In the Superior Court of Pennsylvania

Nos. 3259 EDA 2011 & 471 EDA 2012

ALICIA E. MAYA, individually, and BRIANNA MAYA,
By and through her natural parent and guardian,
Plaintiffs/Appellees,

v.

JOHNSON & JOHNSON and McNEIL–PPC, INC.

Appeal of McNeil–PPC, Inc.

BRIEF FOR PLAINTIFFS/APPELLEES

On Appeal from the Judgment of the Court of Common Pleas of
Philadelphia County, Pennsylvania at February Term 2009, No. 2879

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Keith M. Jensen
Jensen & Associates, PLLC
1024 North Main Street
Fort Worth, TX 78164
(817) 334–0762

Scott Levensten
The Levensten Law Firm, P.C.
1420 Walnut Street, Suite 801
Philadelphia, PA 19102
(215) 545–5600

Counsel for Plaintiffs/Appellees

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I. COUNTERSTATEMENT OF THE SCOPE AND STANDARDS OF REVIEW

As the Supreme Court of Pennsylvania explained in *Birth Center* v. *St. Paul Cos.*, 567 Pa. 386, 397, 787 A.2d 376, 383 (2001), when conducting appellate review of a trial court's ruling on a motion for judgment notwithstanding the verdict, "[w]e view the evidence in the light most favorable to the verdict winner and give him or her the benefit of every reasonable inference arising therefrom while rejecting all unfavorable testimony and inferences."

Earlier, in *Moure* v. *Raeuchle*, 529 Pa. 394, 604 A.2d 1003 (1992), the Supreme Court explained:

> [T]he evidence must be considered in the light most favorable to the verdict winner, and he must be given the benefit of every reasonable inference of fact arising therefrom, and any conflict in the evidence must be resolved in his favor. Moreover, [a] judgment n.o.v. should only be entered in a clear case and any doubts must be resolved in favor of the verdict winner. Further, a judge's appraisement of evidence is not to be based on how he would have voted had he been a member of the jury, but on the facts as they come through the sieve of the jury's deliberations.

Id. at 402, 604 A.2d at 1007; *see also Quinby* v. *Plumsteadville Family Practice, Inc.*, 589 Pa. 183, 204, 907 A.2d 1061, 1074 (2006) (same).

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

> A JNOV can be entered upon two bases: (1) where the movant is entitled to judgment as a matter of law; and/or, (2) the evidence was such that no two reasonable minds could disagree that the verdict should have been rendered for the movant. When reviewing a trial court's denial of a motion for JNOV, we must consider all of the evidence admitted to decide if there was sufficient competent evidence to sustain the verdict. In so doing, we must also view this evidence in the light most favorable to the verdict winner, giving the victorious party the benefit of every reasonable

> inference arising from the evidence and rejecting all unfavorable testimony and inference. Concerning any questions of law, our scope of review is plenary. Concerning questions of credibility and weight accorded the evidence at trial, we will not substitute our judgment for that of the finder of fact. If any basis exists upon which the jury could have properly made its award, then we must affirm the trial court's denial of the motion for JNOV. A JNOV should be entered only in a clear case.

American Future Systems, Inc. v. *Better Business Bureau*, 872 A.2d 1202, 1215 (Pa. Super. Ct. 2005) (citation omitted), *aff'd*, 592 Pa. 66, 923 A.2d 389 (2007).

With regard to McNeil's appeal from the trial court's denial of a new trial, in *Harman ex rel. Harman* v. *Borah*, 562 Pa. 455, 756 A.2d 1116 (2000), the Supreme Court of Pennsylvania explained: "[a]lthough all new trial orders are subject to appellate review, it is well–established law that, absent a clear abuse of discretion by the trial court, appellate courts must not interfere with the trial court's authority to grant or deny a new trial." *Id.* at 466, 756 A.2d at 1121–22.

Moreover, in *Harman*, Pennsylvania's highest court proceeded to observe:

> The harmless error doctrine 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.

Id. at 467, 756 A.2d at 1122.

II. COUNTERSTATEMENT OF THE CASE

A. Relevant Factual History

Leading up to Saturday, November 25, 2000, Brianna Maya was a beautiful, normal three–year–old child. R.2033a–34a, 1341b–42b (T.T. 4/21/11 a.m. at p.66–69).

That evening, Brianna began coughing and seemed to have a low fever. R.2035a, 1343b (*Id.* at 72–73). As a result, that night Brianna's mother, Alicia Maya, administered to Brianna a dose of over–the–counter Children's Motrin, an analgesic NSAID (non–steroidal anti–inflammatory) drug manufactured by defendant McNeil–PPC, Inc. R.2035a, 1343b (*Id.* at 73).

Alicia Maya, Brianna's mother, testified at trial that she was familiar with the warnings that accompanied Children's Motrin and that if those warnings had mentioned "rash" and "blisters" among the medications' risk, Mrs. Maya testified that she would not have purchased Children's Motion nor have administered the medication to Brianna. R.2037a–38a, 1345b–46b (*Id.* at 83–84); R.2069a–70a, 1409b–10b (T.T. 4/26/11 a.m. at p.43–46). Indeed, after testifying that she would not have purchased Children's Motrin had "rash" and "blisters" been mentioned in that medication's warning label in 2000, Mrs. Maya testified, referring back to her refusal to accept any form of anesthesia during Brianna's childbirth:

> 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?
>
> 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.

R.2070a. 1410b (T.T. 4/26/11 a.m. at p.46).

It was not until 2005, however, that McNeil updated its warning label for Children's Motrin to include those necessary warnings expressly mentioning "rash" and "blisters." R.1912a–13a, 448b–49b (T.T. 3/31/11 a.m. at p.93–96).

Tragically, that improvement in the label's warnings came far too late for Brianna. The child received four more doses of Children's Motrin on Sunday, November 26th. R.2041a, 1350b (T.T. 4/21/11 a.m. at p.101). Brianna received her sixth dose of Children's Motrin on the morning of Monday, November 27, 2000. R.2041a, 1350b (*Id.* at 102). On Monday, Brianna's father took her to see her pediatrician, who incorrectly diagnosed Brianna's condition as mycoplasma pneumonia and prescribed an antibiotic known as Pediazole for that condition. R.2042a, 1351b (*Id.* at 106–07); R.3502a–03a, 3529a (Ct. Ex. 3 at p.20–22, 96). On her way home from work on Monday evening, Brianna's mother picked up the Pediazole from the pharmacy. R.2042a, 1351b (T.T. 4/21/11 a.m. at p.107). Brianna's rash had gotten far worse by the time her mother had arrived home that evening, and, according to Alicia's testimony, when Alicia arrived home Brianna was "crying and screaming that her pee pee hurt." R.2043a–44a, 1352b–53b (*Id.* at 109, 113).

After arriving home from the doctor's office on Monday, Brianna received two additional doses of Children's Motrin. R.2044a, 1353b (*Id.* at 114). Brianna also received

her first dose of Pediazole on Monday evening after her mother arrived home. R.2044a, 1353b (*Id.* at 113). Brianna received her ninth dose of Children's Motrin on the night of Monday, November 27th and then received a final, tenth dose of Children's Motrin around 3 a.m. on the morning of Tuesday, November 28th. R.2045a, 1354b (*Id.* at 118).

Brianna's father took her back to the pediatrician on the morning of Tuesday, November 28, 2000 after Brianna had spent the entire night awake and complaining. R.2045a–46a, 1354b–55b (*Id.* at 119–20). After examining Brianna, the pediatrician directed that Brianna and her father proceed immediately across the street to the emergency room of the hospital adjacent to the pediatrician's office. R.2046a–1355b (*Id.* at 121–23). Brianna's mother, Alicia Maya, immediately left work and made her way to the hospital as quickly as possible. R.2046a, 1355b (*Id.* at 122–23). Upon arriving at the hospital, Alicia observed that the rash across Brianna's body had transformed into blisters, and that the blisters were continuing to grow in size. R.2046a–47a, 1355b–56b (*Id.* at 123–26). According to the mother's testimony at trial, "[a]t this point she had blisters in her mouth. During the examination, the nurse had noticed that she had a blister on her vagina. Off and on, Brianna was crying saying that she had to go to the bathroom but that it burned or it hurt her pee pee, so she was refusing to go to the bathroom." R.2047a, 1356b (*Id.* at 126).

What Brianna was experiencing and the child's treating health care workers were observing was the onset of horrifying conditions known as Stevens Johnson

Syndrome/Toxic Epidermal Necrolysis (SJS/TEN).[1] These life–threatening reactions, although rare, have among their known causes NSAID pain relievers, including Children's Motrin. R.1911a–13a, 447b–49b (T.T. 3/31/11 a.m. at p.88–96). Expert medical professionals who treated Brianna testified at trial that, in their opinion, Children's Motrin was, with 99% certainty, the cause of Brianna's TEN. R.1893a–94a, 413b–14b (T.T. 3/30/11 p.m. at p.80–81); R.1955a–56a, 779b–80b (4/7/11 p.m. at p.64–65).

A horrendous nightmare scenario that is all too common with TEN ensued. On the afternoon of Tuesday, November 28th, based on the severity of her worsening condition, Brianna was transferred by ambulance on a two–hour trip from Volunteer Hospital in Martin, Tennessee to Lebonheur's Children's Hospital in Memphis, Tennessee. R.2047a–48a, 1356b–57b (T.T. 4/21/11 a.m. at p.127–30). By the early morning hours of Wednesday, November 29, 2000, Brianna's rash had developed into blisters that had rapidly spread and erupted across her entire body, and her eyes had swollen shut. R.2048a–50a, 1357b–59b (*Id.* at 131–34, 136). Due to the risk of infection, Brianna underwent several debridement surgeries (a very painful procedure involving the forceful sloughing off of the skin using highly abrasive material), requiring skin grafts of either cadaver skin or pigskin to protect her underlying skin. R.2050a–51a, 1359b–60b (*Id.* at 137–40); R.2058a–59a, 1369b–70b (T.T. 4/21/11 p.m. at p.13, 18). At

[1] Used precisely, SJS involves 1–9% of a person's total body surface area. SJS/TEN overlap involves 10–29%. TEN is a diagnosis reserved for when 30% or more of someone's total body surface area has burned off, sloughed off, or is an open wound. R.1835a, 120b (T.T. 3/24/11 a.m. at p.48–49).

Lebonheur's Children's Hospital, Brianna's condition quickly deteriorated, and she was moved into the intensive care unit due to her rapidly decreasing oxygen levels. R.2049a, 1358b (T.T. 4/21/11 a.m. at p.134).

On Friday, December 1, 2000, Brianna's treating physicians in Memphis decided that it was necessary to transfer her to Shriner's Burn Hospital in Galveston, Texas, which occurred around midnight that day by airplane. R.2052a–54a, 1362b–64b (*Id.* at 151–59); R.2057a, 1368a (4/21/11 p.m. at p.9–10). By the time she arrived at Shriner's, over 84% of Brianna's body surface was covered with open, burn–like wounds. R.1865a, 267b (T.T. 3/28/11 a.m. at p.117). For several days thereafter, Brianna's symptoms continued to worsen, as she suffered from low blood pressure, oxygen deprivation, and internal bleeding. R.1982a, 1117b (T.T. 4/15/11 p.m. at p.19–20); R.2057a, 1368b (4/21/11 p.m. at p.9–10). She received multiple blood transfusions. R.1982a, 1117b (T.T. 4/15/11 p.m. at p.19–20). Her open wounds covered so much of her body that family members could only communicate their presence by touching the tip of one unaffected toe. R.1981a–82a, 1116b–17b (*Id.* at 16–17). Brianna was also sedated because she was on a ventilator and in an attempt to relieve her excruciating pain. R.2060a, 1373b (T.T. 4/21/11 p.m. at p.29).

At trial, the primary treating burn surgeon at Shriner's testified that he and Brianna's entire primary care team had determined approximately nine days after the onset of Brianna's symptoms that the cause of Brianna's TEN was her ingestion of over–the–counter Children's Motrin. R.1959a, 801b (T.T. 4/8/11 a.m. at p.20–21). Brianna remained hospitalized at Shriner's until December 16, 2000. R.1959a, 801b (*Id.* at 20);

R.2063a, 1387b (4/21/11 p.m. at p.88). She then stayed at the adjacent Ronald McDonald House until December 19, 2000, at which time she and her family returned home to Martin, Tennessee. R.2063a–64a, 1387b–88b (T.T. 4/21/11 p.m. at p.88–89). Thereafter, however, she and her family relocated to Clearlake, Texas, where Brianna could receive specialized treatment required due to TEN's devastating effect on the mucous membranes of Brianna's eyes. R.1983a, 1118b (T.T. 4/15/11 p.m. at p.24).

In essence, due to TEN, Brianna's eyelids fused to her eyeballs, necessitating 16 eye surgeries and leaving Brianna unable to see at all from one eye and legally blind in that eye. R.1972a–75a, 1020b–21b, 1024b–25b (T.T. 4/13/11 a.m. at p.104, 111, 123–24). Her eyelashes had to be permanently removed because they were growing inward and causing irritation and damage. R.2065a, 1392b (T.T. 4/21/11 p.m. at p.107–08).

The damage to Brianna's skin has left her unable to perspire normally, and thus she must avoid strenuous activities in hot and humid conditions that were frequently experienced in her new home state of Texas. R.1984a, 1121b (T.T. 4/15/11 p.m. at p.34). Her pulmonary fibrosis and lung scarring have permanently reduced the capacity of her lungs and have increased her risk of asthmatic attacks and upper respiratory infections. R.1943a, 652b (T.T. 4/5/11 a.m. at p.123).

At the time of trial, Brianna was 13 years old. R.2085a, 1507b (T.T. 4/27/11 p.m. at p.11). At trial, the jury heard testimony and saw evidence that TEN also had caused a complete fusion of Brianna's vaginal walls, which prevented any menstruation. R.1937a, 645b (T.T. 4/5/11 a.m. at p.92). According to her obstetrician/gynecologist, TEN caused Brianna to suffer retrograde or backed–up menstruation for six months. R.1937a, 645b

(*Id.* at 93). This required several surgeries to repair. R.1937a–43a, 645b, 647b–52b (*Id.* at 95, 103–23). At trial, Brianna's treating OB/GYN testified that, due to the extent of the damage that TEN had caused to Brianna's reproductive system, she will be unable to experience sexual intercourse or bear any children. R.1944a, 655b (*Id.* at 132–33). Rather, the only way that Brianna could have a child would be through in–vitro fertilization carried by a surrogate. R.1944a, 655b (*Id.* at 133–34).

At trial, Brianna's mother testified that she would never have purchased Children's Motrin in 2000 to administer to Brianna if the medication's warnings mentioned "rash" and "blisters" and, in addition, that she would not have purchased the medication if its packaging contained what became the amended and improved 2005 label. R.2037a–38a, 1345b–46b (T.T. 4/21/11 a.m. at p.83–84); R.2069a–70a, 1409b–10b (4/26/11 a.m. at p.43–46). Moreover, Brianna's pediatrician, Dr. Brewer, testified at trial that she was unaware in 2000 that rash was a symptom that was related to Motrin and could precede the development of SJS/TEN. R.3529a (Ct. Ex. 3 at p.96).

At the trial of this case, after hearing all of the evidence, the arguments of counsel, and the instructions of the trial court, the jury was instructed that in order to find in favor of the plaintiff on her claim for negligent failure to warn, the jury had to decide whether McNeil should have and could have warned of "rash" and "blisters" in Children's Motrin's warning label in the year 2000, whether the FDA would have approved of such warnings, and whether the absence of those warnings was a cause of Brianna's TEN. R.2465a–67a, 2469a–70a, 2326b–28b, 2330b–31a (T.T. 5/19/11 a.m. at p.25–26, 30–33, 40–45). The jury also had to decide whether Brianna's ingestion of

Children's Motrin was a factual cause of Brianna's TEN.[2] R.2468a–69a, 2329b–30b (*Id.* at 37–40). Ultimately, the jury found in Brianna's favor on plaintiff's claim for negligent failure to warn and against Brianna on her claim for negligent design defect. R.2483a, 2364b (T.T. 5/20/11 p.m. at p.3–4). The jury also declined to impose any punitive damages against McNeil. R.2483a–84a, 2364b–65b (*Id.* at 4–5). Additional information about the jury's verdict is set forth in the "Relevant Procedural History" section of this brief, immediately below.

B. Relevant Procedural History

Brianna Maya, by and through her parent and natural guardian Alicia Maya, and Alicia Maya individually initiated this lawsuit in the Court of Common Pleas of Philadelphia County in February 2009. R.9a–10a (Trial court's docket). Defendant McNeil, the manufacturer of Children's Motrin, has its headquarters in Fort Washington, Pennsylvania. R.128a (Plaintiffs' complaint).

Trial of this matter commenced on March 23, 2011 and concluded on May 16, 2011. R.75b–2211b (Trial transcript). When Judge Quinones submitted this case to the jury, all that remained were Brianna's claims against McNeil for negligent failure to

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[2] On appeal, McNeil does not challenge the legal sufficiency of plaintiff's evidence proving that Children's Motrin was the cause of Brianna's horrifically injurious TEN. Because McNeil is not challenging on appeal the jury's finding that Children's Motrin caused all of the horrific injuries that were at issue in Brianna's suit against McNeil, the jury's finding that Children's Motrin caused all of Brianna Maya's horrific injuries must be accepted as true for purposes of this appeal. *See Keller* v. *Mey*, 67 A.3d 1, 7 (Pa. Super. Ct. 2013).

warn, negligent design defect, and an accompanying request for punitive damages on those claims. R.2487a–88a (Jury verdict slip).

On May 24, 2011, the jury returned its verdict in favor of Brianna Maya and against McNeil in the amount of $10 million in compensatory damages on Brianna's claim for negligent failure to warn. R.2483a, 2364b (T.T. 5/20/11 p.m. at p.3–4). The jury specifically found that McNeil negligently failed to warn of risks associated with over–the–counter Children's Motrin and that McNeil's negligent failure to warn of those risks was a factual cause of Brianna's injuries. *Id.* Yet the jury's verdict was not wholly in plaintiff's favor, as the jury found in favor of McNeil on plaintiff's claim for negligent design defect. R.2483a, 2364b (*Id.* at 4). And the jury also found that an award of punitive damages against McNeil was not warranted. R.2483a–84a, 2364b–65b (*Id.* at 4–5).

Although $10 million is not a small verdict, far larger verdicts ($48 million and $63 million) have been awarded against pharmaceutical companies in similar SJS/TEN cases.[3] As described in more detail above, Brianna has suffered and will continue to suffer mightily, not only in terms of past pain and suffering, but also when taking into account her blindness, inability to have sexual relations or experience childbirth, and the lifelong disfigurement and physical and economic consequences from which she

[3] *See* "California State Jury Awards $48.1 Million In Motrin Injury Case," LexisNexis Legal Newsroom Litigation, October 4, 2011, *available online at*: http://www.lexisnexis.com/legalnewsroom/litigation/b/litigation-blog/archive/2011/10/04/california-state-jury-awards-48-1-million-in-motrin-injury-case.aspx ; "Family awarded $63 million in Motrin case," The Boston Globe, February 13, 2013, *available online at*: http://bostonglobe.com/business/2013/02/13/plymouth-family-awarded-million-motrin-case/zEdJIbAWaas4zQVVSvIirI/story.html .

will continue to suffer throughout the rest of her life. Perhaps recognizing that the evidence could have justified a far larger award of damages, McNeil on appeal is not challenging the jury's verdict as excessive.

Defendant McNeil timely filed a lengthy post–trial motion seeking judgment notwithstanding the verdict (j.n.o.v) or, in the alternative, a new trial. R.2489a–549a (McNeil's post–trial motion). Following briefing and oral argument, the trial court denied McNeil's post–trial motion. R.2655a (Trial court's order denying McNeil's post–trial motion). The trial court entered final judgment on January 6, 2012. *See* Exhibit A to Brief for Appellant (Judgment).

III. SUMMARY OF THE ARGUMENT

Since 2005, the packaging for over–the–counter Children's Motrin has contained an allergy alert warning that explicitly mentions "rash" and "blisters." In 2000, however, when Alicia Maya purchased Children's Motrin to administer to her daughter Brianna, that medication's packaging and warnings lacked any mention of either "rash" or "blisters." In addition, Brianna's pediatrician, Dr. Brewer, testified that in 2000 she did not know that skin rash could be an early warning sign of SJS or TEN caused by Motrin.

The jury's verdict in plaintiff's favor on her claim of negligent failure to warn establishes that the jury found that the label for Children's Motrin could have and should have warned of "rash" and "blisters" in 2000, and that the label for prescription Motrin could have and should have included mention of "rash" as an allergic reaction to that medication. The jury's verdict also demonstrates that the jury found that had McNeil provided adequate warnings about the risks of Children's Motrin to Alicia Maya and Dr. Brewer, Brianna's horrific injuries would have been entirely or substantially avoided. As explained herein, more than sufficient evidence supports the jury's findings in these respects, and therefore the trial court's denial of McNeil's motion for j.n.o.v. should be affirmed.

McNeil's opening brief also offers this Court a grab bag of ten assorted theories supposedly entitling McNeil to a new trial. Yet, as is all too often the case, an appellant's specification of such a multiplicity of errors only serves to confirm that none has merit. As detailed below, none of the ten grounds for a new trial that McNeil has

raised on appeal constitutes error or an abuse of discretion. Moreover, McNeil's grounds for a new trial would fail to amount to harmful error even if error or an abuse of discretion could be established. It is thus noteworthy that the lengthiest argument subsection of McNeil's entire opening brief is devoted to criticizing the conduct of plaintiff's counsel, confirming the adage that where neither the facts nor the law supports a party's argument, the party's best remaining strategy consists of simply pounding the table.

As demonstrated below, none of the grounds for a new trial that McNeil is pursuing on appeal has merit or entitles McNeil to a retrial of this matter. If the parties can agree on any one thing, the original trial of this matter took far too long. Judge Quinones has since relocated to a lifetime position as a U.S. District Judge for the Eastern District of Pennsylvania. And the plaintiff, now a teenager, will continue to suffer the horrific consequences of her injuries every hour of every day for the remainder of her life. Although, as explained below, neither side is entirely satisfied with the jury's verdict in this case, a new trial is neither warranted nor legally appropriate.

For all of the reasons set forth herein, the judgment that the trial court entered on the jury's verdict in this case should be upheld, and the trial court's denial of McNeil's post–trial motion should be affirmed.

IV. ARGUMENT

A. McNeil's Strategy Of Raising Ten Issues On Appeal Demonstrates That None Of McNeil's Substantive Arguments Has Merit

Failing to heed the admonition of Senior Third Circuit Judge Ruggero J. Aldisert — who has literally written the book on effective appellate advocacy — the Brief for Appellant that McNeil has filed raises ten separate issues on appeal. As the Supreme Court of Pennsylvania stated in *Commonwealth* v. *Ellis*, 534 Pa. 176, 626 A.2d 1137 (1993): "We concur with the view of an eminent appellate jurist, Judge Ruggero Aldisert, that the number of claims raised in an appeal is usually in inverse proportion to their merit and that a large number of claims raises the presumption that all are invalid." *Id.* at 183, 626 A.2d at 1140.

Stated plainly, if McNeil had any meritorious grounds for either j.n.o.v. or a new trial, surely McNeil would not need to advance nine separate grounds seeking those forms of relief. As demonstrated below, McNeil's lack of confidence in its merits–related arguments is well–justified, as none of those arguments provides this Court with any valid basis for reversal.[4]

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[4] Judge Quinones's opinion explaining her reasons for denying McNeil's post–trial motion observed that McNeil had included 23 separate grounds for appeal — many containing numerous subsections — in the Rule 1925(b) statement of errors complained of on appeal McNeil filed in the trial court. R.2663a–73a. Based on her view that McNeil had improperly and in bad faith filed such a lengthy Rule 1925(b) statement of errors, Judge Quinones recommended in her opinion that this Court should hold that McNeil has waived all grounds for appeal. *See* Exhibit B to Brief for Appellant (Opinion at 17–20).

In so recommending, Judge Quinones relied on precedent that was created under a former, now superseded, version of Rule 1925(b). More recently, the Supreme Court of

B. The Three Grounds For J.N.O.V. That McNeil Is Pursuing On Appeal Are Entirely Without Merit

1. McNeil cannot point to any "clear evidence" that the FDA would not have approved a warning label for Children's Motrin in 2000 that mentioned that signs of serious allergic reactions included "Rash" and "Blisters," and thus the trial court properly rejected McNeil's federal preemption argument

In 2005, the federal Food and Drug Administration recommended an amended allergy warning label for over–the–counter ibuprofen, including Children's Motrin. R.1845a, 168b (T.T. 3/24/11 p.m. at p.89). That proposed warning label, which McNeil voluntarily agreed to implement, for the very first time contained explicit mention that serious allergic reactions to ibuprofen requiring the cessation of use and the seeking of immediate medical help included "rash" and "blisters." R.1854a, 189b (T.T. 3/25/11 a.m. at p.68–69); R.2794a, 2798a (Ex. D–2573). As explained in the following sections of this brief, at trial, Brianna Maya's mother testified that if the warning label for Children's Motrin in 2000 included mention of "rash" and "blisters," Alicia Maya would never have purchased the product nor administered any doses of Children's Motrin to Brianna. R.2069a–70a, 1409b–10b (T.T. 4/26/11 a.m. at p.43–46). And Brianna's pediatrician, Dr. Brewer, testified that in 2000 she did not know that skin rash could be an early warning sign of SJS or TEN caused by Motrin. R.3529a (Ct. Ex. 3 at p.96). Based on that testimony, the jury reasonably could have concluded that had

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Pennsylvania promulgated an amended version of Rule 1925(b), applicable to this case, which specifies that an overwhelming number of errors or issues set forth in a Rule 1925(b) statement is no longer a valid ground for finding appellate waiver unless the Rule 1925(b) statement contains either repetitive or frivolous issues. See Pa. R. App. P. 1925(b).

prescription Motrin's warning label included mention of "rash" as an allergic reaction to that medication, Dr. Brewer would have been aware that rash was an early sign of SJS/TEN. R.3528a (Ct. Ex. 3 at p.94) (testimony of Dr. Brewer that, in and before 2000, she relied on the Physicians' Desk Reference, which contains the warning labels for all prescription drugs, to learn of the risks and benefits of drugs).

In *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the U.S. Supreme Court held, with regard to the manufacturer of a brand name prescription drug, that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570–71. Thus, in *Levine*, the U.S. Supreme Court ruled that the FDA's approval of a drug's warning label does not insulate the manufacturer of an FDA–approved drug from liability on a state law failure to warn claim unless the FDA specifically precluded the manufacturer from giving the very warnings that the plaintiff claims should have been given. As the U.S. Supreme Court's opinion in *Levine* explains, "absent clear evidence that the FDA would not have approved a change to [a medication's] label, we will not conclude that it was impossible for [the drug's manufacturer] to comply with both federal and state requirements," *id.* at 571, and thus federal preemption did not preclude the plaintiff's state law failure to warn claim.

Moreover, the U.S. Supreme Court recognized in *Levine* that whether the FDA would or would not reject the particular warning label that the plaintiff claims the medication should have contained constituted a finding of fact based on the evidence

before the jury at trial. *See id.* at 572. In this case, the trial court permitted the jury to hear all of the evidence that the parties wished to present on the issue of federal preemption, and the trial court explicitly instructed the jury that if the FDA would not have permitted McNeil in 2000 to give the warnings that plaintiff contended were required, then the jury must find in McNeil's favor. R.2470a, 2331b (T.T. 5/19/11 a.m. at p.45–46).

The record is replete with evidence that more than adequately supports the jury's findings in this regard. McNeil was aware that the FDA–approved label for prescription Motrin has since 1989 listed SJS and TEN in the category of probable causal relationship resulting from the ingestion of Motrin. R.2717a (Ex. D–2229). And, in 2005, the FDA recommended improving the warning label of over–the–counter Motrin by including specific mention of "skin reddening," "rash," and "blisters" as examples of the types of "severe allergic reaction[s]" that Motrin can cause. R.2794a, 2798a (Ex. D–2573). No mention of these types of allergic reactions was contained in the warning label for over–the–counter Children's Motrin when Brianna's mother purchased the medication in 2000.

To be sure, SJS/TEN are rare reactions to ibuprofen, but given the seriousness (and, indeed, the utter horrid nature) of these reactions, and given that McNeil unquestionably knew or should have known of ibuprofen's ability to cause SJS/TEN in 2000, the jury had more than an adequate evidentiary basis to find that McNeil could have and should have specifically warned of "rash" and "blisters" as potential allergic reactions to Children's Motrin in 2000.

The evidence at trial established that advance approval from the FDA was not necessary in order for McNeil to make these changes to the Motrin label so that they would have appeared on the label as of 2000. Plaintiff's FDA regulatory affairs expert, Dr. Randall Tackett, testified that under the "Changes Being Effected" or CBE regulation of the federal Food and Drug Administration, McNeil did not need prior FDA approval to add to McNeil's label for over–the–counter Motrin specific mention of "skin reddening," "rash," and "blisters" as examples of the types of "severe allergic reaction[s]" that Motrin can cause. R.1850a–51a, 185b–86b (T.T. 3/25/11 a.m. at p.55–56); R.1988a–89a, 1135b–36b (4/15/11 p.m. at p.91–95). The U.S. Supreme Court discussed the "Changes Being Effected" regulation, which applies equally to over–the–counter and prescription drugs, in *Levine*, 555 U.S. at 568–71.

As in *Levine*, here McNeil is unable to point to any "clear evidence that the FDA would not have approved a change" to the warning label for Children's Motrin in 2000 containing mention of "rash" and "blisters." McNeil's argument that simply because the FDA approved a particular warning label demonstrates the FDA would have rejected a more informative and more accurate warning label was itself rejected by the U.S. Supreme Court under the similar circumstances presented in *Levine* and should likewise be rejected by this Court.

Here, the trial court correctly instructed the jury that if the jury believed McNeil's argument that the FDA would have rejected a change to the warning label for Children's Motrin in 2000 containing mention of "rash" and "blisters," then the jury had to return a verdict in favor of McNeil on plaintiff's claim for negligent failure to warn.

R.2470a, 2331b (T.T. 5/19/11 a.m. at p.45). Consequently, the jury's verdict in plaintiff's favor on that claim demonstrates that McNeil failed to convince the jury to find as a fact that the FDA would not have approved a change to Children's Motrin's warning label as of 2000 to include mention of mention of "rash" and "blisters."

To summarize, McNeil cannot deny that it knew of the risk of SJS/TEN from ibuprofen (including Children's Motrin), because SJS and TEN have been listed as adverse reactions on the warning label for prescription Motrin since at least 1989. And McNeil cannot plausibly maintain that the FDA would not have allowed the warning label for Motrin to contain mention of "rash" and "blisters" by 2000, given that the FDA approved the inclusion of that very language in the warning label in December 2005. Finally, the jury here specifically rejected McNeil's assertion that the FDA would not have allowed the addition of those terms to the warning label as of 2000, and the evidence of record more than adequately supports rejection of McNeil's defense in that regard.

2. Abundant evidence established that an adequate allergy warning for Children's Motrin that mentioned "Rash" and "Blisters" would have avoided all harm to Brianna Maya because her mother would not have purchased or administered that medication to Brianna

At trial, Brianna Maya's mother, Alicia Maya, testified in great detail that before purchasing Children's Motrin and administering that medication to treat Brianna's fever, Alicia carefully read and reviewed that medication's warning label. R.2037a–38a, 1345b–46b (T.T. 4/21/11 a.m. at p.83–84). Brianna's mother further testified that she

would not have purchased Children's Motrin, nor ever administered any doses of Children's Motrin to Brianna, if the medication's warning label had included mention of "rash" and "blisters." R.2069a–70a, 1409b–10b (T.T. 4/26/11 a.m. at p.43–46). Children's Motrin's warning label did not include those words in 2000, when Alicia Maya purchased the medication, but the warning label was altered in 2005 to include those words, which still appear on that medication's warning label.

McNeil argues in its second ground for j.n.o.v. on appeal that plaintiff's evidence as a matter of law is insufficient to establish the element of proximate cause because, according to McNeil, plaintiff is unable to establish that an adequate warning label would have avoided Brianna's use of Children's Motrin. Based on the evidence and testimony from Brianna's mother described immediately above, more than sufficient evidence exists in this record from which the jury could find that an adequate warning label containing mention of "rash" and "blisters" would have entirely avoided Brianna's use of Children's Motrin.

McNeil's argument in support of its request for j.n.o.v. on this ground misstates both the pertinent evidence of record and the governing law. McNeil begins by asserting that Alicia Maya decided to purchase Children's Motrin based on the recommendation of Brianna's pediatrician, Dr. Brewer, that when a child's fever reaches a certain temperature, the best way to treat such a fever is to alternate doses of Children's Tylenol and Children's Motrin. Then, based on that testimony, McNeil reasons that Alicia Maya would have purchased Children's Motrin and administered

that medication to Brianna regardless of what the warning label for Children's Motrin did or did not state.

The jury's verdict on that point is not subject to being set aside on a request for judgment notwithstanding the verdict because Mrs. Maya testified at trial that she read and reviewed the Children's Motrin warning label, and would not have purchased or administered Children's Motrin to Brianna, if the warning label had mentioned "rash" or "blisters," without regard to Dr. Brewer's recommendation to use both over–the–counter medications to treat a child's fever. R.2037a–38a, 1345b–46b (T.T. 4/21/11 a.m. at p.83–84); R.2070a, 1410b (4/26/11 a.m. at p.46). Mrs. Maya's testimony on this precise point at trial did not contain any reference to relying on Dr. Brewer's recommendation to use Motrin:

> Q. Is there any relationship between what your thought process would have been in 2000 in making these purchasing decisions [if "skin reddening," "rash," or "blisters" had appeared on the Motrin label] 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?
>
> 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.

R.2070a, 1410b (T.T. 4/26/11 a.m. at p.46).

Where the evidence at trial may permissibly viewed in two competing ways — as it can be regarding whether Mrs. Maya would have purchased Motrin for her daughter's use if that medication had contained an adequate warning label in 2000 — and the jury resolves the evidentiary dispute in favor of the plaintiff, an appellate court simply cannot adopt the opposite view of the evidence and hold that j.n.o.v. must be entered in favor of the defendant. *See American Future Systems*, 872 A.2d at 1215.

Whether Alicia Maya would have purchased Children's Motrin and administered that medication to Brianna if the medication's warning label had contained mention of "rash" and "blisters" was a sharply contested issue at trial. The jury, after hearing all of the evidence and receiving a proper proximate cause instruction from Judge Quinones, resolved that factual issue in favor of the plaintiff. McNeil, in its appellate brief, has undertaken a complex and convoluted argument to contend that plaintiff's evidence on this issue was based on impermissible hypotheticals that were supposedly "contrary to fact."

What McNeil ignores, to its peril, is that the jury's determination of what would have happened if Children's Motrin had contained an adequate warning label necessarily required the jury to decide what the ultimate outcome would have been if the facts pertaining to Children's Motrin's warning label differed from what they actually were in 2000. Juries engage in this very sort of fact–finding in every failure to warn case, and the defendant cannot achieve j.n.o.v. by asserting that the jury should have believed the defendant's view of what would have happened had adequate

warnings been given when the jury instead has found that the plaintiff's view is supported by a preponderance of the evidence.

McNeil's argument is also legally unfounded, because it ignores the difference between this case — involving an over–the–counter non–prescription medication — and cases involving prescription drug failure to warn claims. For example, in *Lineberger* v. *Wyeth*, 894 A.2d 141 (Pa. Super. Ct. 2006) — which involved a negligent failure to warn claim pertaining to a *prescription* drug — this Court recognized that under the so–called "learned intermediary doctrine," warnings pertaining to prescription drugs are directed to the physician rather than the patient.

This Court proceeded to hold in *Lineberger* that a doctor's testimony that he would have prescribed the same medication even if he had received the warning that plaintiff claimed was adequate would defeat the plaintiff's ability to recover even if the plaintiff herself testified that she would not have ingested the prescription drug had *she*, the patient, received an adequate warning of the medication's risks.

Brianna Maya's case, by contrast, involves an over–the–counter medication for which the warnings are directed to the patient/purchaser rather than to the physician. McNeil's argument that Dr. Brewer's recommendation of Children's Motrin renders irrelevant Alicia Maya's testimony that adequate warnings would have caused her not to purchase or use the medication on Brianna is predicated on legal principles that only apply to prescription drug negligent failure to warn cases. Because this case does not involve a prescription drug, McNeil's argument for j.n.o.v. on this basis is legally unsound and should be rejected.

In sum, the evidence more than adequately supports the jury's finding that Alicia Maya would not have purchased Children's Motrin or administered that medication to Brianna if the medication's warning label had contained mention of "rash" and "blisters." McNeil's argument to the contrary fails to view the evidence in the light most favorable to plaintiff and has a legally erroneous basis, being grounded in precedent that applies only in the prescription drug context.

3. Plaintiff's evidence more than adequately supports the jury's findings that an adequate warning label would have informed Dr. Brewer that rash could be a precursor to SJS/TEN and that stopping Children's Motrin when Brianna's parents first consulted Dr. Brewer would have avoided Brianna's utterly horrific injuries

The third and final ground for j.n.o.v. that McNeil advances on appeal is based on an amalgam of two different evidentiary–related arguments. First, McNeil observes that the allergy warning label that Brianna contends Children's Motrin should have contained would have advised the patient to stop using Children's Motrin and consult a doctor if a rash appears. McNeil observes that on Monday, November 27, 2000, Brianna's father took her to see her pediatrician, and Dr. Brewer did not recommend discontinuing Children's Motrin even though Brianna had rash–like symptoms. Secondly, McNeil asserts that even if Dr. Brewer had told Brianna's parents to discontinue administering Children's Motrin due to Brianna's rash–like symptoms, the evidence fails to establish that discontinuing the medication at that point would have ameliorated Brianna's injuries to any extent.

Once again, McNeil's argument in favor of its request for j.n.o.v. on appeal impermissibly fails to view the evidence in the record in the light most favorable to the plaintiff. Dr. Brewer testified at trial, on videotape, that in 2000 when Brianna experienced the horrific consequences of SJS/TEN resulting from Children's Motrin, Dr. Brewer was not aware that rash was a potential precursor to SJS/TEN as a result of ingesting Children's Motrin. R.3529a (Ct. Ex. 3 at p.96).

McNeil argues in its Brief for Appellant that the purpose of having adequate warnings on over–the–counter Children's Motrin is for the benefit and use of the consumer — here, Brianna's mother, Alicia Maya — and not to convey information to physicians such as Brianna's pediatrician, Dr. Brewer. What McNeil's argument overlooks, however, is that as to Dr. Brewer it was the inadequacies in the label for prescription Motrin that were most relevant. Dr. Brewer testified in great detail at trial, through a prerecorded videotaped deposition displayed to the jury, that the label for prescription Motrin failed to advise that rash was a precursor to SJS/TEN and that if McNeil had warned her that rash was a precursor to SJS/TEN then she would have immediately discontinued Brianna's use of that medication. R.3523a, 3528a–31a, 3534a–35a (Ct. Ex. 3 at p.77–78, 94, 96, 102–04, 116–17).

Secondly, there was far more than adequate evidence for the jury to conclude that Brianna's failure to discontinue Children's Motrin after initially consulting with Dr. Brewer's office early on Monday, November 27th — which caused Brianna to ingest four or five additional doses of Children's Motrin out of the total of ten that she

ingested overall during this period — fueled and significantly exacerbated the severity of her SJS/TEN reaction to Children's Motrin.

Specifically, the jury heard from two highly qualified expert witnesses — Dr. Tackett and Dr. John Schulz — that continuing to fuel an allergic reaction by continuing to supply doses of the allergen unquestionably worsens the patient's allergic reaction, in the nature of continuing to add fuel to a fire. Dr. Tackett testified that "[y]ou have a better prognosis if you stop the drug." R.1858a, 227b (T.T. 3/25/11 p.m. at p.59). Dr. Tackett further testified that "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 stage. And we know that the prognosis or the ability to recover from it is much improved the sooner you stop the drug." R.1927a, 580b (T.T. 4/4/11 a.m. at p.77–78).

Similarly, Dr. Schulz testified at trial that "people in whom [the offending medication] was stopped faster * * * tended to do better." R.1888a, 388b (T.T. 3/30/11 a.m. at p.122–23). Dr. Schulz and numerous other witnesses testified regarding a study published in March 2000 (R.3079a (Ex. P–24 (Garcia–Doval study))) which demonstrated that the early discontinuation of drugs that cause SJS or TEN, including ibuprofen/Motrin, decreased death and injury from SJS/TEN. R.1888a, 388b (T.T. 3/30/11 a.m. at p.122–23); R.2227a, 2238a, 1841b, 1853b (T.T. 5/10/11 a.m. at p.63, 108–10). Dr. Schulz also observed that by failing to stop the administration of Children's Motrin early on Monday, November 27th, "she's descending into this firestorm of a disease [SJS/TEN], and the causative agent is still being given." R.1888a–89a, 388b–89b (T.T. 3/30/11 a.m. at p.123–24).

Based on the evidence described above, the jury had more than a sufficient evidentiary basis on which to find that Brianna's prognosis would have been improved if Dr. Brewer's office would have advised ending Children's Motrin early on Monday, November 27, 2000, which Dr. Brewer's office would have advised if the warning label for Motrin had been adequate.

Moreover, as a matter of law, Brianna does not have to establish that her SJS/TEN would have been entirely avoided had McNeil issued proper warnings, which as a result would have caused Dr. Brewer to issue a "stop use" instruction on Monday, November 27th. Rather, all that plaintiff had to establish was that her condition would not have been as horrific as it ultimately ended up being if she had discontinued using Children's Motrin sooner.

In *Neal* v. *Bavarian Motors, Inc.*, 882 A.2d 1022, 1028 (Pa. Super. Ct. 2005), this Court recognized that "[m]ost personal injuries are by their very nature incapable of division." (quoting *Capone* v. *Donovan*, 480 A.2d 1249, 1251 (Pa. Super. Ct. 1984)). In *Neal*, this Court quoted the following two additional passages from *Capone* with approval:

> If the tortious conduct of two or more persons causes a single harm which cannot be apportioned, the actors are joint tortfeasors even though they may have acted independently.

and

> If two or more causes combine to produce a single harm which is incapable of being divided on a logical, reasonable, or practical basis, and each cause is a substantial factor in bringing about the harm, an arbitrary apportionment should not be made.

Neal, 882 A.2d at 1027–28 (quoting *Capone*, 480 A.2d at 1251).

Earlier, in *Carlson* v. *A. & P. Corrugated Box Corp.*, 364 Pa. 216, 72 A.2d 290 (1950), Pennsylvania's highest court explained:

> It is a familiar legal doctrine that where two tortfeasors are guilty of concurrent negligence each is responsible for the full amount of the resulting damage and is not entitled to any apportionment of liability. There is no reason why the same rule should not apply where one of the operative agencies, instead of being a tortfeasor, is a force of nature.

Id. at 224, 72 A.2d at 294 (citation omitted). Because the evidence here properly allowed the jury to conclude that Brianna's injuries would have been significantly lessened and perhaps entirely avoided had she stopped ingesting Children's Motrin once Dr. Brewer had been contacted about Brianna's rash–like symptoms, the Supreme Court's ruling in *Carlson* requires the rejection of McNeil's suggestion that it would be unfair and contrary to Pennsylvania law to hold McNeil liable for all of plaintiff's damages.

Moreover, to the extent that McNeil is arguing that it can only be held responsible for the proportion of the injuries to Brianna that McNeil's negligence had caused, that argument is directly contrary to Pennsylvania law. *See Martin* v. *Owens–Corning Fiberglas Corp.*, 515 Pa. 377, 528 A.2d 947 (1987). In *Martin*, the Supreme Court held that the defendant could be held liable for the full amount of damages necessary to compensate the plaintiff for injuries to his respiratory system resulting from a combination of asbestosis caused by defendant's products and emphysema caused by plaintiff's cigarette smoking, for which the defendant bore no responsibility. *Id.* at 381–85, 528 A.2d at 949–51. This result was proper, the Court ruled, because it was impossible to determine to what degree each cause had contributed to bringing about

the single condition from which the plaintiff suffered. *Id.*; *see also Harsh* v. *Petroll*, 584 Pa. 606, 621–23, 887 A.2d 209, 218–19 (2005).

Similarly, this Court explained in *Smith* v. *Pulcinella*, 656 A.2d 494 (Pa. Super. Ct. 1995) (Saylor, J.), that "an arbitrary apportionment should not be made" when two or more causes combine to cause a single harm. *Id.* at 496 (internal quotations omitted). Indeed, under Pennsylvania law, it is the burden of the defendants, and not the plaintiff, "to present evidence of such a nature that damages could be apportioned." *Corbett* v. *Weisband*, 551 A.2d 1059, 1079 (Pa. Super. Ct. 1988) (*citing Martin* v. *Owens–Corning Fiberglas Corp.*, *supra*). McNeil did not present any such evidence, and thus McNeil's argument that it cannot be held liable for all of Brianna's damages is both legally and factually unsupported.

* * * * *

As demonstrated above in subsections B.2. and B.3. of the Argument section of this brief, more than adequate evidence exists to support the jury's finding of proximate cause with respect to both Alicia Maya and Dr. Brewer. It is nevertheless important to note that, under Pennsylvania law, McNeil bears the burden of establishing on appeal that, after viewing the evidence and the inferences therefrom in a light most favorable to plaintiff, insufficient evidence exists as to both of plaintiff's alternate methods of proving proximate cause in order for McNeil to obtain j.n.o.v.

McNeil failed to request or obtain a special verdict slip that would have required the jury to identify the basis or bases for the jury's finding in favor of plaintiff on the issue of proximate cause, and on appeal McNeil does not argue that the trial court erred

or abused its discretion in failing to require the jury to specifically identify the grounds on which the jury found proximate cause.

In *Halper* v. *Jewish Family & Children's Serv.*, 600 Pa. 145, 963 A.2d 1282 (2009), Pennsylvania's highest court endorsed and adopted the so–called "general–verdict rule," a rule which provides that "when the jury returns a general verdict involving two or more issues and its verdict is supported as to at least one issue, the verdict will not be reversed on appeal." *Id.* at 156–57, 963 A.2d at 1288–89 (internal quotations omitted). As the Supreme Court further explained, "[a] defendant who fails to request a special verdict form in a civil case will be barred on appeal from complaining that the jury may have relied on a factual theory unsupported by the evidence when there was sufficient evidence to support another theory properly before the jury." *Id.* at 157, 963 A.2d at 1289.

As the Supreme Court of Pennsylvania proceeded to hold in *Halper*, "because a general verdict was returned and the evidence supported one of the [plaintiffs'] theories, the verdict must stand." *Id.* As applicable here, in order to obtain j.n.o.v. on the issue of proximate cause, McNeil must establish that the jury — even after viewing the evidence and all inferences therefrom in the light most favorable to plaintiff — indisputably lacked sufficient evidence to find in plaintiff's favor on either of plaintiff's theories of proximate cause: first, that Brianna's use of Children's Motrin would have been entirely avoided if the medication contained warnings of "rash" and "blisters" in 2000; and, second, that Brianna's injuries would have been averted in whole or in part had Dr. Brewer's office advised ending Brianna's use of Children's Motrin early on

Monday, November 27, 2000, which Dr. Brewer's office would have advised if the warning label for Motrin had been adequate.

Because more than adequate evidence exists in support of both of plaintiff's proximate cause theories, and because McNeil is clearly unable to establish that adequate evidence exists in favor of neither of those theories of proximate cause, the trial court's order denying McNeil's motion for j.n.o.v. should be affirmed.

C. The Trial Court Did Not Abuse Its Discretion In Rejecting All Of The Grounds For A New Trial That McNeil Continues To Pursue On Appeal

1. The trial court properly rejected as irrelevant, prejudicial, confusing, and a waste of time McNeil's attempt to cast doubt on Dr. Brewer's testimony that she did not know rash was a precursor of SJS/TEN by using the fact that some 10 years earlier Dr. Brewer herself had suffered from SJS

As explained above, Brianna Maya's pediatrician, Dr. Brewer, testified at trial that she did not appreciate in 2000 that rash can be a precursor of SJS/TEN caused by Children's Motrin. R.3529a (Ct. Ex. 3 at p.96). For the first of its six grounds for new trial raised on appeal, McNeil argues that Judge Quinones abused her discretion by failing to allow McNeil to impeach Dr. Brewer's testimony in that regard with Dr. Brewer's admission during discovery that Dr. Brewer herself had suffered from SJS some ten years earlier, in or around the year 1990.

As this Court explained in *Rettger* v. *UPMC Shadyside*, 991 A.2d 915 (Pa. Super. Ct. 2010), "[o]ur Rules of Evidence vest the trial court with the authority to determine the admissibility of evidence as well as to control the scope of examination. Rule 403

stresses the importance of clear, concise, and expeditious presentation, allowing for the exclusion of evidence that is confusing, cumulative, or unfairly prejudicial." *Id.* at 925 (internal citation omitted). This Court's ruling in *Rettger* goes on to note that "[a]ppellate review of the court's rulings under these rules is limited to determining whether the trial judge abused his discretion. As applied to rulings on the evidence, this standard requires not only technical error but also demonstrated harm; '[e]videntiary rulings which did not affect the verdict will not provide a basis for disturbing the jury's judgment.'" *Id.* at 925 (internal citations omitted).

Although, as plaintiff demonstrates below, the trial court properly excluded the evidence of Dr. Brewer's SJS from some 10 years earlier as entirely irrelevant, *see* Pa. R. Evid. 402 ("Evidence that is not relevant is not admissible."), even if the evidence were somehow relevant, the trial court properly excluded the evidence on grounds of prejudice, confusion, and waste of time, *see* Pa. R. Evid. 403 ("Although relevant, evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.").

To begin with, the evidence that Dr. Brewer suffered from SJS in or around 1990 was totally irrelevant to this case, because McNeil has failed to establish either that rash was a precursor to Dr. Brewer's SJS or, more broadly, that rash is always necessarily a precursor to SJS. As McNeil explains in its Brief for Appellant, McNeil wanted to impeach Dr. Brewer's testimony that in 2000 Dr. Brewer did not realize that Brianna

Maya's rash was a precursor of SJS/TEN caused by Children's Motrin merely because Dr. Brewer herself had SJS in or around 1990.

Yet, as the trial court recognized, the evidence that Dr. Brewer suffered from SJS in 1990 was irrelevant because McNeil failed to provide any evidence to bridge the two logical leaps necessary to make the evidence of Dr. Brewer's SJS actually relevant: either that Dr. Brewer's SJS itself had rash as a precursor[5] or that SJS in all cases has rash as a precursor. Moreover, the reason that McNeil did not attempt to convince the trial court that SJS in all cases has rash as a precursor is, in all likelihood, because that assertion is simply not scientifically correct.[6] In other words, merely because Dr. Brewer had SJS in 1990 does not mean that her SJS had rash as a precursor, nor is there any evidence in the record to establish that Dr. Brewer did have rash as a precursor to her SJS in 1990. For

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[5] At the time of her videotaped deposition in 2010, Dr. Brewer's SJS had occurred some 20 years earlier. R.1821a (Brewer Dep. Trans. 6/30/10 at p.161). Nowhere in that deposition did counsel for McNeil ask Dr. Brewer if Dr. Brewer's own SJS involved rash as a precursor, and therefore the jury in this case would not have heard any testimony from Dr. Brewer that Dr. Brewer's own SJS involved rash as a precursor.

[6] The leading case control studies addressing the relationship between medications and SJS/TEN, which both opposing parties heavily relied on at trial, fail to support McNeil's suggestion that all instances of SJS or TEN involve or "pass through" a rash. R.3047a (Ex. D–3317 (Roujeau, et al., "Medication Use and the Risk of Stevens–Johnson Syndrome or Toxic Epidermal Necrolysis," New England J. of Med. 333:1600 (1995) (omitting any mention of rash from the publication)); R.3055a (Ex. D–3349 (Sheridan, et al., "Long–Term Consequences of Toxic Epidermal Necrolysis in Children," Pediatrics 109(1):74–78 (2002) (similarly omitting any mention of rash from the publication)); R.3060a (Ex. D–3354 (Mockenhaupt, et al., "The Risk of Stevens–Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Anti–Inflammatory Drugs: A Multinational Perspective," J. Rheumatology, 30:2234–40 (2003) (while noting that rash may be a symptom of SJS/TEN, the article fails to assert that rash is always a symptom of or precursor to SJS/TEN)).

these reasons, the trial court did not abuse its discretion by excluding this evidence as irrelevant.

Moreover, even in the extraordinarily unlikely event that the evidence that Dr. Brewer had SJS in 1990 could be considered relevant evidence, the trial court did not abuse its discretion under Rule 403 in excluding the evidence as prejudicial, confusing, and a waste of time. Dr. Brewer's specific testimony was that in 2000 she did not appreciate or recognize that Brianna Maya's rash was a precursor of SJS/TEN that could be caused by Children's Motrin. R.3529a (Ct. Ex. 3 at p.96). Dr. Brewer's own SJS occurred some ten years earlier, which was very remote in time. Permitting testimony about Dr. Brewer's SJS would have caused the jury to speculate about what caused her condition and what the symptoms turned out to be, which are matters that extend far beyond the scope of truly relevant evidence, and may have even been intended to embarrass Dr. Brewer by exposing in a public forum sensitive and otherwise confidential details of her own medical history.

Indeed, the trial court's exclusion of this evidence may have even served to strengthen McNeil's defense of the case. One of McNeil's overarching themes in its defense of this case was that SJS and TEN are conditions that only manifest themselves with extreme rarity, and thus a traditional cost–benefit analysis would not require that warnings for those conditions be supplied on the labeling of Children's Motrin. Having the jury hear that not only Brianna Maya but also her pediatrician Dr. Brewer had both experienced SJS within a 10 year period would provide the jury with concrete evidence directly contradicting McNeil's argument that the illness occurs with great infrequency.

At bottom, McNeil asks this Court to conclude that the mere fact that Dr. Brewer suffered from SJS ten years before Brianna Maya did would provide a valid evidentiary basis for the jury to conclude that Dr. Brewer was not telling the truth when Dr. Brewer testified at trial, unequivocally, that she did not recognize that rash was a precursor of SJS/TEN caused by Children's Motrin. For the reasons explained above, McNeil's argument would have required the jury to make two impermissible logical leaps in the absence of any evidence either that Dr. Brewer's own SJS had rash as a precursor or that SJS/TEN in all cases has rash as a precursor. In the absence of this necessary evidence, the trial court most certainly did not abuse its discretion in ruling that McNeil could not introduce evidence of Dr. Brewer's own SJS some ten years earlier to impeach Dr. Brewer's testimony that she did not recognize that rash was a precursor of SJS/TEN caused by Children's Motrin.

2. The trial court's failure to give a heeding presumption charge to the jury did not prejudice McNeil, which retained every incentive to argue — if only the evidence had in any way supported such an argument — that Mrs. Maya would not have heeded an adequate Children's Motrin warning

Following the conclusion of the evidence, the opposing parties met with Judge Quinones to discuss the trial court's charge to the jury. Counsel for the plaintiff requested a so–called "heeding instruction," which under Pennsylvania law is a rebuttable presumption that the purchaser of a product would have followed the product's warnings if the product had contained adequate warnings. McNeil, by contrast, opposed any heeding instruction. R.2219a, 1786b (T.T. 5/5/11 a.m. at p.43–45).

Originally, Judge Quinones advised the parties that she intended to deliver a heeding instruction charge to the jury (R.2389a, 2228b (T.T. 5/17/11 a.m. at p.44–45)), but ultimately Judge Quinones reconsidered and did not deliver a heeding instruction as part of the trial court's charge to the jury, which Judge Quinones delivered after the parties had presented their closing arguments to the jury.

Although a heeding instruction delivered to the jury would only have benefitted the plaintiff, and although McNeil argued to the trial court and continues to maintain on appeal that no heeding instruction was appropriate, McNeil nevertheless advances a rather bizarre argument for a new trial based on these circumstances. McNeil argues that because the trial court had informed the parties that the trial court would be delivering a heeding instruction, McNeil was prejudiced because its attorney therefore opted not to argue to the jury that the evidence failed to establish that Mrs. Maya would have not purchased Children's Motrin to administer to Brianna if the medication's warning label contained mention of "rash" and "blisters."

Under Pennsylvania law, a heeding presumption is a rebuttable evidentiary presumption. *See Viguers* v. *Philip Morris USA, Inc.*, 837 A.2d 534, 538 (Pa. Super. Ct. 2003), *aff'd*, 584 Pa. 120, 881 A.2d 1262 (2005). An evidentiary presumption allows the jury to find whatever facts the presumption encompasses even in the absence of affirmative proof of those facts if the jury determines it is appropriate to do so. As a result, the trial court's failure to deliver the promised heeding presumption jury instruction only threatened to harm the plaintiff, who at all times bore the burden of

proving that an adequate Children's Motrin warning would have averted harm to Brianna Maya.

A heeding presumption is particularly important in cases where the purchaser of a product or, in prescription drug cases, the prescriber is no longer available to testify concerning what the purchaser or prescriber would have done if an adequate warning had been supplied. For example, because Pennsylvania law does not follow the heeding presumption in prescription drug negligent failure to warn cases in which the learned intermediary doctrine applies, the death or incapacitation of the prescribing physician may preclude any recovery by the plaintiff. Similarly, if a plaintiff is killed or rendered totally incapacitated by a piece of heavy equipment that contained inadequate warnings, the heeding presumption may be necessary to allow the plaintiff any possibility of recovery.

Here, by contrast, the heeding presumption had no impact whatsoever on the evidence or arguments of either party in this case. As the trial court correctly recognized in its opinion, Brianna Maya's mother, Alicia, testified clearly and unambiguously to the jury that she would not have purchased Children's Motrin for Brianna's use if the medication's warning label had contained mention of either "rash" or "blisters." *See* Exhibit B to Brief for Appellant (Opinion at 42–43). That testimony, no doubt, was the reason why the trial court's omission of any heading presumption charge from the jury instructions did not prove fatal to plaintiffs' case — the plaintiffs were not relying on the existence of any such heeding presumption to establish any element of plaintiffs' necessary evidentiary proof.

It is entirely unpersuasive for McNeil to maintain on appeal that the trial court's promised delivery of a rebuttable heeding presumption charge in any way influenced McNeil's decision whether or not to argue to the jury concerning whether Alicia Maya would or would not have purchased Children's Motrin had the medication contained adequate warnings consisting of a mention of "rash" and "blisters" as potentially serious allergic reactions to the medication. As this Court explained in *Viguers*, "[i]n order to rebut the heeding presumption, the defendant need only produce evidence 'sufficient to support a finding contrary to the presumed fact.'" *Viguers*, 837 A.2d at 538. In other words, in accordance with this Court's own longstanding precedent, the rebuttable heeding presumption drops out of the case entirely whenever the defendant produces evidence sufficient to support a finding contrary to the presumption that the warning would have been heeded. Thus, if McNeil had any evidence or argument that sufficed to disprove Mrs. Maya's testimony that she would not have purchased Children's Motrin if the medication had contained an adequate warning, then McNeil had every motivation to highlight that evidence or argument to the greatest extent possible in its closing argument.

In essence, McNeil is improperly asking this Court to adopt a "heads I win, tails you lose" approach to the issue of the heeding presumption. McNeil contends that if the trial court had given the jury such an instruction, the trial court would have committed reversible error. But then, based on the facts of this case, McNeil proceeds inconsistently to argue that the trial court's failure to deliver the supposedly erroneous heeding presumption was itself reversible error.

For the reasons explained above, the trial court's failure to give a heeding presumption instruction to the jury only threatened to injure the plaintiff. But in actuality, this was not a case in which either side's strategy was impacted by whether or not such a jury instruction was given. The plaintiff did not rely on the presumption, because Mrs. Maya was available to testify and did testify that an adequate warning would have caused her not to purchase Children's Motrin or administer the medication to Brianna. And the possibility that a heeding presumption instruction might be given to the jury should not have influenced McNeil's closing argument strategy either, because any evidence that McNeil could have pointed to that was contrary to the presumption would have caused the presumption to drop from the case entirely. For these reasons, this Court should reject this utterly frivolous ground for a new trial.

3. The trial court did not abuse its discretion in presenting the jury with a "concurring cause" instruction where the opposing parties each advocated for different causes of Brianna's injuries, and the jury reasonably could have concluded that both causes combined to result in those injuries

The next ground for a new trial that McNeil advances in the Argument section of its Brief asserts that a trial court errs or abuses its discretion when it provides the jury with an otherwise proper concurring cause instruction in a case where the opposing parties disagree over whether one cause or another cause was responsible for the entirety of the plaintiff's harm.

More specifically, while plaintiff Brianna Maya argued that Children's Motrin was the cause of her SJS/TEN, McNeil argued that a different medication was instead

the cause of Brianna's SJS/TEN. Importantly, McNeil's own expert witness testified at trial that he could not exclude the possibility that *both* Motrin and another drug caused Brianna's TEN. R.2249a, 1986b–87b (T.T. 5/11/11 p.m. at p.59–60). As the trial court correctly recognized, the evidence that the opposing parties introduced and the parties' competing arguments over causation made it both necessary and appropriate for the trial court to charge the jury concerning what the legal consequences would be to the jury's verdict if the jury were to find that the two causes combined to cause Brianna's damages. *See* Exhibit B to Brief for Appellant (Opinion at 110–11).

It is noteworthy that McNeil does not challenge as legally inaccurate the trial court's concurring causes instruction. Rather, McNeil is simply dissatisfied with the state of the law, which provides that if McNeil's medication combined with another medication to cause Brianna's SJS/TEN, the jury could still opt to hold McNeil liable for the full measure of Brianna's damages. Surely if Pennsylvania law provided that when two concurring causes combine to produce an injury the plaintiff can recover from neither defendant, McNeil would not be arguing that no concurring charge instruction should have been given.

The harsh all–or–nothing approach for which McNeil's concurring causes argument advocates has no basis in Pennsylvania law. Assume a case in which the plaintiff sues a defendant, asserting that the defendant's negligence caused injury and harm to the plaintiff. Assume further that the defendant's lone defense to the claim was that the plaintiff's own negligence was entirely to blame for the plaintiff's injury and resulting damages.

Presumably it would be McNeil's contention in that hypothetical case that the trial court would be committing legal error in instructing the jury concerning the law of comparative negligence, given that neither opposing party was contending that their respective negligence combined to produce the plaintiff's injury and damages. *But see Eichman* v. *McKeon*, 824 A.2d 305, 318–19 (Pa. Super. Ct. 2003) ("The law is clear that a trial court must instruct the jury on comparative negligence whenever there is any such evidence of negligence on the part of the plaintiff.").

As the Supreme Court of Pennsylvania explained in *Commonwealth, Dep't of Transp.* v. *Patton*, 546 Pa. 562, 686 A.2d 1302 (1997), "[w]hen a challenge is made to the jury instructions, the appellate court must look at the charge in its entirety, against the background of evidence in the case, to determine whether an error of law was committed and whether prejudice resulted." *Id.* at 567, 686 A.2d at 1305.

Similarly, in *Goldmas* v. *Acme Markets, Inc.*, 574 A.2d 100 (Pa. Super. Ct. 1990), this Court observed:

> It is now well established in this Commonwealth that portions of a jury charge are not reviewed for error in isolation. Rather, an appellate court is bound to examine the charge in its entirety against its evidentiary background. From the examination we must determine, first, whether any error was committed and, if so, whether the error was prejudicial to the complaining party.

Id. at 104. As the Supreme Court's ruling in *Patton* and this Court's ruling in *Goldmas* demonstrate, whether or not a trial court's jury instructions are erroneous can only be evaluated based on the evidentiary background in the case. In this case, that evidentiary background fully justified the trial court's concurring cause instruction.

Here, the trial court properly recognized that the parties' diametrically opposed causation arguments could have resulted in the jury's finding that both of the causes contended for individually by the parties combined to cause the plaintiff's injury and harm. It was therefore an appropriate use of the trial court's discretion, rather than an abuse thereof, for the trial court to provide the jury with a legally correct (and substantively unchallenged) concurring cause instruction under the facts and circumstances of this case.

4. McNeil's fourth ground for a new trial — asserting that the trial court supposedly misread McNeil's proposed jury instruction telling the jury not to consider that other drugs had been withdrawn from the market — is entirely without merit

McNeil's fourth ground for a new trial asserts that the trial court omitted the word "not" from McNeil's proposed jury instruction informing the jury that "you may [not] consider * * * what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct." When McNeil objected to the trial court's reading of this jury charge at trial, both the trial judge and counsel for plaintiff observed that the trial judge had read this specific charge exactly as McNeil had submitted it. R.2476a, 2337b (T.T. 5/19/11 a.m. at p.69). McNeil, in its Brief for Appellant, asserts that the trial court misunderstands McNeil's argument, but the trial court's opinion contains no sign of any misunderstanding. Rather, the contemporaneous record shows that trial court disagreed that McNeil's proposed instruction was read to the jury with the word "not" left out.

Moreover, even if trial judge had in fact mistakenly omitted the word "not" from this particular jury charge, any error was waived and constituted harmless error at most. To begin with, this ground for new trial as set forth in McNeil's Brief for Appellant contains no citation to any case law or any legal authorities whatsoever. As this Court explained in *Harris* v. *Toys "R" Us–Penn, Inc.*, 880 A.2d 1270 (Pa. Super. Ct. 2005), "[w]e have repeatedly held that failure to develop an argument with citation to, and analysis of, relevant authority waives that issue on review." *Id.* at 1279. Accordingly, this Court should hold that McNeil has waived this ground for a new trial.

The trial court's supposed error in any event represents nothing more than harmless error, because the evidence introduced at trial pertaining to the withdrawal of other medications from the market by other manufacturers was relevant only to plaintiff's claim for negligent design defect, as to which the jury returned a finding in McNeil's favor. In *Lance* v. *Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010), *alloc. granted*, 609 Pa. 269, 15 A.3d 429 (2011), where this Court recognized a claim for negligent design defect under Pennsylvania law involving a prescription drug, the prescription drug at issue had been permanently removed from the market by the FDA. Similarly, other manufacturers' withdrawal from the market of other medications may have been relevant to plaintiff's request for punitive damages, but again the jury found in McNeil's favor on that form of relief.

Here, plaintiff's negligent failure to warn claim is the only claim as to which the jury found in Brianna Maya's favor, and as to that claim the issue of the withdrawal of other medications from the market by other manufacturers was entirely irrelevant. It

was not and is not Brianna's argument in support of her negligent failure to warn claim that Children's Motrin should not have been available for sale on the market in 2000 or remained available for sale at the time of trial. Rather, Brianna's argument was merely that the medication's warning label should have included "rash" and "blisters" among the signs of serious allergic reaction in 2000, as the medication's label now does and has done since 2005.

For these reasons, even if this Court were to find, contrary to Judge Quinones' own first–hand account, that she omitted the word "not" from this particular jury instruction, and even if this Court were to conclude that McNeil's failure to cite any legal authority in support of its argument did not constitute a waiver, this Court should nevertheless conclude that the omission of the word "not" — if in fact any such omission occurred — constituted harmless error at most and does not provide any valid basis for a new trial.

5. McNeil advances the same consistently rejected amalgam of evidentiary complaints in this case that drug manufacturer defendants have advanced in earlier similar cases — involving other risks of the drug, post–usage evidence, foreign regulatory matters, advertisements not seen by the plaintiff, and supposedly "preempted" evidence — and this Court should likewise reject these new trial arguments here

Before concluding its new trial arguments with a lengthy cataloguing of the "rampant, prejudicial misconduct" in which plaintiff's trial counsel supposedly engaged at trial, the next to last ground for a new trial advanced in McNeil's Brief for

Appellant consists of a potpourri of supposedly erroneous and prejudicial evidentiary rulings that the trial court returned against McNeil and in favor of the plaintiff.

Before responding to the five categories of supposedly impermissible evidence that the jury was permitted to consider, it is important to recall precisely what claims were before the jury in this case. The jury was considering not only plaintiff's negligent failure to warn claim, but also plaintiff's claim for negligent design defect and plaintiff's contention that McNeil's conduct was wanton, willful, and recklessly indifferent so as to merit an award of punitive damages under Pennsylvania law.

The risks of Motrin other than SJS/TEN were unquestionably relevant to plaintiff's negligent design defect claim and plaintiff's request for punitive damages. However, that evidence was simply not relevant to plaintiff's negligent failure to warn claim, and thus there is no reason to believe that the jury made any use of that evidence in connection with the only claim as to which Brianna Maya prevailed in this case. Thus, McNeil's challenge to the admission of this evidence is not only legally erroneous, but any error constitutes harmless error at most.

McNeil's challenge to evidence of post–2000 notices that McNeil had received of conditions or diseases resulting from Children's Motrin should be denied, because that evidence was relevant to establish causation, to establish the feasibility of the adequate warnings that McNeil finally did institute in 2005, and to plaintiff's claims of negligent design defect and punitive damages. McNeil, in its Brief for Appellant, acknowledges that the trial court gave the jury a limiting instruction that this evidence should only "be considered for the limited purpose of notice and not causation." Because juries are

presumed to follow the lawful instructions of the trial court, *see Commonwealth* v. *Chmiel*, 777 A.2d 459, 469 (Pa. Super. Ct. 2001) ("juries are presumed to follow instructions of trial court"), here the admission of this evidence neither constituted an abuse of discretion nor harmful error.

McNeil's discussion of so–called "preempted evidence" in its Brief for Appellant addresses a category of evidence that simply does not exist. Here, the jury was instructed that it could only find in favor of Brianna Maya if the jury found that the FDA would have permitted the warning label in 2000 that Brianna contended Children's Motrin should have then contained. R.2470a, 2331b (T.T. 5/19/11 a.m. at p.45–46). McNeil's Brief for Appellant concedes that "the trial court's instructions ultimately took this issue off the table." Brief for Appellant at 51. If this issue was off the table by McNeil's own concession, surely this argument provides no ground for granting a new trial or finding harmful error.

Next, McNeil argues that the trial court erred in admitting evidence of advertisements for Children's Motrin that Alicia Maya, Brianna's mother, had not seen. To begin with, the testimony of Alicia Maya establishes that she did see advertisements for Children's Motrin. R.2068a, 1408b (T.T. 4/26/11 a.m. at p.37). Moreover, the existence of these advertisements were relevant to the jury's consideration of plaintiff's request for punitive damages, which the jury resolved in McNeil's favor. As the trial court's opinion recognized, these advertisements, to the extent that they were even relevant to plaintiff's negligent failure to warn claim, were neither harmful to McNeil nor helpful to plaintiff in connection with that claim. As such, the trial court's

admission of advertisements that plaintiff's mother may not have seen did not constitute an abuse of discretion, given plaintiff's claim for punitive damages, nor did the admission of these ads constitute harmful error.

Finally, a new trial is not required due to the supposedly improper introduction of evidence pertaining to the regulation by foreign entities of ibuprofen products sold outside of the United States. The testimony at issue in the first portion of the record to which McNeil cites (R.1934a–35a, 631b–32b (T.T. 4/5/11 a.m. at p.39–40)) establishes only that ibuprofen's warnings in the United States differed in some unspecified ways from the warnings in use in other countries, but the substance of the differences were not described to the jury. And McNeil's other objection pertains to a different NSAID medication that was withdrawn from the market in other countries *and* in the United States (R.2022a, 1234b (T.T. 4/19/11 a.m. at p.66–67)), and thus this alleged transgression (which arose in a lengthy introduction by plaintiff's counsel to a question to a witness) cannot constitute harmful error, because the foreign regulatory response was identical to the response of regulators in the United States. Moreover, the trial court instructed the jury both before trial commenced and again before jury deliberations began that the statements and questions of counsel are themselves not evidence. R.1828a, 77b (T.T. 3/23/11 p.m. at p.17); R.2416a, 2322b (5/19/11 a.m. at p.10). A jury is presumed to follow the instructions it receives from the trial court. *See Commonwealth* v. *Naranjo*, 53 A.3d 66, 71 (Pa. Super. Ct. 2012) ("Juries are presumed to follow a court's instructions."). Consequently, McNeil is unable to demonstrate that the supposedly

improper introduction into evidence of what McNeil refers to as "foreign regulatory matters" constitutes grounds for a new trial.

In sum, the potpourri of supposed evidentiary errors on which McNeil relies as the fifth ground for a new trial fail, either individually or as a group, to represent an abuse of discretion or harmful error. Accordingly, the trial court's decision rejecting these grounds for a new trial should be affirmed.

6. Judge Quinones did not abuse her discretion in concluding that plaintiff's counsel did not engage in misconduct at trial and that McNeil's complaints about the conduct of plaintiff's counsel at trial did not justify a new trial

At the outset of the "Law and Discussion" section of Judge Quinones' post–trial opinion in this case, she writes:

> 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 lodged against each other.

See Exhibit B to Brief for Appellant (Trial court's Rule 1925(a) opinion at 17).

Perhaps stung by this language, in the sixth and final ground for a new trial contained in McNeil's Brief for Appellant, McNeil asserts that counsel for the plaintiff engaged in "rampant, prejudicial misconduct" justifying a new trial. Of course, Judge Quinones, who sat through the entire trial and observed the actions of all counsel, did not agree and denied McNeil's motion for a new trial on this (and all other) grounds.

On appeal, McNeil's presentation focuses on essentially three points. First, McNeil argues that plaintiff's counsel drew too much attention during the trial to the fact that McNeil was a wealthy corporation. Second, McNeil asserts that plaintiff's counsel improperly drew attention to the fact that the FDA was inadequately funded and an ineffective regulator of drug safety and the pharmaceutical industry in general. And third and finally, McNeil asserts that plaintiff's counsel supposedly again and again disregarded objections that the Judge Quinones had sustained. Judge Quinones' charge to the jury more than adequately addressed and eliminated any potential prejudice to McNeil stemming from any of these complaints.

Plaintiff has little to add to the trial court's persuasive rejection of McNeil's motion for a new trial based on the conduct of plaintiff's counsel. *See* Exhibit B to Brief for Appellant (Opinion at 51–73). First of all, successful plaintiffs' attorneys practicing in Philadelphia are renowned for the zealous forcefulness with which they represent their clients. Attorneys such as Tom Kline and Shanin Specter, Robert Mongelluzi, Tom Duffy, and others too numerous to name are known and highly regarded for the relentlessness with which they pursue a case, both inside and outside of the courtroom. This case involved a three–year–old child whose life was destroyed by permanent injuries she sustained due to McNeil's negligent failure to warn about the true risks of Children's Motrin. The mere $10 million that a Philadelphia jury awarded to the plaintiff will need to sustain her as she faces a lifetime of blindness, continued pain and suffering, and the lasting effects of being unable to carry a child or have normal sexual relations with a spouse. This is not the type of a case in which counsel for the plaintiff

has any need to apologize for his zealous pursuit of his client's best interest. Rather, anything less than that would be unacceptable.

Moreover, the jury's verdict does not represent the decision of fact–finders who were unable to evenhandedly sift through the evidence and decide this case based on the law and the facts. The jury ruled in favor of the plaintiff on her negligent failure to warn claim but ruled against the plaintiff on her claim for negligent design defect. Even more notably, the jury decided against awarding punitive damages. This was far from a runaway jury. In an SJS/TEN case involving Children's Motrin and a young girl who sustained similarly horrific injuries recently tried to a verdict in Massachusetts, the jury awarded compensatory damages to the child exceeding $50 million and to the parents exceeding $10 million. *See* "Family awarded $63 million in Motrin case," The Boston Globe, February 13, 2013, *available online at*: http://bostonglobe.com/business/2013/02/13/plymouth-family-awarded-million-motrin-case/zEdJIbAWaas4zQVVSvIirI/story.html .

Plaintiff's trial counsel pleads guilty to having been a zealous advocate for his client during the trial of this case, and trial counsel's only regret is that the jury did not award an even more adequate recovery for the horrifically injured child plaintiff in this case. However, as Judge Quinones noted in her Rule 1925(a) post–trial opinion, there is plenty of blame to go around concerning the conduct of trial counsel in this case, and counsel for McNeil is hardly blameless. Yet, as Judge Quinones correctly recognized, none of the supposed misconduct about which McNeil complains rises to the level of requiring a new trial, nor does the jury's verdict evidence any unfairness stemming

from the supposed misconduct of plaintiff's counsel about which McNeil complains on appeal. Because all sides received a fair trial, and because neither side is entitled to a perfect trial (if one has ever existed in the history of humankind), this Court should affirm Judge Quinones' well–reasoned denial of McNeil's motion for a new trial based on the supposed misconduct of plaintiff's counsel.

V. CONCLUSION

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

Respectfully submitted,

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Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458

Keith M. Jensen
Jensen & Associates, PLLC
1024 North Main Street
Fort Worth, TX 78164
(817) 334–0762

Scott Levensten
The Levensten Law Firm, P.C.
1420 Walnut Street, Suite 801
Philadelphia, PA 19102
(215) 545–5600

Counsel for Plaintiffs/Appellees

CERTIFICATE OF SERVICE

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

Service by First Class U.S. Mail addressed as follows:

Alfred W. Putnam, Jr., Esquire
David F. Abernathy, Esquire
D. Alicia Hickok, Esquire
Drinker Biddle & Reath, LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103
(215) 988–2907

and

Charles Lifland, Esquire
O'Melveny & Myers LLP
400 South Hope Street
18th Floor
Los Angeles, CA 90071
(213) 430–6000

Counsel for appellant McNeil–PPC, Inc.

Dated: September 17, 2013

Howard J. Bashman
2300 Computer Avenue
Suite G–22
Willow Grove, PA 19090
(215) 830–1458