pagsuyuin was expected to leave the country and would thereafter be unavailable to testify. Plaintiffs' counsel objected and argued that the interruption would affect the presentation of the testimony of other witnesses scheduled for March 28th. Counsel also objected to starting Mr. Pagsuyuin's testimony because defense counsel would not agree to when Dr. Tackett's testimony would be completed.[120], [121] To resolve the impasse, this trial judge requested of Mr. Pagsuyuin (who was present in court) that he not extend his trip and should expect to be called to testify after his return.[122] Clearly, it is within the trial judge's discretion the proper administration of its calendar and the courtroom, including when witnesses can be called to testify. Whenever possible, it is this court's practice to complete the testimony of a particular witness to facilitate the jury's understanding of the evidence and opinions offered. Scheduling problems are difficult to avoid. However, absent an abuse of discretion, said issue is not grounds for a new trial. The record does not support a finding that this trial court abused its discretion on any scheduling rulings made.

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[118] N.T. 3/22/2011 p.m. at 5:3-10.
[119] N.T. 3/25/2011 a.m. at 4:16-18.
[120] *See*, N.T. 3/25/2011 a.m. at 4:14-9:8.
[121] This trial judge agrees with the Superior Court's mention that "experts as well as counsel and the court each have very busy schedules. The realities of today's world make great demands on all these parties. Attempts must be made to accommodate, as best as possible, the particular scheduling difficulties." ***George v. Ellis***, 820 A.2d 815, 818 (Pa. Super. 2003).
[122] N.T. 3/25/2011 a.m. at 13:15-14:15.

Unfortunately, the testimony of witnesses and the presentation of evidence went longer than anyone anticipated. This delay was due, in part, to the fact that both Plaintiffs' and Defendants' counsel presented lengthy oral argument at the start *and* end of practically each day of trial to resolve either recent overnight (or previous) issues, motions, or simple gripe sessions against each other, which did very little to move the flow of the case. Defendant McNeil cannot convincingly or legally argue that it was prejudiced because it presented its defense long after the date the jurors had been told trial was expected to conclude. There was no restriction or limitation imposed on Defendant McNeil's ability to fully present its case.

Alleged Disregard for the Court's Rulings

Defendant McNeil contends that Plaintiffs' counsel committed misconduct when he presented information and evidence which were contrary to the trial court's previous rulings, ignored the trial court's contemporaneous rulings, and repeatedly made speaking objections to the trial court's orders. Specifically, Defendant McNeil avers that Plaintiffs' counsel repeatedly introduced evidence of foreign regulatory actions, products which were withdrawn, and activities in other countries. This trial judge notes that when these attempts arose, Defendant McNeil's objections were sustained, and, where appropriate, a curative instruction was given; for example, the jury was directed not to consider the regulatory activities outside of the United States.[123]

With regard to Plaintiffs' counsel's references to other lawsuits, see the discussion, *infra*, *Alleged Improper Evidentiary Inferences*, at p. 70.

As to Defendant McNeil's contention that counsel ignored the court's contemporaneous rulings, the record does not support this claim. The trial transcript reveals that when Defendant McNeil's objections were sustained to improperly posed questions, the question was rephrased to

[123] *See* N.T. 4/15/2011 p.m. at 123:14-22.

the satisfaction of defense counsel and no other objection was made.[124]

Lastly, as to the specific "speaking objections" to which Defendant McNeil refers, the record reveals that those particular cited instances were never objected to by the defense.[125] Furthermore, even if an objection was made, there is no legal prohibition to counsel voicing the grounds or basis for the objection, rather than simply saying the word "Objection". Defendant McNeil includes the following examples in its argument:

- . . . Can you explain to us whether or not you have an opinion as to her prior use of Ibuprofen and whether it might have sensitized Brianna Maya?
-

MR. JENSEN: Beyond the scope.

THE WITNESS: I think –

THE COURT: Excuse me, doctor. There's an objection. Is it beyond the scope of his report?

MR. JONES: I don't think so, Your Honor.[126]

- Q. And in the past had Brianna Maya experienced, both in the past and future, similar symptoms with a viral illness?

MR. JENSEN: Compound and irrelevant.

THE COURT: Overruled.

THE WITNESS: Yes.[127]

- Q. . . . And if we look at these records on April the 7th of 1999, is one of those occasions or not where Brianna Maya experienced symptoms similar to those experienced in this case?

  A. I would have to –

  MR. JENSEN: Hold on. She's leading with the document again, Your Honor. He already said he doesn't remember these occasions. She can't lead with a

[124] *See, e.g.*, N.T. 4/19/2011 a.m. at 51:3-53:5.
[125] *See, e.g.*, N.T. 5/3/2011 p.m. at 21:18; 25:20; 26:12-15; 26:23-25; 29:19-21; 31:19-20; 35:7-8; 37:10; 38:11-20; 39:20; 40:5-9; 47:14-15; 48:7-8; 56:11; 57:1-2; 57:16; 58:12-13; 77:21; 83:4-5.
[126] N.T. 5/3/2011 p.m. at 21:15-23.
[127] *Id.* at 25:18-22.

document.

THE COURT: Objection sustained. You're leading.

MR. JENSEN: Take the document down.[128]

- MS. JONES: Let me ask that we pull up Defense Exhibit 1003.

  MR. JENSEN: Leading again, Your Honor.

  THE COURT: Are you objecting?

  MR. JENSEN: No foundation, Your Honor.

  THE COURT: Overruled.[129]

- A study called the EUROSCAR Study which I think for a variety of –

  MR. JENSEN: Objection. He's not talking about medical literatures he's not an author of.

  THE COURT: Objection is overruled.[130], [131]

At the commencement of trial, this trial judge clearly instructed counsel that if either had an objection to a question posed, they could provide a one or two word basis for the objection.[132] Anything more that was required to be stated was to be done at a requested sidebar and the court would decide whether the request for a sidebar was necessary. Based upon this trial judge's careful review of the record, this court opines that Defendant McNeil's argument is without merit and does not warrant a new trial. It is noted that the "speaking objections" Defendant McNeil takes issue with were also utilized by its own counsel.[133]

Alleged Prejudicial Comments About Defendant McNeil

Next, Defendant McNeil posits that this trial judge permitted Plaintiffs' counsel to make

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[128] N.T. 5/3/2011 p.m. at 26:7-18.
[129] N.T. 5/3/2011 p.m. at 29:17-22.
[130] N.T. 5/3/2011 p.m. at 83:2-6.
[131] *See also*, N.T. 5/3/2011 p.m. at 31:17-21; 35:7-9; 37:7-12; 38:9-13; 39:19-21; 47:11-16; 48:5-9; 56:7-12; 57:12-20; 77:17-21.
[132] N.T. 3/23/2011 a.m. at 45:21-47:5.
[133] *See, e.g.*, N.T. 3/25/2011 a.m. at 41:14-15; 148:4-5; 3/30/11 p.m. at 56:15.

prejudicial comments which: (a) turned this matter into a referendum on the drug industry rather than a trial of the facts relating to minor Plaintiff; (b) allowed improper reference to the size of Defendant McNeil's legal team to induce prejudice and, indirectly, to infer its wealth and suggest to the jury to impose the burden of proof on Defendant McNeil when the law requires Plaintiff to bear the burden of proof; and (c) invited the jury to decide the case based not on the evidence but instead on sympathy for Plaintiff and/or as punishment because Defendant McNeil is a large corporation with large law firms representing it.

This trial judge finds these allegations extreme, outrageous, and without merit. Suffice it to state that at the beginning of trial, the jury was essentially directed to decide the case solely on the evidence presented, not on sympathy or bias, and that it must not consider testimony or exhibits where an objection was sustained or stricken from the record.[134] It is presumed that juries follow the instructions given by the trial court. ***Commonwealth v. Ragland***, 991 A.2d 336, 341 (Pa. Super. 2010), *appeal denied*, 2010 Pa. LEXIS 1908 (Pa. Aug. 26, 2010) (citing ***Commonwealth v. Housman***, 986 A.2d 822 (Pa. 2009)).

As an example of what Defendant McNeil has highlighted as a prejudicial comment, it is noted first that the comment was made by the witness not counsel. Immediately thereafter, this trial judge issued *sua sponte* a curative instruction; to *wit*:

> WITNESS [Dr. Tackett]: . . . the problem with the FDA is that it's generally underfunded, overburdened, and overtaxed with regard to the structure that it has.
>
> Q. Have you reached –
>
> THE COURT: Wait, excuse me. Ladies and Gentlemen, the FDA is not part of our concerns in this case. It comes in for other matters, but whether or not this policy and this opinion, whether they're underfunded or Congress is not funding them appropriately, that is not our concern in this case. Okay?[135]

[134] N.T. 3/23/2011 p.m. at 18:5-7.
[135] N.T. 3/24/2011 a.m. at 141:2-14.

This trial judge acknowledges that comments pointing to the wealth of Defendant McNeil were permitted since Plaintiffs' complaint contained a claim for punitive damages. Restatement (Second) of Torts, Section 908 sets forth three factors to be considered in awarding punitive damages: (1) the character of the act; (2) the nature and extent of the harm, and (3) the wealth of the defendant. It is enough for the jury to weigh these factors in arriving at an appropriate punitive damage award, if that is the jury's decision. Section 908(2) of the Restatement (Second) of Torts; ***Kirkbride v. Lisbon Contractors, Inc.***, 555 A.2d 800, 803 (Pa. 1989), *on remand*, 560 A.2d 908 (Pa. Super. 1989); *see also*, ***Hollock v. Erie Ins. Exch.***, 842 A.2d 409, 419 (Pa. Super. 2004), *appeal dismissed*, 903 A.2d 1185 (Pa. 2006). Under the circumstances, highlighting the wealth of a defendant is proper. However, this trial judge issued curative instructions to Plaintiffs' comments regarding an "army of lawyers" and Defendant McNeil being a "32 billion dollar company."[136] These comments obviously had no prejudicial impact since the jury did not award Plaintiffs punitive damages, and the compensatory amount awarded to Brianna was not exorbitant.

Finally, as to Defendant McNeil's claim that the case became a "referendum on the drug industry", this trial judge disagrees. The presentation of the evidence was fact-intensive as to the progression of events leading to Brianna's injuries, incorporated with the trial testimony of numerous expert witnesses, who recounted in detail the sequence of symptoms with which they were familiar by either a review of the medical records and/or the treatment rendered to her. Some opinion testimony addressed the pharmaceutical industry and was pertinent to the case. However, these opinions were far from a cry for a referendum on the drug industry. In this trial judge's estimation, Defendant McNeil's views on this issue are out of proportion to the evidence of record.

[136] See N.T. 5/18/2011 a.m. at 112:18-22; 156:15-16; 156:25-157:3; 158:20-22.

Alleged Improper Evidentiary Inferences

Defendant McNeil advances the argument that this trial judge erroneously permitted Plaintiffs' counsel to make improper evidentiary inferences such that a new trial is warranted. It contends that even after the trial court sustained objections, Plaintiff's misconduct continued.

The example raised by Defendant McNeil involved the issue of the fenfluramine (Fen-Phen) litigation exchange between Plaintiffs' counsel and Ms. Pawelski. Reviewing the trial transcript, this trial judge accepts Plaintiffs' explanation that it was the witness who raised the subject matter, and because she did so in answering his question in an obtuse and factually inaccurate manner, counsel sought to correct a misstatement by mentioning his involvement, not that he took a "critical role", in the Fen-Phen action. Specifically, Ms. Pawelski suggested that the FDA, upon its *own* investigation, removed Fen-Phen from the market.[137] Plaintiffs' counsel decidedly refuted the statement, recognizing the non-responsiveness and irrelevancy of it, and stated that Fen-Phen was not removed from the market until he filed a lawsuit that influenced the drug's withdrawal from the market and not because of the FDA's own initiative.[138] This trial judge intuited Plaintiffs' counsel taking advantage of the door having been opened to continue on this potentially irrelevant line of questioning and sustained further references to the Fen-Phen litigation.[139] This trial judge opines that the reference originally made to the Fen-Phen litigation by Defendant McNeil's own employee does not constitute a reversible error.

Next, Defendant McNeil advances that Plaintiffs' counsel, during opening statement, improperly criticized it for failing to contact the Maya family. Defendant McNeil objected and the objection was sustained. Thereafter, Defendant McNeil did not request that this trial judge admonish the jury to disregard the statement or have the comment stricken from the record after

[137] N.T. 4/19/2011 a.m. at 51:9-13.
[138] *Id.* at 51:21-25.
[139] *See* N.T. 4/19/2011 a.m. at 52:2-20.

its objection was sustained. Thus, in this trial judge's opinion, this argument is without merit since the objection was sustained. *See* ***Manley***, *supra*, 985 A.2d at 267.

As to Defendant McNeil's contention that Plaintiffs presented cumulative and repetitive testimony, this argument is also meritless. Plaintiffs presented testimony from family members who directly witnessed the traumatic events that befell Brianna Maya, their personal involvement pre- and post-reaction to the medication and the physical manifestation of TEN. Plaintiffs also presented various expert witnesses, many who personally treated Brianna within their specific medical specialties and offered opinions that served to buttress the causation theory of her TEN reaction and the particular bodily injury suffered. To briefly reiterate: Dr. Sanford was Brianna's treating burn surgeon and responsible for her primary care while at Shriner's Hospital and testified to the burn-like wounds over 84% of her body;[140] Dr. Tseng was Brianna's treating eye surgeon and a specialist in the treatment of TEN;[141] Dr. Pliskow is Brianna's treating gynecologist and gynecologic surgeon,[142] whose practice concentrates on the care and treatment of patients with SJS and TEN;[143] and Dr. Schulz, another treating burn surgeon. [144] Accordingly, this trial judge is not persuaded by Defendant McNeil's argument that the diversity of these expert witnesses' backgrounds and testimonies overlapped each other and/or was cumulative. Clearly, the testimony of these treating experts was critical to the understanding of the extent of the multi-organ damage caused by TEN, and Brianna's current injuries and future damages. The testimony was not cumulative, repetitive or redundant and did not violate Pa. R.E. 403.

Alleged Improper Remarks during Closing Argument

In its post-trial motion, Defendant McNeil alleges that Plaintiffs' counsel made improper

[140] N.T. 4/7/2011 a.m. at 62:7-11; 69:13-16.
[141] N.T. 4/13/2011 a.m. at 4:21-24; 84:5-9.
[142] N.T. 4/5/2011 a.m. at 45:13-19.
[143] *Id.* at 62:21-63:3.
[144] N.T. 4/7/2011 a.m. at 72:24-73:3.

remarks and false statements during closing argument; including, *inter alia,* false statements regarding Defendant McNeil and medical testimony; and imploring the jury to decide the case on sympathy for the Plaintiffs. Defendant McNeil offered the following examples to illustrate its argument:

- False assertion that Defendant McNeil did not comply with the law.[145]
- Stating that the Children's Motrin OTC *label* does not contain the phrase "Stop use and ask a doctor."[146]
- Stating that "[Brianna's] pediatrician, had no knowledge between the relationship of rashes, on one hand, or SJS or TEN on the other".[147]
- Inviting the jury to decide the case based on its sympathy for the Plaintiffs by referring to the "army of lawyers" representing Defendant McNeil, which was objected to after Plaintiffs' counsel's closing argument.[148]

Closing argument is the attorney's last opportunity to outline the evidence to the jury in the light most favorable to the client. As such, attorneys are permitted to modulate their voices and engage in oratorical flair. "If the lawyer became indignant, if he used voice modulations and gestures, and exhorted with spirited language the jury to return a verdict for his client for a sum of money commensurate with the loss he had sustained, that is all part of our adversary system of trial." ***Purcell***, *supra*, 191 A.2d 662, 671 (Pa. 1963). When improper remarks are made in closing arguments, "the trial judge who breathed the atmosphere of the case is far more able to determine whether the parties received a fair trial than [is the appellate court]"). ***Med-Mar, Inc. v. Dilworth***, 257 A.2d 910, 918 (Pa. Super. 1969). So long as no liberties are taken with the evidence, a lawyer is free to draw such inferences as he wishes from the testimony and to present his case in the light most suited to advanced his cause and win a verdict in the jury box. ***Hycrza***,

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[145] N.T. 5/18/2011 a.m. at 39:6-15.
[146] *Id.* at 39:6-15 (emphasis in original).
[147] N.T. 5/16/2011 p.m. at 63:5-7.
[148] *See* N.T. 5/18/2011 a.m. at 52:15-19; 55:12-14; 90:24-91:3; 112:18-20; 144:23-145:4.

supra, 978 A.2d at 977; ***Wagner v. Anzon, Inc.***, 684 A.2d 570, 578 (Pa. Super. 1996), *appeal denied*, 700 A.2d 443 (Pa. 1997) (citation omitted). However, this latitude does not include a discussion of facts not in evidence which is prejudicial to the opposing party. ***Wagner***, *supra*, 684 A.2d at 578. In general, any prejudicial remarks made by counsel during argument can be handled within the broad powers and discretion of the trial judge and the court's actions will not be disturbed on appeal unless there is an obvious abuse of discretion. ***Id.***

Prior to the presentation of closing arguments, this trial judge instructed the jury to listen carefully to counsel's outline of the evidence, noting that the argument itself, *is not evidence*,[149] and to disregard any law suggested or argued by counsel.[150] Following Plaintiffs' closing argument, Defendant McNeil made several objections which were argued outside the presence of the jury while it was on a lunch recess. Defendant McNeil offered four objections; to *wit*: that Plaintiffs' counsel referred to Defendant McNeil as a "32 billion-dollar company" despite there being no evidence of record to support this claim; that Plaintiffs' counsel sought to impose the burden of proof on the defendants by repeatedly arguing that there was no dispute on the record or that matters were uncontested and had they been contested; that Defendant McNeil and its "army of lawyers" would have brought in evidence or hired experts; that there was no evidence of record to support the statement that Defendant McNeil had any sponsorship potential or involvement in the EUROSCAR Study; and that Plaintiffs' counsel misrepresented that Mr. Willy Pagsuyuin was in charge of pharmaco-vigilance when, in fact, he was in the Regulatory Affairs Department.[151]

This trial judge agreed *only* to issue curative instructions regarding Defendant McNeil's wealth. The following narrative is a synopsis of what transpired:

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[149] N.T. 5/18/2011 a.m. at 31:3.
[150] N.T. 5/19/2011 a.m. at 7:22-25.
[151] *See* N.T. 5/18/2011 a.m. at 154:17-156:11

MS. JONES:
And, Your Honor, in light of the fact that you sustained the objections to points 1[152] and 2,[153] will you be giving a curative instruction to the jury?

THE COURT: Yes.[154]

The court thus gave the following curative instruction:

THE COURT: Before Ms. Jones starts her closing, there were a couple of objections made which have been sustained as to remarks made by Mr. Jensen during his closing, and one of them had to do with the amount of the net worth of McNeil. There was never evidence to that, . .

* * *

THE COURT: Okay. That there was never an amount mentioned as to the net worth of McNeil, the defendant, McNeil.[155], [156]

* * *

In addition, this trial judge cautioned the jury to consider only certain information in deliberating, as follows:

The fact that the defendant is a corporation is irrelevant. Before the Court, both individuals and corporations are equal and both must be judged by equal standards of fairness and impartiality.[157]

* * *

Testimony that I have stricken from the record or told you to disregard is not evidence and must not be considered. The fact that an attorney requested some things to be stricken which may not have been should not affect your

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[152] *See* N.T. 5/18/2011 a.m. at 156:15-16.
[153] *See id.* at 156:25-157:3.
[154] *Id.* at 158:20-22.
[155] *Id.* at 3:13-4:14.
[156] The fact that a curative instruction was given distinguishes this matter from ***Mirabel v. Morales***, 2012 Pa. Super. LEXIS 3478 (wherein the Superior Court found that the trial court abused its discretion in not granting a new trial on both liability and damages due to improper statements made by Plaintiff's counsel at closing argument). Therein, the trial court gave no curative instruction to the jury for statements about the size and wealth of Comcast. ***Id.*** at *15. Further, in the instant matter, Plaintiffs make a claim for punitive damages, whereas the ***Mirabel*** plaintiff did not ("In the absence of punitive damages, it is 'irrelevant, improper, and prejudicial' for a jury to consider the defendant's weath." ***Id.***, fn. 7 (citing ***Feld v. Merriam***, 485 A.2d 742, 749 (Pa. 1984) (citation omitted)). ***Feld*** further indicated that a curative instruction can overcome the prejudice of these types of statements. ***Feld***, 485 A.2d at 748 fn. 6.
[157] N.T. 5/19/2011 a.m. at 14:12-16.

consideration of the evidence.[158]

* * *

> To determine whether punitive damages are warranted, you may consider any and all of the following factors: 1, the character of the defendant's act – acts; 2, the nature and extent of harm to the plaintiff which the defendant caused, or intended to cause with its product; and, 3, the wealth of the defendant insofar as it's relevant in fixing an amount which will punish it and deter it and others from similar acts in the future.[159]

Under the circumstances, this trial judge opines that Defendant McNeil has waived some of the issues raised and with respect to the issues preserved, no error was committed. Defendant McNeil's argument regarding improper comments made during closing arguments lacks merit.

Remittitur

Defendant McNeil argues that the amount of compensatory damages awarded by the jury was exorbitant, was tainted by partiality and/or prejudice, and influenced by Plaintiffs' counsel's egregious misconduct at trial. Relying on these contentions, Defendant McNeil argues that this trial judge erred in denying its request for a remittitur. This trial judge disagrees and opines that Defendant McNeil has not articulated any legal or valid reason to reduce the jury's $10 million award nor has it provided evidence to sustain its allegation that the verdict is unreasonable or the result of undue influence associated with counsel's behavior.

As stated, judicial reduction of a jury award for compensatory damages is appropriate only when the award is plainly excessive and exorbitant in a particular case. ***Doe v. Raezer***, 664 A.2d 102, 105 (Pa. Super. 1995), *appeal denied*, 675 A.2d 1248, 1996 Pa. LEXIS 727 (1996) (citing ***Haines v. Raven Arms***, 640 A.2d 367, 369 (Pa. 1994), supp. 652 A.2d 1280 (Pa. 1995)). "A remittitur should fix the highest amount any jury could properly award, giving due weight to all the evidence offered." ***Id.***, 664 A.2d at 105. The correct question on review is whether the

[158] N.T. 5/19/2011 a.m. at 24:16-22.
[159] *Id.* at 58:14-23.

award of damages falls within the uncertain limits of fair and reasonable compensation, whether the verdict is unsupported by the evidence, or so shocks the sense of justice as to suggest that the jury was influenced by partiality, prejudice, mistake, or corruption. ***Doe***, *supra*, 664 A.2d at 105. It is the appellate court's task to determine whether the trial judge committed a "clear" or "gross" abuse of discretion when conducting its initial evaluation of a defendant's request for remittitur.

Large verdicts are not necessarily excessive verdicts; each case is unique and dependent on its own special circumstances. ***Hyrcza***, *supra*, 978 A.2d at 979 (citing ***Tindall v. Friedman***, 970 A.2d 1159, 1176 (Pa. Super. 2009), *reargument denied*, 2009 Pa. Super. LEXIS 4462 (Pa. Super. Ct. June 1, 2009)). When awarding damages for past or future non-economic loss, a jury may consider, *inter alia*, the age of the plaintiff, the severity of the injuries, whether the injuries are temporary or permanent, the duration and nature of medical treatment, the duration and extent of physical pain and mental anguish on the part of the plaintiff, and the plaintiff's physical condition before the injuries. ***Id.***; *see* Pa. R.C.P. 223.3; Pennsylvania Suggested Standard Jury Instructions (Pa. SSJI) (Civ) 7.130.

Instantly, the presentation of fact witnesses, numerous experts, and hundreds of exhibits took nine (9) weeks. The jury carefully weighed the evidence, requested to review copies of specific documents, and rendered its $10 million verdict in favor of Brianna Maya. This trial judge opines that the verdict was not the result of partiality or prejudice but, rather, the result of an engaged panel who considered the horrific consequences of Brianna's injuries, *inter alia,* the excruciating pain and suffering endured by Brianna, then three years old, at the onset of TEN symptoms; the fact that over 80% of her skin sloughed off within days of the onset of the TEN symptoms; the debridement treatment she endured throughout her hospitalization and during follow-up treatment; the fact that she is legally blind in one eye with a possibility of losing vision

in the other eye; her limited lung capacity and recurring bouts of pneumonia and infections as a result of the sloughing lung tissue and scarring; Brianna's reconstructive surgery to permit her to menstruate, and her future physical inability to have normal sexual relations or bear children; and the everyday care she needs to avoid exposure to the sun and any extraneous activity. Considering the extent of her permanent injuries and the fact that she was 13 years old at the time of trial with a normal life expectancy, the jury appropriately compensated her. As already reflected in this opinion, this trial judge opines Defendant McNeil's accusations of counsel's misconduct are unfounded. Consequently, this trial judge opines that the jury's ability to objectively review the evidence of record was not affected by any such alleged behavior. The evidence of record clearly supports the jury's verdict; a verdict that does not shock the court's sense of justice or conscience and is reasonable under the totality of the circumstances and the injuries Brianna has suffered and will continue to endure. Thus, the denial of the remittitur was proper and was not an abuse of the court's discretion.

Erroneous Evidentiary Rulings

Defendant McNeil argues that this trial judge made numerous erroneous evidentiary rulings throughout the trial, including allowing: evidence that Tylenol was a safer product and that Brianna would not have contracted SJS/TEN had her mother been aware of that fact; evidence of other risks or adverse effects of Children's Motrin which Brianna did not suffer; evidence precluded by the court's rulings of specific motions *in limine;* evidence of withdrawal of other drugs; evidence of information or data not available when Brianna ingested the drug; evidence of "hearsay reports and studies" as proof that ibuprofen caused Brianna's injuries; and evidence elicited from Plaintiffs' numerous experts. In light of the discussion to follow, this trial judge opines that the evidentiary rulings made were correct and the evidence was, therefore,

properly admitted. While it is possible that a different ruling could have been made at times, any such possibility, either singularly or in conjunction with other rulings, does not warrant a new trial. At most, any erroneous ruling would constitute a harmless error which does not warrant granting a new trial, a judgment n.o.v., or a remititur. Defendant McNeil has failed to establish what unfair prejudice was actually suffered by these rulings.

As stated, a new trial is warranted when the trial court clearly and palpably committed an error of law that controlled the outcome of the case or abused its discretion. ***Schuenemann v. Dreemz, LLC***, 34 A.3d 94, 98 (Pa. Super. 2011); ***Schmidt v. Boardman***, 958 A.2d 498, 516 (Pa. Super. 2008), *aff'd*, 11 A.3d 924 (Pa. 2011). If the basis of the request for a new trial is the trial court's rulings on evidence, then such rulings must be shown to have been not only erroneous but also harmful to the complaining party. ***Schuenemann***, *supra*, 34 A.3d at 98; ***Schmidt***, *supra*, 958 A.2d at 516. *See also*, ***Atkins v. Pottstown Memorial Medical Ctr.***, 634 A.2d 258, 260 (Pa. Super. 1993) (the trial court's evidentiary ruling, although erroneous, did not affect the verdict and, therefore, did not require a new trial); ***Cacurak v. St. Francis Med. Ctr. (In re Almar Radiology)***, 823 A.2d 159, 164 (Pa. Super. 2003), *appeal denied*, 844 A.2d 550 (Pa. 2004) (citing ***Yacoub v. Lehigh Valley Medical Associates, P.C.***, 805 A.2d 579 (Pa. Super. 2002), *appeal denied*, 825 A.2d 639 (Pa. 2003)). Evidentiary rulings which do not affect the verdict will not provide a basis for disturbing the jury's judgment. ***Detterline v. D'Ambrosio's Dodge, Inc.***, 763 A.2d 935 (Pa. Super. 2000).

Undisputedly, the admission or exclusion of evidence is within the sound discretion of the trial court, and will only be reversed upon a showing that the trial court abused its discretion or committed an error of law. ***Schuenemann***, *supra*, 34 A.3d at 98. Generally, unless otherwise provided by law, evidence is admissible if it is relevant; that is, if it has any tendency to make the

existence of any fact that is of consequence to the determination of the action more probable or less probable that it would be without the evidence. Pa. R.E. 401; *see also,* ***Commonwealth v. Pitts***, 740 A.2d 726, 733 (Pa. Super. 1999). Relevant evidence logically tends to prove or disprove a material fact. ***Commonwealth v. Weaver***, 768 A.2d 331, 332 (Pa. Super. 2001), *appeal denied*, 788 A.2d 376 (Pa. 2001). Evidence that is not relevant is not admissible. Pa. R.E. 402. If evidence is of consequence to any claim presented it is relevant to the case. *See* ***Nigro v. Remington Arms Co.***, 637 A.2d 983 (Pa. Super. 1993), *appeal dismissed*, 655 A.2d 505 (Pa. 1995).

Although relevant, evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issue, or misleading the jury, or by consideration of undue delay, waste of time, or needless presentation of cumulative evidence. Pa. R.E. 403; ***Pitts***, *supra*, 740 A.2d at 733. To determine whether evidence is relevant requires a two-step analysis. First, the court must determined if the inference sought to be raised by the evidence bears upon a matter in issue in the case and, second, whether the evidence renders the desired inference more probable than it would be without the evidence. ***Commonwealth v. Stewart***, 336 A.2d 284 (Pa. 1975) (citations omitted). The function of the trial court is to balance the alleged prejudicial effect of the evidence against its probative value, and it is not for an appellate court to usurp that function. ***Sprague v. Walter***, 656 A. 2d 890, 909 (Pa. Super. 1995), *reconsideration denied*, 1996 Pa. LEXIS 219 (Pa. Feb. 26, 1996) (citing ***Engle v. West Penn Power Co.***, 598 A.2d 290, 301 (Pa. Super. 1991), *appeal denied*, 605 A.2d 334 (Pa. 1992) (citation omitted)). "Prejudice" for purposes of this rule, does not mean detrimental to a party's case, but rather, an undue tendency to suggest a decision on an improper basis. ***Sprague***, *supra*, 656 A.2d at 909; ***Engle***, *supra*, 598 A.2d at 301. Even where evidence is alleged to be prejudicial but is actually quite relevant to

one of the inquiries in the case, if the probative value of the evidence exceeds its prejudicial nature, the evidence is properly admitted. *See, e.g.*, ***Engle***, *supra;* ***Scullion v. EMECO Indus., Inc.***, 580 A.2d 1356 (Pa. Super. 1990), *appeal denied*, 592 A.2d 45 (Pa. 1991). The mere assertion that evidence is "prejudicial" is both insufficient and a misstatement of the standard. Evidence may be excluded where it is "*unfairly*" prejudicial. ***Commonwealth v. Peer***, 684 A.2d 1077 (Pa. Super. 1996).

Instantly, a central issue in this product liability action is whether the warnings on the label of Children's Motrin were inadequate because the label failed to warn of specific adverse reactions. Plaintiffs had the burden of proof to establish the claims of inadequacy of the label. From the numerous arguments made, it is apparent that Defendant McNeil challenges the presentation of *any* evidence against it that Plaintiffs offered, including what information influenced Alicia Maya's decision to purchase and administer Children's Motrin to her daughter. As part of said proof, Plaintiffs offered the safety profile of Children's Tylenol and compared it to warning information (or lack thereof) on the label of Children's Motrin. Such evidence was clearly relevant and admissible; more so since Plaintiffs' complaint alleged that both OTC Children's Motrin and OTC Children's Tylenol were defective products.

Likewise and despite Defendant McNeil's objections, evidence of the warnings of the risk of gastrointestinal bleeds and liver failure was admissible to establish that the known risks and/or adverse effects of OTC Children's Motrin implied that OTC Children's Tylenol was a safer product than OTC Children's Motrin. This inference was relevant to Plaintiffs' contention that Defendant McNeil had a duty to warn users of the safer product. This evidence further addressed the fact that Defendant McNeil knew and made statements to the FDA regarding warnings of the risk of gastrointestinal bleeds and liver failure with respect to the use of OTC

ibuprofen. (*See* discussion of the 1984 Citizen's Petition, *infra*, at p. 103). It was also relevant to establish Defendant McNeil's knowledge of adverse reactions and obligation to warn of other dire side effects, such as blistering, rash and blindness associated with the use of OTC Children's Motrin. These claimed warnings would have offered Plaintiff Alicia Maya additional information on whether to purchase or not the medication and/or to stop administrating the drug to her daughter once symptoms appeared. This evidence also provided context for the type of information required to justify a label change, a change that was within Defendant McNeil's power and initiative to make. In this trial judge's opinion, this evidence was properly admitted and its probative value far outweighed any prejudicial effect.

Next, Defendant McNeil claims that this trial judge improperly admitted: the testimony of Alicia Maya regarding the Children's Tylenol advertisements that she did not see, despite the trial court's ruling on a motion *in limine* precluding said evidence and despite Ms. Maya's failure to identify in discovery any of the advertisements that allegedly influenced her decision to give Brianna Children's Motrin; and questions to Ms. Maya about what decisions she would have made had she "known that Tylenol had a superior safety profile", was evidence improperly admitted and prejudicial. As background information, the referenced motion *in limine*[160] sought to exclude all marketing and promotional material related to OTC Children's Motrin not reviewed or relied upon by the Plaintiffs.[161] During oral argument on the motion, Defendant McNeil advanced that Plaintiffs failed to identify any advertisement in response to written discovery or at a deposition seeking such information. Plaintiffs' counsel denied that Plaintiff Alicia Maya was asked to identify any and all advertising relied upon at any deposition and that it would be unreasonable to do so, considering the plethora of advertisements that one may see

[160] Docketed under Control Number 11031098.
[161] N.T. 3/22/2011 p.m. at 39:23-40:3.

for Tylenol or Motrin.[162] After considering the motion, responses and oral argument, this trial judge granted the motion *in limine*, precluding Plaintiffs from introducing any evidence or reference to advertisements they did not review, but denied it as to experts relying on such advertising to form their opinions.[163]

As to the specific issue, during the direct examination of Plaintiff Alicia Maya, her counsel presented her with Exhibit 4510, a document previously viewed by the jury.[164] Exhibit 4510 was the second page of *Pediatrics* from January 1996, the year that Brianna Maya was born.[165] This trial judge overruled the ensuing objection by defense counsel and permitted Ms. Maya to be questioned that had she known that "the company that makes both Motrin and Tylenol was advertising that Tylenol had a superior safety profile to Ibuprofen", would that have changed her mind or altered her behavior as to administering Children's Motrin to her daughter.[166] Ms. Maya testified that had she seen an advertisement claiming that "no pediatric medicine is more effective than Tylenol", she would have consulted Dr. Brewer with questions as to why she (Dr. Brewer) recommended giving alternating doses of Motrin and Tylenol.[167] This trial judge acknowledges that this advertisement was used despite the preclusion resulting from the motion *in limine* ruling. Notwithstanding, Ms. Maya's response was relevant to the issue before the jury and did not prejudice Defendant McNeil. What Plaintiff Alicia Maya knew with respect to Children's Motrin (and Children's Tylenol) goes to her decision-making process. Had she known of the different safety profiles, her testimony was that she would have consulted her child's physician. It is unknown whether any information provided by the physician would

[162] N.T. 3/22/2011 p.m. at 42:10-24.
[163] *Id.* at 46:23-47:6.
[164] N.T. 4/21/2011 p.m. at 74:17-18.
[165] *Id.* at 75:13-19.
[166] *Id.* at 76:24-77:5.
[167] *Id.* at 77:24-78:13.

have altered her decision to administer the medication to her daughter. Thus, Defendant McNeil suffered no prejudice by this testimony and the use of the advertisement of the January 1996 issue of *Pediatrics.*

Defendant McNeil's argument that this trial court erred by not enforcing its rulings on motions *in limine* regarding preclusion of "other incidents and determinations regarding Children's Motrin in other countries", is without merit since no such motion *in limine* was filed. Notwithstanding the lack of a written motion, during trial, Defendant McNeil made a timely oral objection to said information,[168] which was sustained with the following curative instruction:

> But before we take a break – ladies and gentlemen, any evidence or any testimony or any questions that regard drugs that were taken off the market anywhere outside of the United States is not relevant to this case. The FDA does not control anything that happens outside of its border so, therefore, anything that any other country does is not of relevancy in this case. Okay. So disregard any testimony with regards to that. [169]

Defendant McNeil did not take any exception to the curative instruction given.

Next, Defendant McNeil contends that this trial judge erred by allowing Plaintiffs to present evidence of information available after Plaintiffs' use of Children's Motrin as though the information was current or known at the time of Brianna's SJS/TEN, thereby falsely suggesting that such later "discovered" information was relevant to determining whether Defendant McNeil was negligent in the information provided on the warning label of Children's Motrin at the time Plaintiffs used the medication. In its post-trial motion, Defendant McNeil highlighted more than 27 situations with subsections (See paragraph 68, a.-v.) where Plaintiffs used post-2000 evidence to argue Defendant McNeil's negligent failure to warn in 2000. In at least 48 out of those enumerated examples, however, Defendant McNeil did not voice any objections and, therefore, in this trial judge's opinion, has waived any appellate issue to this unopposed evidence. Any

[168] N.T. 4/15/2011 p.m. at 122:21-123:2.
[169] *Id.* at 123:14-22.

contention of error is without merit.

To address a reference made, this trial judge will discuss the pertinent testimony of Lynn Pawelski, Vice President of Regulatory Affairs at Defendant McNeil. As background information, she testified that pursuant to Federal Regulation 314.70, "a drug company before FDA approval can make changes to accomplish any of the following – to add or strengthen a contraindication, warning precaution or adverse reaction."[170] Ms. Pawelski agreed that Defendant McNeil was responsible for "making sure that the warnings and the labeling that is approved appears on the product".[171] She testified unopposed that "no readability or comprehension study to determine whether people could understand greater risk information of side effects at any time from 1995 through 2004 for additional warnings that were never in the OTC label from 1995 to 2005" were conducted by Defendant McNeil.[172] She also testified that no study was done after 1995 when Children's Motrin was approved[173] and that the label did not include the following words: skin, rash, blisters, death, blind/blindness/vision, permanent, lesions/bullous lesions.[174] Ms. Pawelski agreed that Defendant McNeil did not investigate SJS/TEN (because there was no "signal" to do so), neither was an investigation analysis or assessment of SJS/TEN done in relation to Ibuprofen, nor any discussions with the FDA on this matter at any time from 1995-2004.[175]

With this backdrop, Defendant McNeil simply claims that inclusion of this evidence was "unduly prejudicial". This trial judge disagrees since this information points to what Defendant McNeil knew in 2000 regarding its obligation to warn of adverse effects, and its lack of updating

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[170] N.T. 4/15/2011 p.m. at 93:2-22.
[171] *Id.* at 73:21-74:3.
[172] *Id.* at 75:25-76:6.
[173] *Id.* at 76:12-13.
[174] *Id.* at 76:13-16; *id.* at 65:1-67:2.
[175] *Id.* at 95:18-96:24.

the warnings on the label. It is important to note that evidence must not be viewed in isolation. The totality of the evidence, including the testimony of Ms. Pawelski, provided a basis for suggesting to the FDA that a stronger label was needed and, consequently, pointed to Defendant McNeil's obligation to warn the consumer. Defendant McNeil had its opportunity to rebut this evidence and the logical inferences derived.

Next, Defendant McNeil argues that that this trial judge allowed incompetent, irrelevant, and hearsay reports of specific incidents, including case reports and adverse event reports, to be used as proof that ibuprofen causes SJS or TEN and/or that it caused Brianna Maya to develop SJS/TEN. Clearly, Defendant McNeil is mistaken since this trial judge explicitly instructed the jury that these reports were only to be considered for the limited purpose of notice and not causation. The jury acknowledged this nuance, as reflected in the record as follows:

> You heard testimony about adverse event reports. Adverse event reports are reports submitted to the FDA after the manufacturer of a drug has received a report indicating an individual using a drug has experienced an adverse event. Adverse event reports do not prove that an individual in the report experienced the adverse event because of the particular drug. The adverse event reports were shown to you for limited purposes of proving that Defendant McNeil, had notice of the reports. You may not rely on these reports as evidence as -- I'm sorry -- as evidence of whether Children's Motrin can cause TEN or did cause Brianna Maya's TEN. You may only consider the adverse event reports when determining whether Defendant McNeil, had notice of the reports, themselves.
>
> Have you understood that comment?
>
> Yes? Let the record reflect the jury has.[176]

Defendant McNeil also criticizes the admission of Plaintiffs' experts' testimony because these experts either were not qualified, testified beyond the scope of their reports, and/or testified relying on inadmissible evidentiary matters. This trial judge disagrees with this overly broad contention and opines that the expert opinions offered were properly admitted.

[176] N.T. 5/19/2011 a.m. at 25:2-23.

It is well settled that the standard for qualifying an expert witness is a liberal one. ***George v. Ellis***, 820 A.2d 815, 817 (Pa. Super. 2003), *appeal denied*, 923 A.2d 1174 (Pa. 2007) (citing ***Rauch v. Mike-Mayer***, 783 A.2d 815 (Pa. Super. 2001), *appeal denied*, 793 A.2d 909 (Pa. 2002)). When determining whether a witness is qualified as an expert the court is to examine whether the witness has any reasonable pretension to specialized knowledge on the subject under investigation. Pa. R.E. 702; *see also,* ***George***, *supra*, 820 A.2d at 817 (citing, ***Miller v. Brass Rail Tavern***, 664 A.2d 525 (Pa. 1995), *remanded*, 702 A.2d 1072 (Pa. Super. 1997)). The court's function is to ascertain whether the proposed witness has sufficient skill, knowledge, or experience in the field at issue as to make it appear that the opinion or inference offered will aid the trier of fact in the search for truth. ***Id.*** at 817 (citing, ***Bergman v. United Servs. Auto. Ass'n***, 742 A.2d 1101 (Pa. Super. 1999)). Specifically, Pa. R.E. 702 provides that if scientific, technical, or other specialized knowledge beyond that possessed by a layperson will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.

In the field of medicine, specialties sometimes overlap and a practitioner may be knowledgeable in more than one area of medicine. ***Id.*** (citing ***Bindschusz v. Phillips***, 771 A.2d 803 (Pa. Super. 2001), *appeal denied*, 790 A.2d 1012 (Pa. 2001)). Doctors will have different qualifications and some doctors will be more qualified than others to provide evidence about specific medical practices. ***Bindschusz***, *supra*, at 809. However, it is for the jury to determine the *weight* to be given to expert testimony in light of the qualifications presented by the witness. ***Id.*** (emphasis added). Additionally, experts need not be equally qualified, for it is the duty of an expert to assist the trier of fact. ***George***, *supra*, 820 A.2d at 818 (citing ***Panitz v. Behrend***, 632

A.2d 562 (Pa. 1993), *appeal denied*, 653 A.2d 1232 (Pa. 1994)); ***Bindschuz***, *supra*, 771 A.2d 803. The trier of fact, however, is not bound by the testimony of an expert witness and is under no obligation to accept the conclusions of an expert witness. ***Id.*** (citing ***Murphey v. Hatala***, 504 A.2d 917 (Pa. Super. 1986), *appeal denied*, 533 A.2d 93 (Pa. 1987).

Defendant McNeil refers to the reasons outlined in numerous motions *in limine* to argue that Plaintiffs' experts were not qualified and/or relied on hearsay to formulate their opinions, and that its motions *in limine* on these issues were erroneously denied. The experts and reasons challenged relate to: Carol Hyland, Royal Bunin, MBA, and Dr. Everett Dillman who were allowed to testify using alleged unsound methodology;[177], [178] Drs. John T. Schulz, III, Scheffer C.G. Tseng, Steven Pliskow and Jonathan Walker, who were allowed to testify outside their respective areas of expertise;[179], [180], [181] Drs. Randall Tackett, Marvin E. Goldberg, and Laura Bix, who offered *ipse dixit* opinions that did not satisfy the *Frye* standard;[182] and Dr. Arthur Sanford, who was allowed to give expert testimony despite being merely a fact witness.[183] This trial judge conscientiously considered the arguments made and opines that the respective motions *in limine* were properly decided. Undisputedly, numerous expert opinions were provided in support of Plaintiffs' numerous claims, particularly, their primary contention that Defendant McNeil negligently failed to warn of the dangers associated with the use of OTC Children's Motrin and the injuries Brianna suffered. The majority, if not all, of Plaintiffs' experts provided testimony involving matters beyond a layperson's common knowledge and which ultimately assisted the jury in its determination of the issues. Understandably, Defendant McNeil would

[177] Motion *in limine* docketed under Control No. 11031106.
[178] Motion *in limine* docketed under Control No. 11031117.
[179] Motion *in limine* docketed under Control No. 11031107.
[180] Motion *in limine* docketed under Control No. 11031109.
[181] Motion *in limine* docketed under Control No. 11031122.
[182] Motion *in limine* docketed under Control No. 11031113.
[183] Motion *in limine* docketed under Control No. 11031128.

prefer that none of the experts' testimony be allowed. However, the adversary trial system does not favor such an approach. Based upon their qualifications, experience and, in some instances, their active involvement in Brianna's care, these expert opinions were properly admitted.

As an example of its concern, Defendant McNeil is critical of the testimony of Carol Hyland and Royal Bunin who addressed the specific care and costs of Brianna Maya's future medical care. Defendant McNeil characterized the life-care planning as a way "for litigants to skirt the discovery process and rules of evidence so that they can put damage information before the jury in a tidy package without introducing the direct testimony of the various healthcare providers."[184] Defendant McNeil provided an apt description of how Ms. Hyland generated a report, which in turn, Mr. Bunin relied on to provide expert testimony on the financial aspect of this care.[185] Defendant McNeil provides no legal precedence to support its argument that this reliance is not proper. Obviously, there is none. Pa. R.E. 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinion or inferences upon the subject, the facts or data need not be admissible in evidence.

Surely, an expert may rely on data of others to formulate an opinion. Here, the jury heard extensive testimony related to Brianna's injuries. To call upon the "various healthcare providers" to testify directly as to each injury Brianna suffered, as Defendant McNeil proposes, is unnecessary, although many did testify. As to Mr. Bunin, as an expert, he is permitted to extrapolate from those medical providers' records and the totality of the evidence reviewed to calculate the cost for future medical care. This trial judge opines that no error was committed in allowing him (or any other expert) to do so.

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[184] Defendants' Motion *in Limine* No. 15 to Exclude Plaintiffs' Experts Carol Hyland and Royal Bunin, MBA, at p. 3.

[185] *Id.*, at p. 6.

Defendant McNeil's rather flip tone of its motion *in limine* suggesting that Plaintiffs included additional costs unrelated to any identifiable medical need, *i.e.*; "certainly the Mayas could find a competent ophthalmologist in Tennessee", a reference to the medical treatment received from Dr. Tseng[186] demonstrates either Defendant McNeil's total lack of appreciation for the severity of Brianna's injuries and the lengths her parents have gone to obtain the best available medical care for Brianna to save what is left of her vision, or a total lack of sensitivity to Brianna's catastrophic injuries. This trial judge is surprised by Defendant McNeil's attack on the qualifications of *each* of Plaintiff's expert witnesses without articulating valid reasons and opines that this attack is uncalled for and is highly improper. Even Defendant McNeil's use of the buzz phrase "*methodologies*" phrase is erroneous.

Case on point is Defendant McNeil's argument regarding the qualifications of and the methodologies used by Drs. Randall Tackett, Everett Dillman, Marvin Goldberg, and Laura Bix, citing ***Frye v. United States***, 293 F. 1013 (D.C. Cir. 1923). Specifically, Defendant McNeil characterizes Dr. Tackett, a professor of over 30 years at the University of Georgia, College of Pharmacy,[187] as a popular expert favored by the plaintiffs' bar with respect to SJS/TEN litigation and argues that his theories were "created solely for litigation that remains secret from the scientific community."[188] Defendant McNeil is critical of Dr. Dillman, Plaintiffs' economist, arguing that his "relative impact" analysis[189] was irrelevant to the factors identified by Tennessee law for determining punitive damages. It further claims that Dr. Goldberg, a marketing professor at Pennsylvania State University, and Dr. Bix, an associate professor at the School of Packaging

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[186] Defendants' Motion in *Limine* No. 15 to Exclude Plaintiffs' Experts Carol Hyland and Royal Bunin, MBA, at p. 10.
[187] N.T. 3/24/2011 a.m. at 8:13-17.
[188] Defendants' Motion in Limine No. 15 to Exclude Plaintiffs' Expert Testimony of Dr. Randall Tackett, at p. 8.
[189] Characterized as a determination of how much Johnson & Johnson would have to pay, relative to its net worth, to sustain the same financial impact that an assumed penalty would have on the average American household, relative to its net worth. Defendants' Motion *in Limine* No. 20 to Exclude Expert Testimony of Dr. Everett Dillman, at p. 3.

at Michigan State University, were erroneously permitted to testify regarding the warning label on the bottle of Children's Motrin, since neither is a medical doctor nor a regulatory expert. In addition, Defendant McNeil assert that Dr. Goldberg is unqualified to testify that the warnings were inadequate for reasons unrelated to SJS and TEN, since those deficiencies were not part of the failure to warn claim. This trial judge disagrees.

The ***Frye*** principles only apply when a party seeks to introduce *novel* scientific evidence. ***Trach v. Fellin***, 817 A.2d 1102, 1108 (Pa. Super. 2003), *appeal denied*, 847 A.2d 1288 (Pa. 2004) (citing ***Frye***, *supra*, 293 F. at 1014); *see* ***Commonwealth v. Blasioli***, 713 A.2d 1117, 1119 (Pa. 1009). Contrary to Defendant McNeil's contentions, *Frye* does not apply every time science enters the courtroom. ***Trach*** *supra*, 817 A.2d at 1108, (citing ***Blum v. Merrell Dow Pharmaceuticals, Inc.***, 705 A.2d 1314 (Pa. Super. 1997), *aff'd*, 764 A.2d 1 (Pa. 2000)). ***Frye*** is an exclusionary rule of evidence and must be construed narrowly so as not to impede admissibility of evidence that will aid the trier of fact in the search for truth. ***Id.***, 817 A.2d at 1104; *see also* Pa. R.E. 702, at Comment—1998, noting that Rule 702 does not alter Pennsylvania's adoption of the ***Frye*** standard and does not change the rule for qualifying a witness as an expert enunciated in ***Miller v. Brass Rail Tavern***, *supra*.

As to the criticism of Dr. Tackett, this trial judge carefully reviewed his extensive résumé and found that he possessed specialized knowledge in the field of pharmacology, toxicology, regulatory affairs, and the internal workings of how the Federal Drug Administration (FDA) approves a drug for the market[190] having conducted academic research for at least 11 drug companies.[191] With these credentials, no error was committed in allowing him to testify as an expert. That the plaintiffs' bar chose to call him as an expert does not affect his credentials,

[190] N.T. 3/24/2011 a.m. at 53:24-55:21; 61:6-11.
[191] *Id.* at 31:4-32:15.

expertise, or ability to testify. At most, this inclination goes to bias and to the weight to be given to his opinions.

Defendant McNeil further claims that Dr. Tackett was allowed to proffer an opinion he was not qualified to make; to *wit*: he testified that the distribution of rashes proves that drugs were the cause of Brianna Maya's SJS/TEN despite the lack of any reliable basis for that testimony. However, a careful review of the trial transcript reveals that Defendant McNeil is mistaken. Dr. Tackett did not state that the distribution of rashes *proved* that drugs were the cause of SJS/TEN, instead, he stated that where on the body the rash occurred, suggests that the cause is drugs; to *wit*:

> Basically, if the lesions tend to be on the trunk or more central, that is usually associated with a more severe drug reaction, and more likely to be with SJS and TEN.[192]

As a pharmacologist and toxicologist, Dr. Tackett has the expertise to voice this opinion. Having heard the timeline of Brianna's symptoms and injuries, the jury was free to weigh Dr. Tackett's opinion and make whatever association it deemed appropriate as to whether Brianna's rash was the result of ingesting Children's Motrin.

Defendant McNeil also objects to Dr. Tackett's accusation that it [Defendant McNeil] hid information from the FDA and that the FDA would not have approved Children's Motrin for OTC sale had it been given complete information. This testimony was not, as charged, irrelevant and speculative, or beyond the scope of his expertise. Dr. Tackett's opinion was based on his familiarity with the process of drug approval and the FDA regulations. In his expert report, Dr. Tackett referenced statements made by Defendant McNeil in the Citizen's Petition submitted to the FDA in 1984, and criticized Defendant McNeil's stated inability to have provided stronger warnings on the label. Likewise, even though none were assessed against Defendant McNeil,

[192] N.T. 3/24/2011 a.m. at 50:20-23.

this testimony was relevant to the issue of whether punitive damages were warranted.

As to Dr. Dillman, Plaintiffs' economist, this trial judge denied Defendant McNeil's motion *in limine* to preclude Dr. Dillman's testimony, which was premised on the argument that the jury would be permitted to assess its conduct if it decides to impose punitive damages. On this contention, this trial judge opines that no additional discussion is needed since, as previously discussed: (1) Pennsylvania law and not Tennessee law controls in this litigation (*see Choice of Law*, *supra*, at p. 28); and (2) the jury did not award punitive damages. Despite the opinions offered by Dr. Dillman, Defendant McNeil is unable to establish what prejudice, if any, it suffered.

As to Dr. Goldberg, the marketing professor, and Dr. Bix, the associate professor of packaging, Defendant McNeil argues that they were erroneously permitted to testify regarding the warning label on the bottle of Children's Motrin since neither is a medical doctor nor a regulatory expert. In addition, Defendant McNeil asserted that Dr. Goldberg is unqualified to testify that the warnings were inadequate for reasons unrelated to SJS and TEN, since those deficiencies were not part of this failure to warn claim. This trial judge disagrees.

As stated, the test whether someone is qualified an expert witness is whether the witness has any reasonable pretension to specialized knowledge on the subject under investigation. If the person does, he/she may testify and the weight to be given to such testimony is for the trier of fact to determine. ***Freed v. Geisinger Med. Ctr.***, 971 A.2d 1202, 1206 (Pa. 2009), *remanded*, 5 A.3d 212 (Pa. 2010); ***McClain v. Welker***, 761 A.2d 155, 156 (Pa. Super. 2000), *appeal denied*, 771 A.2d 1286 (Pa. 2001) (both enunciating the holding in ***Miller***, *supra*, 664 A.2d at 528).

In qualifying him as an expert, this trial judge considered that Dr. Goldberg: had a Ph.D. degree in marketing; possessed over 40 years of experience in marketing; conducted research on

what marketing techniques impact children and adults; was knowledgeable in the literature as it related to marketing and consumer behavior; published research on the effects of advertising on consumers; was acknowledged with an award for significant contributions to the understanding of marketing and public policy; and had been qualified to testify as an expert with respect to Defendant McNeil's negligent marketing practices in two other failure to warn cases involving children who suffered from SJS/TEN following the ingestion of Children's Motrin. Such an extensive knowledge base provides more than sufficient expertise for Dr. Goldberg to offer opinions regarding labeling aesthetics and the consumer's ability to spot warnings to assist the jury in deciding whether Defendant McNeil negligently failed to warn of the risks of SJS/TEN. The court's function as a gatekeeper was to determine whether he or any other expert had the required specialized knowledge on the subject matter in dispute. Having made that determination, it is for the jury to weigh the expert's opinion against other experts and assess the credibility of all of the witnesses. In this trial judge's opinion, all of the experts who testified were duly qualified in their respective fields of expertise, and no error was committed in said determination.

Likewise, Dr. Bix was duly qualified; to *wit*: she has a Ph.D. degree in packaging with a specialty in healthcare packaging; has published over 40 peer-reviewed articles; has taught courses in "Packaging Laws and Regulations"; has consulted with Defendant McNeil regarding labeling and impact on consumer behavior; and has conducted research on understanding attentive behaviors and comprehension of labels. The opinions expressed in her expert report were relevant and addressed the issue of the warnings on labels and how these warnings (or lack thereof) affect the behavior of consumers.

Defendant McNeil did not retain a burn expert yet was critical of Plaintiffs' expert Dr.

Schulz, a burn surgeon at Yale University who, when at Harvard University, was associated with Shriner's Burn Hospital.[193] Addressing this criticism, this trial judge opines that Dr. Schulz's opinions were not based on "novel methodology" but on personal experience acquired from treating TEN patients, providing critical care in a multi-disciplinary collaborative environment, treating critical and non-critical burn patients, publishing on TEN in the peer-reviewed medical journals as well as in biological chemistry and physiology literature, and his stringent training in scientific method.[194]

Defendant McNeil claims that neither Dr. Pliskow nor Dr. Walker were qualified by education, training or experience to offer an opinion that Children's Motrin can cause SJS/TEN or that it caused SJS/TEN in Brianna Maya. Plaintiffs agreed that Dr. Walker would not and, this trial judge finds, did not offer testimony that Children's Motrin caused Brianna Maya's TEN.[195] As to Dr. Pliskow, Brianna Maya's treating gynecologist and surgeon[196] with experience in the care and treatment of patients with SJS and TEN,[197] the evidence of record supports this trial judge's opinion that Dr. Pliskow did not testify to matters outside his area of expertise. As described earlier, the TEN reaction caused the walls of Brianna Maya's labia to fuse in a similar manner as her eyelids fused to the eyeballs (as testified to by Dr. Tseng). Dr. Pliskow surgically made it possible for Brianna to have normal menstruation, which she had not been able to have as a result of this fusion caused by the TEN reaction. Despite the success of this surgery, Dr. Pliskow opined that she will never be able to have normal sexual intercourse or bear children. He further opined that this reality will affect Brianna's emotional/mental

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[193] N.T. 4/7/2011 a.m. at 72:24-73:3.
[194] *See* Plaintiffs' Response in Opposition to Defendants' Motion *in Limine* No. 16 to Exclude Expert Opinions of John T. Schulz, III, M.D., Ph.D., at p. 18.
[195] See Plaintiffs' Response in Opposition to Defendants' Motion *in Limine* No. 21 to Limit the Testimony of Steven Pliskow, M.D. and Jonathan Walker, M.D. at p. 3.
[196] N.T. 4/5/2011 a.m. at 45:13-19.
[197] *Id.* at 62:21-63:3.

development as she matures into womanhood and she may require psychotherapeutic treatment. Dr. Pliskow's vast qualifications, which enabled him to give opinions as to causation of Brianna Maya's SJS/TEN, include his medical practice, extensive involvement in having the FDA change the label for all NSAIDs, and his 54 medical publications concerning the relationship between Ibuprofen and SJS/TEN.[198] His opinion on the emotional or physiological impact these conditions will have on Brianna, as a woman, are also within his expertise. Based upon the totality of the evidence presented, this trial judge opines that Defendant McNeil's insistence that Dr. Pliskow testified outside his area of expertise is without foundation.

Defendant McNeil further argues that since Dr. Tseng is an ophthalmologist and not a dermatologist, toxicologist or infectious disease expert, he is not qualified to render a causation opinion nor is he qualified to opine as to FDA labeling requirements. Defendant McNeil argues that Dr. Tseng concentrates his medical expertise in eye surgery and the treatment of TEN as it relates to eye involvement.[199] However, Dr. Tseng's professional background reveals that he is a pathologist, a skin cell biologist with fellowship training in dermatology, a professor of cell biology and anatomy[200] and has published extensively on SJS/TEN,[201] including an in-depth report entitled "What Causes TEN", which references 17 peer-reviewed publications spanning 22 years.[202] Having this professional background, in this trial judge's opinion, more than qualifies Dr. Tseng to testify on the issue of causation. A review of his opinion testimony reveals that Dr. Tseng did not testify as to FDA labeling requirements.

Lastly, in this brief treatment of expert qualifications, Defendant McNeil's contention

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[198] *See* Plaintiffs' Response in Opposition to Defendants' Motion in *Limine* No. 21 to Limit the Testimony of Steven Pliskow, M.D. and Jonathan Walker, M.D. at p. 8.
[199] N.T. 4/13/2011 a.m. at 84:5-9.
[200] See Plaintiffs' Response in Opposition to Defendants' Motion in Limine No. 17 to Exclude Expert Opinions of Scheffer C.G. Tseng, M.D., Ph.D., Exhibit 2.
[201] *See id.* at p. 6.
[202] *See id.*, at p. 15.

that Dr. Sanford was erroneously permitted to give expert testimony, despite being "merely a fact witness", is disingenuous. As previously noted, Dr. Sanford was duly qualified in the field of critical care and as a burn surgeon, including treatments related to patients that may have SJS and TEN.[203] He was also the physician primarily responsible for Brianna Maya's care and treatment at Shriner's Hospital.[204] Plaintiffs designated Dr. Sanford as an expert and produced a report which contained opinions reached in 2000 while treating Brianna. Dr. Sanford's opinions and conclusions were formed within the course and scope of the treatment rendered to Brianna Maya. Dr. Sanford based his treatment plan on his own experience and research, which resulted in a published and peer reviewed SJS/TEN study. Dr. Sanford's opinions also accounted for other possible causes of Brianna Maya's TEN, specifically Pediazole, and concluded that Children's Motrin was the sole cause of Brianna Maya's TEN.[205]

Defendant McNeil's contention that experts were allowed to testify to causation based upon individual adverse events or case reports which were not admissible and not a proper basis for determinations as to causation has been previously addressed, *see* discussion under the subheading *Legal Insufficiency of the Evidence to Support Plaintiffs' Claims, supra,* at p. 42. Notwithstanding, suffice it to state that the individual adverse event or case reports were admitted for the purpose of "notice" only, and the jury was instructed to consider them as such and for no other purpose. No additional comment is needed.

As to Defendant McNeil's argument that experts were permitted to testify beyond the scope of their reports, this trial judge opines that this is an overly broad assertion. Without a more defined citation, this trial judge is unable to address how this bald assertion warrants a new

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[203] N.T. 4/7/2011 a.m. at 62:7-11.
[204] *Id.* at 69:13-16.
[205] *See* Plaintiffs' Response in Opposition to Defendants' Motion in Limine No. 22 to Exclude "Expert" Opinions of Dr. Arthur Sanford, at p. 9.

trial. This trial judge made appropriate rulings to maintain admissible parameters of witnesses' testimony. To the extent that Defendant McNeil is opposing something not addressed in this opinion, this trial judge hesitates to guess what that may be.

As to Defendant McNeil's argument that the conglomeration of the opinions offered by Plaintiffs experts was improper and cumulative in that multiple experts gave opinions relating to causation of SJS or TEN by ibuprofen, generally, and in Brianna Maya's case, specifically, this contention has been given thorough discussion in *Legal Insufficiency of the Evidence to Support Plaintiffs' Claims, supra,* at p. 48. Suffice it to state that although some expert opinions may have overlapped, the experts addressed the "causation" issue from the perspective of their respective individual specialty. No error was committed because of this overlap, one that is expected, particularly, in the field of medicine and Brianna's extensive injuries.

Defendant McNeil asserts that various experts were permitted to testify to opinions based on "facts" not proven by competent evidence, including hearsay statements made by Sean Maya, Brianna Maya's natural father, who was not present at trial.[206] Similarly, Defendant McNeil argues that some experts were permitted to bolster their opinions with references to opinions testified to by other experts in the trial. A review of the transcript reveals that references to Sean Maya's statements were insignificant. Specifically, these references consisted of his involvement in taking his daughter to the doctor and calling his wife to tell her that she needed to pick up the prescription of Pediazole on her way home.

As to the expert bolstering allegation, this trial judge is aware that an expert witness cannot bolster his credibility by reading into the record the report of a non-testifying expert who has not been subjected to cross-examination. ***Cacurak***, *supra*, 823 A.2d at 172; *see, e.g.*, ***Oxford***

[206] Brianna Maya's parents divorced when she was still young and her mother remarried. Alicia Maya's husband was present during the trial.

Presbyterian Church v. Weil McLain Company, Inc., 815 A.2d 1094 (Pa. Super. 2003); ***Allen v. Kaplan***, 653 A.2d 1249 (Pa. Super. 1995), *appeal granted, in part*, 663 A.2d 692 (Pa. 1995), *motion granted*, 1997 Pa. LEXIS 2555 (Pa. Nov. 25, 1997) (new trial warranted where expert read into record report of non-testifying expert who had not been subjected to cross-examination; ***Cooper v. Burns***, 545 A.2d 935 (Pa. Super. 1988), *appeal denied*, 563 A.2d 888 (Pa. 1989). Relying on the cited case law, this trial judge opines that Defendant McNeil is mistaken in its argument that certain experts referred to opinions testified to by other experts testifying in the trial. Since those experts were *in* the trial and subject to cross-examination, no error occurred.

Additionally, of the six instances referenced by Defendant McNeil on this issue, three objections were never made and, therefore, any objection now articulated is considered waived; two contained no grounds for the objection, and one was based on the testimony offered at trial by Alicia Maya and Dr. Brewer (who testified via videotaped deposition).[207] Based upon the transcript review and case law, this contention is without merit.

Defendant McNeil's complaint that error was committed for allowing Plaintiffs' counsel to comment on its size and its "army of lawyers", has been addressed in *Prejudicial Misconduct by Plaintiffs' Counsel at Trial*, under the sub-heading *Alleged Prejudicial Comments About Defendant McNeil*, *supra*, at p. 67, and needs no further discussion except to reiterate that this trial judge issued a curative instruction to the jury instructing them to disregard any remark or inference to Defendant McNeil's net worth.[208]

Next, Defendant McNeil argues that error was committed in excluding evidence concerning Dr. Brewer's personal experience with and knowledge of SJS; *i.e.*; that she had suffered SJS. This issue arose when Plaintiff submitted a motion *in limine* seeking to exclude

[207] N.T. 3/30/2011 a.m. at 110:5-19.
[208] N.T. 5/18/2011 a.m. at 158:18-22.

the health status of persons other than Plaintiff, including Dr. Brewer.[209] At oral argument on the motion, counsel for Defendant McNeil agreed to such exclusions and deferred to this trial judge's ruling when portions of Dr. Brewer's deposition came up at trial.[210] However, upon solicitations by Plaintiffs' counsel to other witnesses regarding Dr. Brewer's knowledge of the relationship between rash, SJS/TEN and ibuprofen/Motrin, defense counsel asked the trial court to reconsider its motion *in limine* ruling to permit portions of Dr. Brewer's deposition where she testifies that she had SJS.[211] Specifically, the trial transcript reveals the following:

> Q. What did Dr. Brewer – did Dr. Brewer state she had knowledge of the relationship between rash and SJS or TEN when she was Brianna's treating physician in 2000 or not?
>
> A. She did not.
>
> Q. Did she also give testimony as to what she would have done had she had the knowledge which McNeil did not put in the Bible of the relationship between –
>
> MR. ABERNATHY: Objection.
>
> BY MR. JENSEN:
>
> Q. – rash and SJS and TEN had she knew? Did she –
>
> THE COURT: Sustained.[212]

- Q. Did Dr. Brewer without knowledge, in fact, recommend, knowing that Brianna was on Motrin coming in Monday, that she keep taking Motrin or not, sir?

  MR. ABERNATHY: Objection

  THE COURT: Sustained.[213]

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[209] Motion *in limine* docketed under Control No. 11031163.
[210] N.T. 3/22/2011 a.m. at 103:4-21.
[211] N.T. 5.16/2011 p.m. at 59:7-60:24.
[212] N.T. 4/12/2011 p.m. at 98:21-99:6.
[213] *Id.* at 100:2-6.

- Q. Were you in the courtroom when Dr. Brewer testified by video and said that she did not understand there was any relationship between rash, on the one hand, and SJS or TEN on the other hand.

  MS. JONES: Objection, Your Honor.

  THE COURT: Overruled.

  THE WITNESS: Yes, I was.

  BY MR. JENSEN:
  Q. And what's your understanding of that?

  A. That she did not know that there was any connection between the two.

  Q. So your doctor didn't know there was any connection between rash and SJS and TEN . . . .[214]

- Q. For a doctor who's relying on this document – not physicians you know, Dr. Stern. For a doctor like Dr. Brewer who does not know there's a relationship between rash and SJS/TEN, there's nothing in this document to tell them that, isn't that true?[215]

Defendant McNeil argues that a reasonable jury might have rejected Plaintiffs' arguments concerning the extent of Dr. Brewer's knowledge of SJS and TEN had it been aware that she herself developed that condition prior to her treatment of Brianna Maya. Defendant McNeil further argued that Plaintiffs' counsel falsely stated that Dr. Brewer did not know there was a relationship between rash, and thus, the information about Dr. Brewer's personal experience with SJS/TEN should have been offered to the jury. However, a review of the transcript shows that Plaintiff's counsel did not mislead the jury. In her deposition, Dr. Brewer stated that she, in fact, had no such knowledge of the relationship between a rash and SJS:

> So I am reading Dr. Brewer's testimony.
> Question by me: "Would it be fair or not, Dr. Brewer, to state that because you did not know that Ibuprofen, Motrin could cause SJS and TEN in 2000, that you also did not know that if someone had a rash or other involvement that could be leading to SJS to take them off Motrin?"

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[214] N.T. 4/21/2011 a.m. at 115:12-24.
[215] N.T. 5/11/2011 p.m. 51:4-8.

"Answer: Yes."[216]

This trial judge opines that no error was committed in granting the motion *in limine*, which precluded evidence that Dr. Brewer experienced SJS, as being irrelevant and immaterial. The question related to her knowledge as Brianna's pediatrician and the relationship between ibuprofen, Motrin, rash and SJS/TEN. Thus, the exclusion was not in error.

Next, Defendant McNeil contends that this trial judge erroneously allowed Plaintiffs to present evidence of the contents of the warnings on *prescription* ibuprofen labels for the purpose of arguing that the prescription label failed adequately to advise Brianna Maya's pediatrician of the risk of SJS or TEN. The issue before the jury was the adequacy of the warnings to consumers of the *over-the-counter* label and not the adequacy of the prescription label to warn a physician. While Defendant McNeil is correct that the warnings on the prescription label were presented to the jury, the evidence was allowed to demonstrate that Defendant McNeil had the means and knowledge to develop a label which would adequately warn consumers of the symptoms exhibited by Brianna Maya upon ingestion of OTC Children's ibuprofen, and the course of action the consumer should take. Plaintiffs countered with the argument that if the consumer does not appreciate the risks inherent to the use of the medication because it lacks an adequate label, when unseemly symptoms appear and the patient reports these to a doctor, the corresponding lack of information on the label read by the physician will also fail to enable that physician to advise the patient to stop use of the product. As stated by the experts, stopping the use of Children's Motrin at the first sign of a rash or blisters could possibly have lessened the harm suffered. It is noted that Defendant McNeil offered no satisfactory explanation for the difference in the warnings provided. In this trial judge's opinion no error was committed in

[216] N.T. 5/16/2011 p.m. at 61:13-20.

allowing this evidence. At most, any error committed was a harmless error which does not justify a new trial.

Next, Defendant McNeil argues that this trial judge erred in denying its motion in *limine* to exclude evidence of the 2005 Citizen's Petition since its content was irrelevant, hearsay, and unduly prejudicial. As background, the 2005 Citizen's Petition was a request directed to the FDA asking for the FDA either to withdraw approval of OTC ibuprofen or order that the label warning include information relating to SJS and TEN, and such terms as "life-threatening" and "death".[217] In its response to the Petition, the FDA declined to remove the product from the market, declined to require that companies add "SJS" and "TEN" on the label, and required class labeling applicable to all non-steroidal anti-inflammatory drugs (NSAID), including OTC ibuprofen labeling to contain the words "rash", "skin reddening", and "blisters".[218] When this trial judge queried defense counsel why they would object to this motion, Defendant McNeil responded that it did not object to the FDA's response to the Citizen's Petition, just to the contents of the Petition itself for the reasons stated and because it was submitted by paid expert witnesses on behalf of Plaintiffs.[219]

The content of the 2005 Citizen's Petition addresses Plaintiffs' theory of causation. Dr. Tackett's testimony expanded on this causation theory:

> Q. Any hint of Toxic Epidermal Necrolysis in the consumer label through 2000?
>
> A. No.
>
> Q. Any hint of the symptoms that relate to Toxic Epidermal Necrolysis in the label in the end of 2000?
>
> A. No.

[217] N.T. 3/22/2011 a.m. at 140:22-23; 141:11-19.
[218] *Id.* at 141:22-142:11.
[219] *Id.* at 142:12-143:7.

Q. Should there have been?

A. Yes.

Q. Did that later happen that the symptoms of SJS and TEN got in the label of the over-the-counter Ibuprofen?

A. Yes, after 2005.

Q. Did it happen after you filed your Citizen's Petition?

A. Yes.

Q. Is that one of the items of relief that you sought in your Citizen's Petition?

A. Yes.[220]

In this trial judge's opinion, the reference to the 2005 Citizen's Petition was relevant to Defendant McNeil's knowledge of risks associated with the use of OTC Children's Motrin yet failed to include warnings of those risks on the label.

Likewise, Defendant McNeil argues that this trial judge erred when denying its motion *in limine* requesting the preclusion of the 1984 Citizen's Petition and related litigation on the basis that these documents were irrelevant and unduly prejudicial. In its appeal, Defendant McNeil further contends that by denying this motion, this trial judge violated its First Amendment right to petition the government under the *Noerr-Pennington* doctrine, which immunizes an individual from liability for exercising his First Amendment right to petition the government. *See* ***Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.***, 365 U.S. 127, 5 L. Ed. 2d 464, 81 S. Ct. 523 (1961) and ***United Mine Workers v. Pennington***, 381 U.S. 657, 14 L. Ed. 2d 626, 85 A. Ct. 1585 (1965), both antitrust cases. As to this latter point, this trial judge opines that Defendant McNeil has waived this argument since it was not presented at any time during the course of the trial. As to the contention of irrelevancy, this trial judge disagrees.

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[220] N.T. 3/24/2011 p.m. at 89:2-17.

In order to address this contention, a brief review of the FDA actions to approv over- the-counter ibuprofen is appropriate. In 1974, the FDA approved ibuprofen for prescription use in the United States.[221] Sometime in 1983, Whitehall and Upjohn Company, two distinct pharmaceutical companies, sought approval to market adult ibuprofen over-the-counter and submitted to the FDA *New Drug Applications* (NDA). In May 1984, the FDA approved these NDAs and issued *a Summary Basis for Approval* (SBA) for the OTC switch, and stated that there were no significant differences in the rates of adverse reactions between ibuprofen and acetaminophen. At the time of these FDA approvals, Defendant McNeil manufactured only an acetaminophen product, and disagreed with "certain statements" in the SBA. On March 21, 1984, it submitted a Citizen's Petition opposing the approval for an adult ibuprofen over-the-counter medication. This petition was subsequently denied. On June 18, 1984, Defendant McNeil filed a petition for reconsideration requesting that the FDA delete certain comparisons between ibuprofen and acetaminophen, as it believed them to be inaccurate. Defendant McNeil urged the FDA to consider that the adult OTC label needed to warn, *inter alia*, that persons with kidney or liver disease should not use ibuprofen without first consulting a physician.[222]

During argument on this particular motion *in limine,* Defendant McNeil offered that the 1984 Citizen's Petition was submitted based on scientific data compiled more than two decades prior to the instant litigation and since it made no mention of SJS or TEN, this petition was not relevant. By way of the Petition, Defendant McNeil suggested that the ibuprofen labeling should include more specific warnings of injury to the kidneys, heart, and liver.[223] In response, Plaintiff argued that these disputed documents were relevant to the issue of label warnings, particularly,

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[221] Defendants' Motion *In Limine* No. 6 to Exclude Evidence of McNeil's 1984 Citizen's Petition and Subsequent Petition for Reconsideration, p. 2.
[222] *Id.*, p. 2-3; Plaintiffs' Response in Opposition to Defendants' Motion *In Limine* No. 6 to Exclude Evidence of McNeil's 1984 Citizen's Petition and Subsequent Petition for Reconsideration, p. 3.
[223] N.T. 3/22/2011 p.m. at 10:3-13:10.

what medical facts justify and/or mandate a label change (such that would have properly warned Alicia Maya of the risks of administering Children's Motrin to Brianna) and the position that Defendant McNeil took in 1984 to ensure proper labeling.[224] Plaintiffs further argued that Defendant McNeil's Petition contained statements that should be considered "admissions against interest"[225] to the federal government, since its then position with respect to the effects of OTC ibuprofen appears to be at odds with the position it takes in this litigation and at trial; to *wit*:

- "Of course, everyone agrees that Ibuprofen advertising must be true and not misleading, McNeil has and will continue to insist on this."
- "A safety and efficacy of Ibuprofen has yet to be established as safe for children."
- "There is an unsupportable suggestion that Ibuprofen had the safety and efficacy profile Superior to Acetaminophen."
- "The FDA approval of Ibuprofen for over-the-counter sale will have a direct and immediate impact and the sales of Tylenol will be damaged."
- "The Government contends that McNeil has conceded that Ibuprofen is safe and effective for OTC use. McNeil has made no such concession."
- "If Ibuprofen consumer labeling is inadequate, consumers by the thousands are daily being placed at unnecessary risks."[226]

Plaintiffs argue that these statements from the 1984 Citizen's Petition reflect Defendant McNeil's activism to advise the FDA of the risk of kidney, heart and liver injuries that warranted a label change in 1984. With this backdrop, Plaintiffs argue that Defendant McNeil should have taken a similar stance with regard to ensuring warnings about SJS/TEN were on its label, but failed to do so resulting in an inadequate label that did nothing to prevent Brianna's injuries. Persuaded by this rationale, this trial judge deemed the 1984 Citizen's Petition relevant and

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[224] N.T. 3/22/2011 p.m. at 13:12-23.

[225] Plaintiffs categorized these statements as "admissions against interest" which this trial judge notes is inaccurate and should be abandoned in that an admission differs from a statement against interest. *See* Ohlbaum, Pennsylvania Rules of Evidence, § 803.25[7][a].

[226] Oral argument on Defendants' Motion *In Limine* No. 6 to Exclude Evidence of McNeil's 1984 Citizen's Petition and Subsequent Petition for Reconsideration, N.T. 3/22/2011 p.m. at 14:6-17:6.

admissible, and that any probative value would outweigh any prejudicial effect.

To briefly comment on Defendant McNeil's attempt to invoke immunity offered by the *Noerr-Pennington* doctrine, this trial judge opines that in addition to the argument being waived, its reliance is misplaced. In the ***Eastern Railroad Presidents Conference,*** *supra,* the United States Supreme Court essentially held that an individual is immune from liability for exercising his First Amendment right to petition the government. This immunity existed regardless of the persons' motivation in waging their campaigns, as it recognized that the right of individuals to petition the government "cannot properly be made to depend on their intent in doing so." ***Id.,*** 365 U.S. at 139; ***Wawa, Inc. v. Alexander J. Litwornia & Assocs.***, 817 A.2d 543, 547 (Pa. Super. 2003).

The only instructive case cited by the parties from our jurisdiction[227] involves preliminary objections. There, the court held that immunity is an affirmative defense that the defendant shall plead as new matter in the answer. ***Phillips v. Selig***, 2001, Phila. Ct. Com. Pl. LEXIS 52, *14 (Phila. Ct. Comm. Pl. 2001), *aff'd*, 959 A.2d 420 (Pa. Super. 2008). The court stated "[b]ecause immunity raises fact issues, a court cannot sustain a preliminary objection asserting immunity unless immunity is clear from the face of the pleadings." ***Id.*** (citing ***Logan v. Lillie***, 728 A.2d 995, 998 (Pa. Commw. 1999), *subsequent appeal*, 753 A.2d 322 (Pa. Commw. 2000). The court reasoned that the "*Noerr-Pennington* immunity was not clear from the face of the pleadings and overruled the objections." ***Id.*** Here, Defendant McNeil did not plead immunity in the new matter section of its answer to Plaintiffs' complaint and now attempts to raise it to justify an alleged evidentiary error. This trial judge opines that this justification is without merit.

Lastly, Defendant McNeil claims that this trial judge erred in erroneously admitting evidence of the inadequacy of the FDA. This contention has been addressed. Suffice it to state,

[227] Defendant McNeil cites ***Mann v. Quality Old Time Serv. Inc.***, 120 Cal. App 4th 90, 108 (2004).

the record belies this contention. Without prompting from any counsel, this trial judge *sua sponte* issued a curative instruction immediately upon mention of the FDA being "underfunded, overburdened, and overtaxed". See *Alleged Prejudicial Comments About Defendant McNeil*, *supra*, page 67. Defendant McNeil's issue is unfounded and does not warrant a new trial.

Errors in the Charge Conference and Jury Instructions

Defendant McNeil's final contentions involve allegations of prejudicial errors committed during the charging conference and jury instructions. For the reasons discussed, this trial judge opines that the arguments lack merit.

The standard of review regarding jury instructions is limited to determining whether the trial court committed a clear abuse of discretion or error of law which controlled the outcome of the case. ***Gorman v. Costello***, 929 A.2d 1208, 1211 (Pa. Super. 2007); ***Quinby v. Plumsteadville Family Practice, Inc.***, 907 A.2d 1061, 1069 (Pa. 2006). *See also*, ***Hyrcza***, *supra*, 978 A.2d at 972 (citing ***Buckley v. Exodus Transit & Storage Corp.***, 744 A.2d 298, 305-6 (Pa. Super. 1999) (citation omitted)). A charge will be found to be adequate unless the issues are not made clear to the jury, or the jury was palpably misled by what the trial judge said, or unless there is an omission in the charge which amounts to a fundamental error. An inadequate jury charge or error in a charge may be sufficient ground for a new trial. In reviewing the instructions to the jury, the appellate court must look to the charge in its entirety and not take the challenged words or passage out of context of the whole of the charge. ***Quinby***, *supra*, 907 A.2d at 1069, 1070 (citations and quotations omitted); ***Fragale v. Brigham***, 741 A.2d 788, 790 (Pa. Super. 1999), *appeal denied*, 758 A.2d 662 (Pa. 2000). *See also*, ***McManamon v. Washko***, 906 A.2d 1259, 1271 (Pa. Super. 2006), *appeal denied*, 921 A.2d 497 (Pa. 2007) (quotation omitted); ***Fleishman v. General American Life Ins. Co.***, 839 A.2d 1085, 1087 (Pa. Super. 2003), *appeal denied*, 858

A.2d 110 (Pa. 2004) (quotation omitted). Even if a trial court has refused to give a proposed instruction that contained a correct statement of the law, a new trial will not be granted on the basis thereof if the substance of that instruction was covered by the trial court's charge as a whole. ***Fragale***, *supra*, 741 A.2d at 790; ***Southard v. Temple Univ. Hosp.***, 731 A.2d 603, 616 (Pa. Super. 1999), *rev'd, remanded*, 781 A.2d 101 (Pa. 2001) (citing ***Boutte v. Seitchik***, 719 A.2d 319 (Pa. Super. 1998)); and ***Santarlas v. Leaseway Motorcar Transp. Co.***, 689 A.2d 311 (Pa. Super. 1997).

Defendant McNeil incorrectly contends that error was committed when the jury was instructed that Defendant McNeil was subject to a "high degree" standard of care rather than the normal stand of care for negligence. Defendant McNeil is in the pharmaceutical business. There is no question that manufacturers of potentially dangerous drugs are held to a *high degree* of care. *See* ***Henderson v. National Drug Company***, 23 A.2d 743, 748 (Pa. 1942), where the court held: " . . . the public interest requires the holding of companies which make and sell drugs and medicine for use in the human body to a *high degree* of responsibility under both the criminal and civil law for any failure to exercise vigilance commensurate with the harm which would be likely to result from relaxing it." The Court went on to say, however, that this consideration did not justify the courts in lowering the standards of proof in cases of this kind. "If we did so, the public interest would be ill served." *See also*, ***Hahn***, *supra*, 628 A.2d at 864 (citing ***Incollingo v. Ewing***, 282 A.2d 206, 219 (Pa. 1971), *later proceeding*, 379 A.2d 79 (Pa. 1977) (emphasis added). Since the correct standard of care was properly issued, this trial judge opines that Defendant McNeil's contention on this point is without merit.

Next, Defendant argues that this trial judge erred by instructing the jury that it could consider "what happened with other drugs, such as other drugs being taken off the market, when

evaluating the defendant's conduct", thus, compounding the error (enumerated in statement of error paragraph 8, *supra*) of having admitted evidence relating to other alleged risks or adverse effects of Children's Motrin not suffered by minor Plaintiff. This trial judge is perplexed by this alleged error since Defendant McNeil was the proponent of this very instruction read *verbatim* to the jury. The jury instruction reads as follows:

> You heard reference to drugs other than ibuprofen that were removed from the market.
>
> * * *
>
> You may have heard reference to drugs other than ibuprofen that were removed from the market, or information that may have been reported to companies other than McNeil. You may consider the conduct of other pharmaceutical manufacturers, or what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct.[228]

At the conclusion of the jury instructions but before the jury was excused to deliberate, a sidebar conference was held. Defendant McNeil took exception with the instruction read, acknowledging, on the record, that the instruction was read exactly as submitted [by Defendant McNeil]. The sidebar discussion went as follows:

> . . . The defendants take exception to the instruction on the withdrawal of other drugs. As I heard the instruction, Your Honor, and --
>
> THE COURT: That was from you. That was your charge. I can show it to you. I stumbled, I couldn't read it.
>
> MR. ROBERSON: She did read it verbatim.
>
> MR. ABERNETHY: I'm happy to take a look at the instruction, Your Honor, but I think, as given, it instructed that, simply without qualification that they could consider other drugs and other conduct of other manufacturers. I don't think that's consistent with the law.
>
> THE COURT: Let the record reflect I read his charge as he submitted it to me.

[228] N.T. 5/19/2011 a.m. at 42:10-23.

MR. JENSEN: We agree you did, Your Honor. That was what they submitted.[229]

In this trial judge's opinion, Defendant McNeil cannot take exception to the jury instruction it submitted to this trial judge. Consequently, this allegation of error is without merit.

Defendant McNeil further posits that another error was committed in charging the jury on "concurring causes" defined in the Pennsylvania Standard Civil Jury Instructions (Pa. SSCJI (Civ.) 3.17, claiming that for the jury to receive said concurring causes charge, Plaintiffs must present evidence to support the possible concurring causes. A review of the matter of ***Shamnoski v. PG Energy***, cited in the Subcommittee Notes to Section 3.17, provides the proper foundation for a concurrent causes charge. *See* ***Shamnoski v. PG Energy***, 765 A.2d 297, 304 (Pa. Super. 2000), *rev'd other grounds*, 858 A.2d 589 (Pa. 2004). There, plaintiff argued that the sole factual cause of damages was the negligence of a damn owner in maintaining the damn, while the defendant blamed an act of God for an unusual storm. Here, this trial judge charged the jury as follows:

> You will be asked to determine whether the defendant's negligence was a factual cause of the plaintiff's injuries. Plaintiff may recover for all the injuries the defendant's conduct was a factual cause in producing. The defendant's conduct need not be the sole cause. Other causes may have also contributed.[230]

Plaintiffs steadfastly maintained that Children's Motrin was the sole cause of Brianna Maya's TEN reaction. However, Defendant McNeil's experts, particularly Dr. Stern, offered support for the proposition that something other than Children's Motrin, for instance, Pediazole, the antibiotic given to Brianna Maya just before her symptoms worsened, caused Brianna Maya's TEN reaction.[231] In light of these conflicting opinions, this trial judge opines that the instruction given of the possible causes of Brianna's injuries was proper and does not warrant a

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[229] N.T. 5/19/2011 a.m. at 69:6-25.
[230] N.T. 5/19/2011 a.m. at 39:4-11.
[231] N.T. 5/10/2011 a.m. at 41:10-14.

new trial.

Defendant McNeil further asserts that the trial court misguided counsel by informing them that the jury would be charged on the heeding presumption contained in Pa. SSCJI (Civ.) 8.03(b), which would have been an error under Pennsylvania law. This occurred during the charging conference when Defendant McNeil objected to Plaintiffs' submission on heeding presumption and this trial judge overruled the objection.[232] Although this trial judge ultimately did not give said instruction, Defendant McNeil contends that it limited the closing argument to conform to the court's indication and, therefore, did not argue that the evidence showed that Alicia Maya would not have acted differently even if the label had contained the additional language urged by Plaintiffs. Defendant McNeil further argued that the evidence supported a finding that Plaintiffs would have used the product even if that additional language had been on the label at the relevant time, and had the jury so found, Defendant McNeil could not have been found liable.

While it is an unfortunate event, this trial judge opines that there is no merit in Defendant McNeil's argument when the jury instruction that Defendant McNeil objected to was ultimately *not* given and no exception taken to its omission.[233] Under the circumstances, this allegation of error lacks merit and is further deemed waived. In addition, Defendant McNeil's argument makes little sense since the parties made their closing arguments *prior* to the jury receiving its instructions. Defendant McNeil could have made whatever remarks it wanted to on this issue since the court had indicated it would provide the charge after the closing arguments. It is further noted that if Defendant McNeil's argument was to have merit, the alleged error equally affected Plaintiffs. This trial judge, however, cannot comment on what Defendant McNeil *would*

[232] *See*, N.T. 5/17/2011 a.m. at 23:21-28:8.
[233] *See* Defendant McNeil's Motion for Post-Trial Relief, ¶72.

have argued had the court indicated at the charging conference that the instruction would not be given. Suffice it to state that nothing about the heeding presumption charge prevented Defendant McNeil from making the argument. The heeding presumption is not an absolute declaration nor tantamount to a directed verdict on the issue of factual causation (here, that Alicia Maya would not have acted differently even if the label had contained the additional language urged by Plaintiffs); rather, it is merely a rebuttable presumption for which a party is allowed to rebut with evidence. *See,* ***Coward***, ***Coward v. Owens-Corning Fiberglass Corp.***, 729 A.2d 614, 621 (Pa. Super. 1999), *appeal granted*, 743 A.2d 920 (Pa. 1999). In this context, the Pennsylvania Superior Court expounded that:

> While the heeding presumption benefits a failure to warn plaintiff, it does not change the fact that he still bears the burden of persuasion . . . The heeding presumption [is] rebuttable, and thus, when the opponent of the presumption has met the burden of production thus imposed . . . the office of the presumption has been performed; the presumption is of no further effect and drops from the case. To get past the presumption and to a jury, the opponent of the presumption need only introduce evidence sufficient to support a finding contrary to the presumed fact.

Coward, *supra*, 729 A.2d at 621.

Under the circumstances, this trial judge opines that Defendant McNeil did not suffer any prejudice in the court's omission of the heeding presumption charge.

CONCLUSION

Based on the foregoing discussion, this trial judge is of the opinion that Defendant McNeil's appeal should be quashed on the grounds that the Pa. R.A.P. 1925(b) statement of errors complained of on appeal failed to adhere to proper legal procedure.

In the alternative, in the event that Defendant McNeil's appeal is deemed proper, based upon the analysis and discussion offered, this trial judge opines that no errors of law were committed in denying Defendant McNeil's motion for post-trial relief which warrant the granting of any of the remedies sought. Thus, this trial judge respectfully requests that Defendant's appeal be denied and that the Orders dated May 24, 2011 and October 17, 2011 be affirmed.

BY THE COURT:

NITZA I. QUIÑONES ALEJANDRO, J.

2014 PA Super 152

ALICIA E. MAYA, INDIVIDUALLY, AND BRIANNA MAYA, BY AND THROUGH HER NATURAL PARENT AND GUARDIAN	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
JOHNSON AND JOHNSON AND McNEIL-PPC, INC.	:	
APPEAL OF: McNEIL-PPC, INC., Appellant	:	No. 3259 EDA 2011

Appeal from the Order Dated October 18, 2011,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. February Term, 2009, No. 002879

ALICIA E. MAYA, INDIVIDUALLY AND BRIANNA MAYA, BY AND THROUGH HER NATURAL PARENT AND GUARDIAN	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
JOHNSON & JOHNSON AND McNEIL-PPC, INC.	:	
APPEAL OF: McNEIL-PPC, INC., Appellant	:	No. 471 EDA 2012

Appeal from the Order Dated January 6, 2012,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. February Term, 2009, No. 002879

BEFORE: FORD ELLIOTT, P.J.E., WECHT AND MUSMANNO, JJ.

OPINION BY FORD ELLIOTT, P.J.E.:**FILED JULY 22, 2014**

McNeil-PPC, Inc., appeals[1] from the order of January 6, 2012,[2] entering final judgment for plaintiffs/appellees for $10 million, plus statutory post-judgment interest, in this pharmaceutical failure to warn case. After careful review, we affirm.

The trial court has aptly summarized the facts of this case as follows:

> The salient facts which occurred within a week's span of time and the procedural history, as defined by the pleadings, memoranda, trial testimony and exhibits, can be summarized as follows:
>
> > On Saturday, November 25, 2000, Brianna Maya (Brianna) was a three-year old girl residing with her parentes [sic] in

[1] Co-defendant Johnson & Johnson was dismissed as a party at the conclusion of trial.

[2] McNeil also appealed from the October 18, 2011 order denying its post-trial motions.

> Generally, an appeal will only be permitted from a final order unless otherwise permitted by statute or rule of court." ***Johnston the Florist, Inc. v. TEDCO Constr. Corp.***, 441 Pa.Super. 281, 657 A.2d 511, 514 (1995). An appeal from an order denying post-trial motions is interlocutory. ***Id.***; Pa.R.A.P. 301(a), (c), and (d). An appeal to this Court can only lie from judgments entered subsequent to the trial court's disposition of post-verdict motions, not from the order denying post-trial motions. ***Id.***

Fanning v. Davne, 795 A.2d 388, 391 (Pa.Super. 2002), ***appeal denied***, 825 A.2d 1261 (Pa. 2003). Accordingly, we will dismiss the appeal at No. 3259 EDA 2011 as interlocutory and superseded by the subsequent appeal at No. 471 EDA 2012.

Martin, Tennessee. That evening, she attended a play with her grandmother, Marilyn Crist, who testified that during the intermission, she called her daughter, Alicia E. Maya (Brianna's mother/Ms. Maya), inquiring whether she should take Brianna home since the child was coughing and felt slightly warm. To not disappoint her daughter, Ms. Maya advised her mother to stay and watch the rest of the play. When she arrived home around 10:30 p.m., Ms. Maya gave Brianna a dose of over-the-counter (OTC) Children's Motrin, a medication manufactured by Defendant McNeil, for the fever that had developed.

Early Sunday morning, November 26, 2000, Ms. Maya was awoken by Brianna, who was still feverish. She gave Brianna a second dose of OTC Children's Motrin. Around 4:00 p.m., Ms. Maya noticed a rash on Brianna's neck near the top of her chest. She did not perceive this rash to be a life-threatening allergic reaction since Brianna had experienced a similar rash sometime in February 1999. This time, however, Brianna's eyes were pinkish. A third dose of OTC Children's Motrin was given to Brianna after Ms. Maya spoke with Susan Brewer, M.D., Brianna's pediatrician, who instructed her to alternate OTC Children's Motrin with OTC Children's Tylenol. Throughout the day, Brianna was given two additional doses of OTC Children's Motrin, alternated with OTC Children's Tylenol for her fever.

Ms. Maya testified that prior to administering the OTC Children's Motrin to Brianna, she read the label and dose instructions. She recalled that the warnings on the label indicated that

"hives, wheezing, facial swelling, or shock" could result from consuming OTC Children's Motrin, and to "call your doctor" if symptoms persisted.

Due to Brianna's persistent fever, Ms. Maya decided Brianna should be examined by Dr. Brewer. On Monday, November 27, 2000, Sean Maya, Brianna's father, took his daughter to Dr. Brewer, who examined and diagnosed Brianna with mycoplasma pneumonia, and prescribed Pediazole. Ms. Maya picked up the prescription later that day and when she arrived home around 6:00 p.m., she found Brianna screaming, crying, and complaining that her "pee pee hurt." Ms. Maya observed that Brianna's eyes were red with a runny discharge and that she had a fever, red lips, and a collar of red rash on her chest. After carefully reading the dosing instructions, Ms. Maya gave Brianna a dose of the Pediazole antibiotic, and continued alternating OTC Children's Motrin and OTC Children's Tylenol throughout the evening. Ms. Maya testified that if the warnings on the Children's Motrin label had advised to "stop use" upon presentation of certain symptoms, she would have done so.

On Tuesday morning, November 28, 2000, Brianna was rushed to Volunteer Hospital in Martin, Tennessee, with a rapidly spreading rash over her entire body, her eyes red with discharge, and blisters on her mouth, chest and vaginal area. On Dr. Brewer's recommendation based upon the severity of her worsening condition, Brianna was emergently transferred to Lebonheur's Children's Hospital in Memphis, Tennessee, later that same day.

By the early morning hours of Wednesday, November 29, 2000, Brianna's rash had developed into blisters that rapidly spread and erupted all over her body and her eyes had swollen shut. Because of the increased risk of infection from so many open blisters and wounds, Brianna underwent several debridements (forcefully sloughing off the skin using a highly abrasive material), requiring skin grafts of either pigskin or cadaver skin to protect the exposed underlying skin. Brianna quickly deteriorated and was monitored in the intensive care unit for rapidly decreasing blood oxygen levels.

On Friday, December 1, 2000, a medical decision was made to transfer Brianna to Shriner's Burn Hospital in Texas, which occurred around midnight via a private jet plane. Upon arrival at Shriner's Hospital, approximately 84.5% of Brianna's total body surface was covered with open, burn-like wounds. (In the presentation of the evidence, the jury was shown numerous photos of Brianna taken contemporaneously with the treatment rendered).

For several days, Brianna's symptoms continued to worsen and she experienced a drop in blood pressure, hypoxia (decreasing oxygen), fluid in her lungs, which had to be continually suctioned out, and internal bleeding, which required multiple blood transfusions. Her open wounds covered the majority of her body to such an extent that family members could only touch the tip of one unaffected toe. Brianna was sedated to help the healing process and relieve the excruciating pain.

Arthur Peter Sanford, M.D., the primary treating burn surgeon at Shriner's Burn Hospital, testified that approximately nine days after the first onset of symptoms, the medical staff determined that the possible cause of Brianna's condition was the ingestion of OTC Children's Motrin (pediatric ibuprofen). Dr. Sanford testified that Brianna's condition was diagnosed as toxic epidermal necrolysis (TEN), described as an especially severe form of Stevens Johnson Syndrome (SJS), a rare but life-threatening disease that causes severe blistering and sloughing off of skin, together with serious damage to the mouth, eyes, throat, and esophagus. Treatment for the disease is similar to that given burn victims, as the separation of the top layer of skin from the deeper layers of skin, is akin to a second-degree or partial-thickness burn.

Brianna remained hospitalized at Shriner's Burn Hospital until December 16, 2000. Thereafter, she was discharged to the Ronald McDonald House adjacent to the hospital where she remained until December 19, 2000, at which time she and her family returned to Martin, Tennessee. However, because TEN affected the mucus membranes of Brianna's eyes requiring specialized treatment, the family relocated to Clearlake, Texas.

Scheffer Tseng, M.D., Brianna's treating ophthalmologist since 2002, opined that Brianna suffered severe eye damage as a result of the TEN reaction as early as December 3, 2009. Dr. Tseng described part of the eye injuries as adhesion and scar tissue on

and between the eyelid and the eyeball, which occurred after the skin sloughed off, causing difficulty with blinking and fully closing the eyelids. Dr. Tseng stated that because of the constantly changing nature of the eyes, a TEN reaction is ongoing and that there is no cure for Brianna's ocular damage or blindness.

Brianna has undergone 16 eye surgeries, all reportedly necessitated because of complications of the TEN reaction. These surgeries were performed at Shriner's Burn Hospital by lead eye surgeon, Brian Wong, M.D., primarily to address the eyelid adhesions and to correct a condition where the eye lashes were growing inward. Eventually, the eyelash follicles were removed via electrolysis to prevent the lashes' inward growth and the constant scratching to the surface of the eye balls which was causing eye irritation and damage.

Ms. Maya testified that due to Brianna's TEN complications, Brianna has had to make lifestyle changes which include, *inter alia*, avoiding exposure to sunlight that can be damaging to her eyes; and strenuous activity in high, humid temperatures due to her inability to perspire normally, pulmonary fibrosis, and the scarring in the lungs which makes respiration difficult and increases the risk of asthmatic attacks and upper respiratory infections.

Steven Pliskow, M.D., an expert obstetrician gynecologist, testified that Brianna suffered gynecological complications due to TEN, which became more evident as Brianna matured into a young lady. He described the fact that

Brianna suffered a complete fusion of both sides of the vaginal wall, which resulted in hematometra and retrograde menstruation, as confirmed by a MRI and ultrasound. Both conditions involved blocked blood in Brianna's uterus, which because of scarring caused the menses to back up through the Fallopian tubes into the abdominal cavity instead of discharging as normal menstruation. Dr. Pliskow testified that the danger of menstrual blood backing up into the abdominal cavity is that it can lead to infection and/or endometriosis, where the lining of the uterus grows inside the abdominal cavity, creating further scarring, abdominal pain, and future complications. While several surgical procedures performed by Dr. Pliskow successfully enabled Brianna to have normal menstruation, Dr. Pliskow opined that the extent of damage to her reproductive system caused by TEN will bar her from having normal intercourse and childbirth. He opined that she would be able to produce a child through in-vitro fertilization carried by a surrogate.

Ms. Maya testified that she would *not* have used OTC Children's Motrin if she had seen the word "blisters" on the package because a medicine should not cause blisters. Ms. Maya also testified that she does not believe, based on the 13½ years of administering OTC Children's Tylenol to her daughter, that Brianna has ever had a reaction to OTC Children's Tylenol.

At trial, both parties presented numerous experts who offered opinions addressing causation, what warnings were and should be on the OTC

> Children's Motrin label, and the relevant scientific studies that had been conducted.

Trial court opinion, 1/7/13 at 4-8 (footnotes and citations to the record omitted) (emphasis in original).

Following a nine-week jury trial, the jury found in favor of Brianna Maya and against McNeil in the amount of $10 million on the negligent failure to warn claim.[3] The jury found in favor of McNeil on the remaining claims for negligent design defect and punitive damages. Post-trial motions were denied, and this appeal followed. McNeil complied with Pa.R.A.P., Rule 1925(b), 42 Pa.C.S.A., and the trial court has filed a Rule 1925(a) opinion.[4]

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[3] Following presentation of the evidence, Johnson & Johnson and Alicia Maya were dismissed as parties, although Mrs. Maya remained as a plaintiff in a representative capacity. Additional claims including strict liability were dismissed, and the plaintiffs voluntarily withdrew a claim for fraudulent misrepresentation. (***Id.*** at 9.)

[4] The trial court observes that McNeil's Rule 1925(b) statement was 11 pages, containing 23 paragraphs, some of which contained numerous sub-issues. (Trial court opinion, 1/7/13 at 19.) The trial court advocates waiver, citing this court's decision in ***Kanter v. Epstein***, 866 A.2d 394 (Pa.Super. 2004), ***appeal denied***, 880 A.2d 1239 (Pa. 2005), ***cert. denied***, ***Spector, Gadon & Rosen, P.C. v. Kanter***, 546 U.S. 1092 (2006), in which this court held that where an appellant's concise statement raises an unduly large number of issues (104 in ***Kanter***), the purpose of Rule 1925 is effectively subverted. However, Rule 1925(b) was revised in 2007 and now states, "Where non-redundant, non-frivolous issues are set forth in an appropriately concise manner, the number of errors raised will not alone be grounds for finding waiver." Pa.R.A.P. 1925(b)(4)(iv). In addition, in ***Eiser v. Brown & Williamson Tobacco Corp.***, 938 A.2d 417 (Pa. 2007) (plurality), our supreme court held that a litigant will not suffer the loss of appellate review due to the volume of issues raised in the absence of bad

McNeil raises the following issues for this court's review:

1. Did the trial court err in concluding a reasonable juror could find McNeil negligent for failing to change an "Allergy Alert" on over-the-counter Children's Motrin by adding warnings about a specific skin condition (SJS/TEN) when the FDA drafted the Allergy Alert aware of a possible link between ibuprofen and SJS/TEN; the FDA rejected McNeil's requests to strengthen the Allergy Alert; and no additional scientific information was unearthed before the injuries here that showed any need for further warnings?

2. Did the trial court err in concluding a reasonable juror could find that the addition of "skin reddening," "rash," or "blisters" to the Allergy Alert would have caused Alicia Maya to refrain from giving her daughter, Brianna Maya, ibuprofen when Ms. Maya testified that she relied on a doctor's advice rather than the label in deciding to give the medication?

3. Did the trial court err in concluding a reasonable juror could have found the addition of "rash" to the Allergy Alert would have prevented the injuries when (a) Ms. Maya testified she relied on a doctor's advice and the doctor advised her to continue ibuprofen after a rash appeared and (b) no expert testified to

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faith. The ***Eiser*** court also distinguished ***Kanter*** on the basis that ***Kanter*** was a relatively straightforward breach of contract action while the lawsuit in ***Eiser*** was a complicated one with a voluminous record. The court in ***Eiser*** observed that "on rare occasions a party may, in good faith, believe that a large number of issues are worthy of pursuing on appeal." ***Id.*** at 427 (footnote omitted). Instantly, as in ***Eiser***, the subject lawsuit is complex and the record contains thousands of pages of testimony. Furthermore, there is no evidence of bad faith or an attempt to thwart the appellate process. We note that McNeil did winnow down the number of issues actually argued in its brief on appeal. Therefore, we decline to find waiver.

a reasonable degree of medical certainty that stopping ibuprofen after the rash would have changed the outcome?

4. Is McNeil entitled to a new trial because the trial court permitted plaintiffs to argue that Brianna Maya's doctor did not understand the relationship between rashes and SJS/TEN, but barred the doctor's testimony that she previously had SJS herself?

5. Is McNeil entitled to a new trial because the trial court told counsel before closings that it would instruct the jury to presume Ms. Maya would have read and heeded their proposed warning if given, thus precluding defense counsel from arguing that the warning would not have mattered, even though the court later did not give the improper instruction?

6. Is McNeil entitled to a new trial because the trial court instructed the jury that it could consider evidence about the withdrawal of other drugs?

7. Is McNeil entitled to a new trial because the trial court instructed the jury that it could find McNeil liable if ibuprofen combined with something else to cause the injury, even though no expert testified that multiple agents combined to cause the injuries?

8. Is McNeil entitled to a new trial because the trial court admitted irrelevant evidence about (a) an alleged failure to warn of un-manifested risks, (b) adverse event reports and other evidence postdating Brianna's injuries, (c) warnings the FDA rejected, (d) advertisements plaintiffs never saw, and (e) foreign regulatory matters?

9. Is McNeil entitled to a new trial because plaintiffs' counsel repeatedly disregarded the

trial court's rulings and made prejudicial comments?

10. Did McNeil's Rule 1925(b) statement waive these issues?

McNeil's brief at 4-5.

> When reviewing the propriety of an order granting or denying judgment notwithstanding the verdict, we must determine whether there is sufficient competent evidence to sustain the verdict. ***Johnson v. Hyundai Motor America***, 698 A.2d 631, 635 (Pa.Super.1997), ***appeal denied***, 551 Pa. 704, 712 A.2d 286 (1998) (citations omitted); ***Rowinsky v. Sperling***, 452 Pa.Super. 215, 681 A.2d 785, 788 (1996), ***appeal denied***, 547 Pa. 738, 690 A.2d 237 (1997) (quoting ***Samuel Rappaport Family Partnership v. Meridian Bank***, 441 Pa.Super. 194, 657 A.2d 17, 20 (1995)). We must view the evidence in the light most favorable to the verdict winner and give the verdict winner the benefit of every reasonable inference arising therefrom while rejecting all unfavorable testimony and inferences. ***Johnson***, ***supra*** at 635; ***Rowinsky***, ***supra*** at 788. We apply this standard in all cases challenging the grant of a motion for J.N.O.V. ***Shearer v. Reed***, 286 Pa.Super. 188, 428 A.2d 635, 637 (1981).
>
> Pennsylvania law makes clear that a judgment notwithstanding the verdict is proper only in clear cases where the facts are such that no two reasonable minds could disagree that the verdict was improper. ***Johnson***, ***supra*** at 635; ***Rowinsky***, ***supra*** at 788. Questions of credibility and conflicts in evidence are for the fact-finder to resolve. ***Commonwealth, Department of Transportation v. Patton***, 546 Pa. 562, 568, 686 A.2d 1302, 1305 (1997); ***Miller v. Brass Rail Tavern, Inc.***, 702 A.2d 1072, 1076 (Pa.Super.1997) (citation omitted). This Court will not substitute its judgment based upon a cold record for that of the fact-finder where issues of credibility and weight are concerned. ***Id.***

Birth Center v. St. Paul Companies, Inc., 727 A.2d 1144, 1154-1155 (Pa.Super. 1999).

McNeil's first three issues relate to the negligent failure to warn claim and causation. First, McNeil argues that it is entitled to judgment as a matter of law because its label was drafted by the FDA. McNeil claims that it could not be found negligent for failing to add "skin reddening," "rash," and "blisters" to the list of symptoms in the Allergy Alert when they were not required by the FDA. McNeil is mistaken. ***See Wyeth v. Levine***, 555 U.S. 555, 570-571 (2009) (rejecting a federal preemption argument and stating 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."). ***See also Daniel v. Wyeth***, 15 A.3d 909, 932 (Pa.Super. 2011), ***appeal granted in part***, 32 A.3d 1260 (Pa. 2011), ***appeal dismissed as improvidently granted***, 82 A.3d 942 (Pa. 2013) (it was for the jury to decide whether Wyeth performed adequate testing of its product before marketing it for sale, regardless of purported compliance with FDA testing requirements).

McNeil also contends that the plaintiffs failed to establish causation, ***i.e.***, that adding "skin reddening," "rash," or "blisters" to the Allergy Alert would have prevented or mitigated Brianna Maya's injuries. According to

McNeil, Mrs. Maya relied on Dr. Brewer's advice and would have administered OTC Children's Motrin to Brianna with or without the additional warnings.

> 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.

Cochran v. Wyeth, Inc., 3 A.3d 673, 676-677 (Pa.Super. 2010), ***appeal denied***, 20 A.3d 1209 (Pa. 2011) (internal quotation marks and citations omitted).[5]

Mrs. Maya testified that she would not have administered Children's Motrin to Brianna if the label had warned her about the possibility of skin rashes, blisters etc.

> Q. And how, if at all, would it have affected your thought process if you looked at the labels for Tylenol and Motrin and you saw nothing about skin reddening, rash, or blisters on the Tylenol label and you saw that it had that in the Motrin

[5] We note that the learned intermediary doctrine does not apply here because Children's Motrin is an over-the-counter drug, so McNeil's duty of care runs directly to the consumer. "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." ***Cochran***, 3 A.3d at 676 (citation omitted).

label, and throw in if you had known that Tylenol had a superior safety profile to Motrin, how, if at all, would that have affected your purchasing decision without Dr. Brewer being a part of this equation?

A. It would have been a no-brainer which medication to purchase, and it would have been Tylenol.

Q. Same question for life-threatening skin reactions. Had that been on the Motrin label, but not on the Tylenol label without Dr. Brewer involved, how would that have affected your purchasing decision, if at all?

A. Same thing, the Motrin wouldn't have been purchased.

Q. Is there any relationship between what your thought process would have been in 2000 in making these purchasing decisions and what you told us about on last Thursday, your choice to endure 36 hours of labor pain for a miniscule risk that may last a couple days, like drowsiness?

MS. JONES: Objection.

THE WITNESS: Yes, absolutely.

BY MR. JENSEN:

Q. How so?

A. I went through 36 and-a-half labors (sic) did not get an epidural or any kind of pain medication simply because I did not want my child to have a minimal or small chance of being groggy after being born. And it's that same mindset that, you know, that I tell you that if I would have known that Motrin could cause all of the things that it has caused my

> daughter, including nearly taking her life, there is no way that I would have purchased it.

Notes of testimony, 4/26/11, a.m. session at 45-46.

McNeil complains that the above hypothetical question excludes Dr. Brewer from the equation, and Mrs. Maya testified that she relies on Dr. Brewer's medical advice. She followed Dr. Brewer's recommendation to alternate doses of Tylenol and Children's Motrin. However, Mrs. Maya also testified that she would have stopped administering Children's Motrin when Brianna first broke out in a rash:

> Do you recall I asked you questions about how many additional doses of Motrin you would not have given Brianna if the label that you had hypothetically stated something it did not state, which is, the hypothetical that it would have stated, "Stop use and call your doctor if," as opposed to the label that you got, just said "Call your doctor if," contrary to what the FDA said should be the case; do you recall that?
>
> A. Yes.
>
> Q. So -- and do you recall when I asked you that, you said had the label said something it did not state, "Stop use and call your doctor if," that you gave the answer that she would have [sic] not have been given four to five additional doses; do you recall that?
>
> A. Yes, that's correct.
>
> Q. And I want to see whether or not we can clear that up. Were you estimating how many she would not have been given had the label said "Stop use," which it didn't say, or please explain?

A. I said she would not have gotten four to five additional doses simply because of when the rash presented, and the fact that she was given Motrin right around the time that the rash presented, so I said four or five.

Q. So do I have it right that you intentionally said four or five because it happened at the same time?

A. Correct.

Q. Okay. And let me reorient the jury. First of all, this is the label I'm now showing, the one that you had -- you believe you had in your possession. It doesn't say "Stop use," it just says "Call your doctor if"?

A. That's correct.

Q. And the jury saw your timeline, and I'm going to go to what you're referring to; and do you understand that this would be your timeline on Sunday at 4:00 p.m.?

A. That is correct.

Q. And tell us what it says here, please, and how it relates to what you just told us that you intentionally said she wouldn't have gotten four or five additional doses, please?

A. At 4 o'clock it says Brianna had red rash on upper chest and lower neck and that she was given a dose of Motrin by me. So that is why I said four or five, because if I would have seen the rash or if it would have said "Rash" she never would have gotten that dose of medication or any of the subsequent doses of medication.

Q. So you said -- is it right to say you said four or five because you're not exactly sure which

> happened first right around 4 o'clock on Sunday?
>
> A. Right, the rash and getting Motrin, that was right in the same timeframe.

Notes of testimony, 4/26/11, a.m. session at 87-89.

Therefore, there was testimony that an adequate warning would have prevented Brianna from receiving the last four or five doses of Children's Motrin. Moreover, two of appellees' expert witnesses testified that stopping the Children's Motrin sooner would have substantially improved Brianna's prognosis. (Trial court opinion, 1/7/13 at 44-46.) For example, Randall Tackett, Ph.D., a pharmacologist/toxicologist, testified that it is crucial to stop using ibuprofen right away if the person develops a skin rash or blisters, and that this information should have been included in the 2000 label:

> We know from the literature that has been -- it's like with every drug, is that if the drug is causing something, then the sooner you stop it, then the side effect is going to be abated or go away. And so it's very important that it tells consumers that to -- they need -- if any of these symptoms occur, that they need to stop the drug because these symptoms may be associated with very serious consequences that if you continue to take the drug can develop.
>
> Q. And here it says, "Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms": And one of the bullet points is skin rash or blisters with fever. Do you see that, Dr. Tackett?
>
> A. I do.

> Q. Was that information, or any information like it, available on the label in 2000 over the counter when Miss Alicia Maya purchased the Children's Motrin for her daughter, Brianna Maya?
>
> A. No.
>
> Q. Should it have been, in your opinion?
>
> A. Yes, it's very important.
>
> Q. Why?
>
> A. Because those are the early signs of SJS and TEN.

Notes of testimony, 3/25/11, a.m. session at 56-58.

> What's very important is we know that if you continue taking the drug, that it can continue to get worse; and so it's important to stop it at the very early signs. And we know that the prognosis or the ability to recover from it is much improved the sooner you stop the drug.

Notes of testimony, 4/4/11, a.m. session at 77-78.

Similarly, John T. Schulz, M.D., testified that stopping the medication sooner would have lessened Brianna's injuries:

> Q. . . . And why is it relevant to your conclusion, Dr. Schulz, that she kept taking Motrin?
>
> A. Well, I mean, it's relevant to the conclusion only insofar as because we know that the causative agent -- getting rid of the causative agent as fast as possible might kind of decrease the severity of the syndrome once it starts. It's relevant that she was still getting it as she's getting very ill.

> Q. And do you know of evidence or studies that pertain to that very testimony you just gave, that --
>
> A. Yes, there are.
>
> Q. And what is it?
>
> A. Well, the evidence, Garcia-Doval was the principal author on that paper.
>
> Q. And what's the evidence that's provided by that?
>
> A. The evidence is -- and it's really the only thing that we have to offer, besides critical care, is try to stop the offending medication; and the evidence was that people in whom it was stopped faster, or in whom it was stopped and were on very short half-life drugs but washed out of their system fast tended to do better.

Notes of testimony, 3/30/11, a.m. session at 122-123.

> Q. And how relevant is it that she's still on Motrin, she's got her 7th dose at 9:00 p.m. Monday night, her 8th dose at, if I can move this and find out, 3:00 a.m. early Tuesday morning, how relevant are these matters to your opinion that she had this – she was getting worse?
>
> A. It matters because she's descending into in [sic] this firestorm of a disease, and the causative agent is still being given. That's why it matters.

Id. at 123-124.

Therefore, as the trial court states, there was sufficient evidence presented as to causation:

> the evidence of record supports the jury's findings that had the warnings on the label included the

> language sought by Plaintiffs, Ms. Maya would not have bought the medication, and/or would have stopped giving her daughter the drug at the first signs of symptoms. The injuries Brianna suffered conceivably may not have been as devastating.

Trial court opinion, 1/7/13 at 47.

Next, McNeil argues that the trial court erred by excluding evidence that Dr. Brewer actually suffered from SJS/TEN herself approximately ten years before Brianna developed SJS/TEN. At trial, plaintiffs' counsel argued that Dr. Brewer was unaware of any relationship between rash and SJS/TEN. Plaintiffs theorized that if the warning label had included this information, Dr. Brewer would have told Mrs. Maya to stop use immediately. McNeil wanted to rebut this evidence with Dr. Brewer's deposition testimony that she herself had SJS/TEN around 1990. According to McNeil, Dr. Brewer must have known of a relationship between rash and SJS/TEN regardless of the warning label.

> "The admissibility of evidence is a matter addressed solely to the discretion of the trial court and may be reversed only upon a showing that the court abused its discretion." ***Commonwealth v. Marshall***, 743 A.2d 489, 492 (Pa.Super.1999), ***appeal denied***, 563 Pa. 613, 757 A.2d 930 (2000) (citation omitted). "Thus our standard of review is very narrow . . . . To constitute reversible error, an evidentiary ruling must not only be erroneous, but also harmful or prejudicial to the complaining party." ***McManamon v. Washko***, 906 A.2d 1259, 1268-1269 (Pa.Super.2006), ***appeal denied***, 591 Pa. 736, 921 A.2d 497 (2007) (citations omitted).

Klein v. Aronchick, 85 A.3d 487, 491 (Pa.Super. 2014).

First, we observe that plaintiffs' counsel's assertion that Dr. Brewer did not understand the relationship between rash and SJS/TEN is based on the following exchange from her deposition:

> Would it be fair or not, Dr. Brewer, to state that because you did not know that Ibuprofen, Motrin could cause SJS and TEN in 2000, that you also did not know that if someone had a rash or other involvement that could be leading to SJS to take them off Motrin? Answer: Yes.

Notes of testimony, 5/16/11, p.m. session at 61. So, Dr. Brewer did not state that she did not appreciate the relationship between rash and SJS/TEN; rather, she stated that she did not know that ibuprofen could cause SJS/TEN. The trial court agreed, stating,

> Hold on a second. Hold on. Your question is a little different. Your question is if someone doesn't know, if someone had a rash to take them off Motrin. The question that you asked Dr. Stern is that there is a relationship between rash and SJS. It's very different.

Id. at 62.[6]

At any rate, McNeil failed to establish that rash is always a precursor to SJS/TEN. Therefore, Dr. Brewer's testimony that she had SJS ten years earlier would not prove that she was aware of a relationship between rash and SJS. The entire premise of McNeil's argument fails. Without proof that

[6] Plaintiffs' counsel asked Robert Stern, M.D., "For a doctor like Dr. Brewer who does not know there's a relationship between rash and SJS/TEN, there's nothing in this document to tell them that; isn't that true?" (Notes of testimony, 5/11/11, p.m. session at 51.)

rash always accompanies SJS, Dr. Brewer's testimony in this regard is wholly irrelevant. The trial court did not err in excluding this evidence.

Next, McNeil asserts it is entitled to a new trial because the trial court erred by failing to give a heeding presumption instruction to the jury.

> "[I]n cases where warnings or instructions are required to make a product non-defective and a warning has not been given, the plaintiff should be afforded the use of the presumption that he or she would have followed an adequate warning, and that the defendant, in order to rebut that presumption, must produce evidence that such a warning would not have been heeded." ***Coward v. Owens-Corning Fiberglas Corp.***, 729 A.2d 614, 621 (Pa.Super.1999), ***appeal granted***, 560 Pa. 705, 743 A.2d 920 (1999). "If the defendant produces evidence that the injured plaintiff 'was fully aware of the risk of bodily injury, or the extent to which his conduct could contribute to that risk,' the presumption is rebutted and the burden of production shifts back to the plaintiff to produce evidence that he would have acted to avoid the underlying hazard had the defendant provided an adequate warning." ***Coward***, 729 A.2d at 622 (quoting ***Pavlik v. Lane Limited/Tobacco Exporters International***, 135 F.3d 876, 883 (3d Cir.1998)).

Lonasco v. A-Best Products Co., 757 A.2d 367, 377 (Pa.Super. 2000), ***appeal denied***, 781 A.2d 145 (Pa. 2001).

> In examining these instructions, our scope of review is to determine whether the trial court committed clear abuse of discretion or error of law controlling the outcome of the case. ***Williams v. Philadelphia Transportation Company***, 415 Pa. 370, 374, 203 A.2d 665, 668 (1964). Error in a charge is sufficient ground for a new trial, if the charge as a whole is inadequate or not clear or has a tendency to mislead or confuse rather than clarify a material issue.

> ***Glider v. Com. Dept. of Hwys.***, 435 Pa. 140, 151-52, 255 A.2d 542, 547 (1969). A charge will be found adequate unless "the issues are not made clear to the jury or the jury was palpably misled by what the trial judge said or unless there is an omission in the charge which amounts to fundamental error." ***Voitasefski v. Pittsburgh Rys. Co.***, 363 Pa. 220, 226, 69 A.2d 370, 373 (1949); A reviewing court will not grant a new trial on the ground of inadequacy of the charge unless there is a prejudicial omission of something basic or fundamental. ***Sweeny v. Bonafiglia***, 403 Pa. 217, 221, 169 A.2d 292, 293 (1961); ***Giorgianni v. DiSanzo***, 392 Pa. 350, 356, 140 A.2d 802, 805 (1958). In reviewing a trial court's charge to the jury, we must not take the challenged words or passage out of context of the whole of the charge, but must look to the charge in its entirety. ***McCay v. Philadelphia Electric Company***, 447 Pa. 490, 499, 291 A.2d 759, 763 (1972).

Stewart v. Motts, 654 A.2d 535, 540 (Pa. 1995).

McNeil's argument in this regard is meritless. Initially, at the charging conference, the trial court indicated it would give the instruction, over McNeil's objection. Ultimately, for whatever reason, the trial court did not give the instruction. (Trial court opinion, 1/7/13 at 111.) It appears the trial court may have simply forgotten. Neither side objected to its omission.

Although the heeding presumption benefits the plaintiffs, McNeil now claims it was error not to give it as the trial court indicated it would, because defense counsel presented his closing argument to the jury under the assumption that they would be charged on the heeding presumption. According to McNeil, in light of the trial court's decision, counsel barely touched warning causation in his closing, arguing merely that even an

"adequate" warning would not have prevented Brianna from being given her first dose of Children's Motrin. (McNeil's brief at 43.) Allegedly, because of the trial court's stated intention to give the heeding presumption instruction, counsel avoided arguing whether an adequate warning would have caused Mrs. Maya to stop administering the drug to Brianna after she exhibited a rash. (***Id.***) McNeil complains that, "The trial court ultimately did not give the instruction, but by that point, McNeil had lost the opportunity to argue this central issue." (***Id.***)

First, we note that the matter could be deemed waived. If McNeil felt that it was somehow prejudiced by the trial court's failure to give the instruction, it could have objected to its omission or, in the alternative, requested to re-open closing arguments. McNeil cannot sit on its hands and now argue that failure to give the jury instruction was reversible error. ***See Keefer v. Byers***, 159 A.2d 477, 480 (Pa. 1960) ("Nor may a party sit by silent, and take his chances on a verdict and then, if it is adverse, complain of a matter which, if erroneous, could have been dissipated timely by the court's prompt rectification of the charge.") (citation omitted).

Second, the heeding presumption charge is a rebuttable presumption and in no way precluded McNeil from arguing to the jury that plaintiffs failed to prove an adequate warning would have prevented Brianna from receiving additional doses of Children's Motrin after she developed a rash and blisters. In addition, as appellees observe, the heeding presumption is most relevant

in cases where the plaintiff is dead or incapacitated and cannot testify as to what he would have done if an adequate warning had been given. (Appellees' brief at 38.) Here, Mrs. Maya testified that she would not have purchased Children's Motrin if the label warned of "rash" and "blisters" and/or would have stopped using the product after Brianna exhibited a rash. Therefore, the heeding presumption was not particularly relevant. There is no error here.

Next, McNeil argues that the trial court erred in giving a "concurring causes" instruction.

> A defective product substantially contributes to a plaintiff's injuries if it is sufficient to cause them or when combined with other contributing factors is sufficient to cause them, even though each alone would have been insufficient. A defendant will not be permitted to avoid responsibility for the injurious consequences of its defective product merely because a defective product of another would have independently caused the same result. The law on this type of substantial contributing factor is aptly set out in the Pennsylvania Suggested Standard Jury Instructions:
>
> > When negligent conduct of two or more persons contributes concurrently to an occurrence or incident, each of these persons is fully responsible for the harm suffered by the plaintiff regardless of the relative extent to which each contributed to the harm. A cause is concurrent if it was operative at the moment of the incident, and acted with another cause as a substantial contributive factor in bringing about the harm.

> Pa. SSJI Civ. 3.26 Concurring Causes (Subcommittee Draft 1978). While this section applies to the negligent conduct of two or more persons, its reasoning applies just as forcibly to the defective products of two or more manufacturers.

Lilley v. Johns-Manville Corp., 596 A.2d 203, 215-216 (Pa.Super. 1991), ***appeal denied***, 607 A.2d 254 (Pa. 1992) (Olszewski, J. concurring).

Instantly, there was testimony that something other than Children's Motrin, ***e.g.***, Pediazole, may have contributed to Brianna's development of SJS/TEN. Dr. Stern testified that an infectious illness or the sulfisoxazole component in Pediazole were responsible for Brianna's SJS which evolved into TEN. (Notes of testimony, 5/3/11, p.m. session at 41, 52.) However, Dr. Stern could not exclude the possibility that Children's Motrin and Pediazole both contributed to Brianna's SJS/TEN. (Notes of testimony, 5/11/11, p.m. session at 59-60.) Therefore, the jury could have reasonably concluded that OTC Children's Motrin and some other agent, ***e.g.***, the antibiotic Pediazole, combined to cause Brianna's illness. The trial court did not err in giving the concurrent causes jury instruction.

Next, McNeil argues that the trial court gave an incorrect jury instruction. McNeil claims that it asked for an instruction to the effect that the jury could not consider drugs other than ibuprofen, or the conduct of other drug manufacturers, in arriving at a verdict. McNeil's request was granted over the plaintiffs' objection. (McNeil's brief at 47.) During the jury charge, the trial court issued the following instruction:

> You heard reference to drugs other than ibuprofen that were removed from the market. There is a word missing. I'm trying to figure out what the word is here. Okay. You may have heard reference to drugs other than ibuprofen that were removed from the market, or information that may have been reported to companies other than McNeil. You may consider the conduct of other pharmaceutical manufacturers, or what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct.

Notes of testimony, 5/19/11, a.m. session at 41-42.

McNeil claims that the trial judge forgot to include the word "not," ***i.e.***, the instruction should have read, "You may ***not*** consider the conduct of other pharmaceutical manufacturers . . ." (emphasis added). Although the trial court claims it gave the requested instruction verbatim, there is support for McNeil's contention in the record. (Trial court opinion, 1/7/13 at 109.) At sidebar following the jury charge, McNeil twice took exception to the charge as given. (Notes of testimony, 5/19/11, a.m. session at 69, 73.) Defense counsel stated, "Our 41 asserted that the jury should be instructed that they could not decide the case based on the conduct of other pharmaceutical companies or other drugs being taken off the market; and I think the opposite is what was given." (***Id.*** at 73.) Nevertheless, the trial court declined to correct the instruction. (***Id.*** at 75.)

The trial court's insistence that it read the instruction exactly as submitted by McNeil makes no sense in light of defense counsel's objections and the fact that the instruction, as given, operates against McNeil. Why

would McNeil ask the trial court to instruct the jury that they can consider the conduct of other drug manufacturers, or what happened with other drugs besides ibuprofen, such as drugs being pulled off the market, when evaluating McNeil's conduct in this case?

Ultimately, however, the issue does not compel a new trial because McNeil was not prejudiced by the trial court's alleged mistake. As appellees point out, the instruction really only pertains to their claims for negligent design defect and punitive damages, both of which the jury resolved in favor of McNeil. (Appellees' brief at 44.) The other drugs/other manufacturers instruction was not relevant to the failure to warn claim. Therefore, at best, it was harmless error.

Next, McNeil argues that it is entitled to a new trial based on a number of erroneous evidentiary rulings. First, McNeil claims that the trial court erred by admitting evidence of risks associated with ibuprofen other than SJS/TEN, ***e.g.***, liver toxicity and gastrointestinal bleeding. (McNeil's brief at 50.) According to McNeil, such evidence was irrelevant and inflammatory. However, evidence of other known risks and/or adverse effects of Children's Motrin other than SJS/TEN was relevant to plaintiffs' negligent design defect claim. This evidence went to plaintiffs' argument that OTC Children's Motrin was a defective product. The evidence was also relevant to prove punitive damages, that McNeil had knowledge of other adverse reactions and side effects and failed to warn consumers. (Trial court opinion, 1/7/13 at 80-81.)

McNeil also argues that the trial court erred in allowing post-2000 evidence including adverse event reports ("AERs"). AERs are reports submitted to the FDA after the manufacturer of a drug has received a report indicating that an individual using the drug has experienced an adverse event. McNeil argues that these AERs related to events that occurred after Brianna's injuries and distorted the jury's analysis of whether McNeil was negligent in November 2000 and whether that negligence caused Brianna's injuries. (McNeil's brief at 51-52.) However, the trial court specifically instructed the jury that they were not to consider the AERs as evidence of causation, only notice. (Trial court opinion, 1/7/13 at 85, citing notes of testimony, 5/19/11, a.m. session at 25.) The jury was instructed that the AERs were admitted for the limited purpose of proving that McNeil had notice of the reports. (***Id.***) Furthermore, the evidence was relevant to plaintiffs' punitive damages claim and to prove the feasibility in 2000 of adequate warnings which were eventually instituted in 2005.

Next, McNeil contends that the trial court improperly allowed plaintiffs to present evidence regarding possible warnings that the FDA actually rejected, including references to SJS, TEN, or "life-threatening" diseases or reactions in the OTC Children's Motrin label. (McNeil's brief at 52.) However, as McNeil concedes, the trial court instructed the jury on this issue:

> As a matter of law, you can not find the defendant is liable for failure to give warnings or instructions that

> the FDA has considered and rejected, or for failing to give warnings that there is clear evidence that the FDA would have rejected. Defendant McNeil contends that the FDA has considered and rejected revised labeling for over-the-counter Children's Motrin that would include reference to SJS or TENS, or that would have warned of, quote, "life-threatening disease" and reaction. Therefore, if you accept defendant's contentions, then you cannot find that the defendant is liable for the failure to provide adequate warnings because they did not include in labeling for over-the-counter Children's Motrin reference to SJS or TENS, or a warning referencing the life-threatening diseases or reactions.

Notes of testimony, 5/19/11, a.m. session at 45-46. "The law presumes that the jury will follow the instructions of the court." ***Commonwealth v. Brown***, 786 A.2d 961, 971 (Pa. 2001), ***cert. denied***, 537 U.S. 1187 (2003) (citations omitted). There is no merit to McNeil's argument in this regard.

Next, McNeil argues that the trial court erred in allowing evidence regarding advertisements which Mrs. Maya may or may not have seen, and upon which she did not rely in administering OTC Children's Motrin to Brianna. (McNeil's brief at 53.) The trial court granted McNeil's pre-trial motion ***in limine*** seeking to exclude evidence of any advertisements which plaintiffs did not actually review; however, at trial, the trial court allowed Mrs. Maya to be questioned regarding an advertisement from Pediatrics in January 1996, the year before Brianna was born. The advertisement claimed that "No pediatric antipyretic/analgesic is more effective," and that "Children's TYLENOL has a superior safety profile to ibuprofen." (Plaintiffs' Exhibit 4510.10a.) Mrs. Maya was asked whether, if she had known that the

company that makes both Motrin and Tylenol was advertising that Tylenol has a superior safety profile, it would have changed anything. (Notes of testimony, 4/21/11, p.m. session at 76-77.) Over objection, Mrs. Maya answered that she would have asked Dr. Brewer about it when she first recommended at Brianna's 18-month well baby exam to start alternating Tylenol with Motrin when she got a high fever. (***Id.*** at 77-78.) Mrs. Maya was also asked whether an advertisement stating that, "no pediatric medicine is more effective than Tylenol" would have changed her conduct; Mrs. Maya replied that if she had seen the advertisement, she would have consulted Dr. Brewer about it. (***Id.*** at 78.)

The trial court acknowledges that the admission of this evidence was contrary to its earlier pre-trial ruling on McNeil's motion ***in limine***. Mrs. Maya testified that while she was familiar with the magazine Pediatrics, she did not recall having seen the advertisement. (***Id.*** at 74-76.) Nevertheless, even if permitting this line of questioning was error, McNeil was not prejudiced. Mrs. Maya testified only that if she had known Tylenol was advertised as being just as effective as Motrin but with a superior safety profile, by a company which manufactured both drugs, she would have asked Dr. Brewer about it. As the trial court remarks, it is unknown what Dr. Brewer would have said or if any additional information provided by Dr. Brewer would have changed Mrs. Maya's decision to administer Children's Motrin to Brianna. (Trial court opinion, 1/7/13 at 82-83.)

Next, McNeil asserts that the trial court erred by permitting evidence of "foreign regulatory matters." For example, Brianna's treating gynecologist, Steven Pliskow, M.D., testified regarding the filing of a Citizen's Petition with the FDA, of which he was a co-signer:

> In addition, I felt that it wasn't fair that patients in our country weren't receiving --"; and, "the issues were clear to me from reading it that patients -- patients and physicians weren't being warned, and that patients in this country weren't receiving the warnings that patients in other countries were receiving. So it wasn't fair.

Notes of testimony, 4/5/11, a.m. session at 39-41. McNeil also complains that during questioning of a witness, plaintiffs' counsel made reference to Oxyphenbutazone having been withdrawn in foreign countries:

> It says, "Drug-induced TEN is a feared but rare adverse reaction with a case fatality rate as high as 25 percent." It goes on to say, "During the period up to 1984 serious skin disorders were reported most frequently with Oxyphenbutazone, which has been withdrawn." I'm not going to continue reading that because it talks about it being withdrawn in places other than America, and Her Honor told us to stay in America. But it says "Was withdrawn." Then let me show you a document that shows it was withdrawn in America.

Notes of testimony, 4/19/11, a.m. session at 66.[7]

First, as appellees correctly observe, Dr. Pliskow never explained the substance of the warnings in other countries or how they materially differed from the warnings on American labels; only that he felt it was unfair

[7] McNeil's objections to the above statements were overruled.

American patients did not receive the identical warnings. (Appellees' brief at 48.) Second, it is axiomatic that statements or questions by counsel are not evidence and the jury was so instructed. (***See*** notes of testimony, 5/19/11, a.m. session at 10 ("Remember, the questions asked by the attorneys and the comments made by them are not evidence.").) In addition, plaintiffs' counsel went on to acknowledge that the drug in question was also withdrawn in America. It is difficult to see how McNeil was prejudiced by that statement.

Moreover, the trial court specifically instructed the jury to disregard evidence of other drugs being removed from foreign markets:

> . . . ladies and gentlemen, any evidence or any testimony or any questions that regard drugs that were taken off the market anywhere outside of the United States is not relevant to this case. The FDA does not control anything that happens outside of its border so, therefore, anything that any other country does is not of relevancy in this case. Okay. So disregard any testimony with regards to that.

Notes of testimony, 4/15/11, p.m. session at 123. Again, juries are presumed to follow the court's instructions. ***Brown***, ***supra***.

Finally, McNeil argues that plaintiffs' counsel's misconduct demands a new trial. McNeil claims that counsel repeatedly disregarded the trial court's rulings and impermissibly referenced McNeil's wealth and its "army of attorneys." McNeil argues that plaintiffs' counsel persistently referred to McNeil's size and the number of lawyers at its disposal, framing the case as a "David and Goliath" battle. (McNeil's brief at 55.) McNeil contends that

plaintiffs' counsel repeatedly asked "loaded questions" of witnesses suggesting that the FDA lacked sufficient resources to adequately monitor drug safety, despite the trial court sustaining McNeil's objections. (***Id.*** at 57.) According to McNeil, counsel purposely inflamed the passions of the jury to the point where they were unable to render a fair and just verdict. (***Id.*** at 55-58.)

> Our standard of review regarding a trial court's denial of a motion for a new trial is limited. The power to grant a new trial lies inherently with the trial court and we will not reverse its decision absent a clear abuse of discretion or an error of law which controls the outcome of the case.

Siegal v. Stefanyszyn, 718 A.2d 1274, 1275 (Pa.Super. 1998), ***appeal denied***, 739 A.2d 1059 (Pa. 1999), citing ***Kiser v. Schulte***, 648 A.2d 1 (Pa. 1994).

> Whether remarks by counsel warrant a new trial requires a determination based upon an assessment of the circumstances under which the statements were made and the precaution taken by the court and counsel to prevent such remarks from having a prejudicial effect. ***Martin v. Philadelphia Suburban Transportation Co.***, 435 Pa. 391, 257 A.2d 535, (1969). It is the duty of the trial judge to take affirmative steps to attempt to cure harm, once an offensive remark has been objected to. ***Millen v. Miller***, 224 Pa.Super. 569, 308 A.2d 115 (Pa.Super.1973). However, there are certain instances where the comments of counsel are so offensive or egregious that no curative instruction can adequately obliterate the taint. ***Dannals v. Sylvania Township***, 255 Pa. 156, 99 A. 475 (1916) (Counsel characterized defense witness as a "drunkard" from the "slums"). ***Saxton v. Pittsburg Railways***, 219 Pa. 492, 68 A. 1022 (1908) (Counsel

> had argued that defendant had suppressed evidence when there was no evidence of this fact).

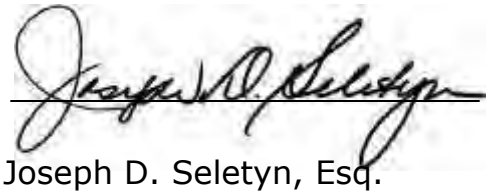
Id. at 1277.

The trial court noted that, "an exorbitant amount of patience was required to control *all* counsel throughout the entire trial," not just plaintiffs' counsel. (Trial court opinion, 1/7/13 at 50 (emphasis in original).) The trial court found that the alleged misconduct did not prevent the jury from sifting through the evidence objectively and returning a verdict that was supported by the evidence presented. (***Id.*** at 50-51.) We observe that the jury found in McNeil's favor on two of the three claims, including punitive damages, despite plaintiffs' counsel's references to McNeil's size and assets. This would seem to indicate the jury's verdict was not the product of passion or prejudice. The trial court, which presided over this nine-week trial and observed the actions of all counsel, has thoroughly examined each allegation of misconduct and determined that a new trial was not warranted. (***Id.*** at 50-75.) We agree and adopt the trial court's analysis in this regard. The trial court did not abuse its discretion in denying McNeil's motion for a new trial.

Having determined that McNeil's issues on appeal are without merit and do not afford it any relief, we will affirm the judgment. The appeal at No. 3259 EDA 2011 is dismissed.

Order entering judgment affirmed.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 7/22/2014