In the Supreme Court of Pennsylvania

Nos. 532 & 533 EAL 2014

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

v.

JOHNSON & JOHNSON and McNEIL–PPC, INC.

Appeal of McNeil–PPC, Inc.

ANSWER OF PLAINTIFFS/RESPONDENTS IN OPPOSITION TO McNEIL–PPC, INC.'S PETITION FOR ALLOWANCE OF APPEAL

On Petition for Allowance of Appeal from Judgment of the Superior Court of Pennsylvania filed July 22, 2014 at Nos. 3259 EDA 2011 and 471 EDA 2012, Reargument En Banc denied September 25, 2014, Affirming the Judgment of the Court of Common Pleas of Philadelphia County, Pennsylvania at February Term 2009, No. 2879 (Hon. Nitza I. Quiñones Alejandro)

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I. INTRODUCTION

On July 22, 2014, a little over eight months after this appeal was orally argued, a unanimous three-judge panel of the Superior Court of Pennsylvania issued a 36-page decision affirming the trial court's judgment in this case. President Judge Emeritus Kate Ford Elliott wrote the opinion of the Superior Court, which thoroughly addressed and rejected all *nine* issues that defendant/appellant McNeil-PPC, Inc. had raised on appeal in challenging the substance of the trial court's denial of McNeil's post-trial motions.

Thereafter, McNeil filed an application for reargument seeking to reargue en banc three of the nine issues that the Superior Court's unanimous panel correctly rejected. On September 25, 2014, the Superior Court issued an order denying McNeil's reargument application without any noted dissent.

Now McNeil has filed a petition for allowance of appeal in this Court seeking to raise four issues for review. The four issues that McNeil asks this Court to review were (in the order presented in McNeil's petition for allowance of appeal) raised as issues six, five, seven, and three in McNeil's opening Brief for Appellant filed in the Superior Court. Thus, the majority of issues on which McNeil seeks allowance of appeal were originally deemed by McNeil as not important enough to be listed among the top tier of the merits-related issues that McNeil chose to raise on appeal to the Superior Court.

None of the four issues that McNeil seeks to present for review satisfy this Court's stringent criteria for granting allowance of appeal. This case's unsuitability for allowance of appeal is established by the following four considerations:

(1) all four of the issues on which McNeil seeks allowance of appeal are unquestionably unique to this case, and McNeil has failed to establish or argue that the issues arise with any frequency elsewhere;

(2) McNeil's application fails to show that the specific aspects of the Superior Court's ruling that McNeil criticizes conflict with any prior rulings of this Court, the Superior Court, or the Commonwealth Court;

(3) McNeil has waived any challenge to the first two of its proposed issues, and the fourth question presented is moot because it challenges only one of the two alternate bases for causation that the Superior Court upheld; thus a ruling in McNeil's favor on the fourth issue would result in no relief in McNeil's favor, as the jury's verdict would continue to rest on an independent and adequate causation ground that both the trial court and the Superior Court have upheld; and

(4) the Superior Court has already unanimously and correctly rejected McNeil's arguments on all four of these points (in addition to the five other merits arguments that McNeil previously pursued on appeal) in a decision that does not recognize the existence of any issues deserving of further review in Pennsylvania's highest court

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McNeil's petition for allowance of appeal fails to establish that these four largely second-tier arguments were incorrectly decided by the Superior Court or are significant enough or of sufficient general applicability to justify this Court's review on allowance of appeal.

II. STATEMENT 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 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,

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[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

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 Lebonheur's Children's Hospital, Brianna's condition quickly deteriorated, and she was

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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).

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 a care-flight 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, 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, Dr. Arthur Sanford, testified that approximately nine days after the onset of Brianna's symptoms he and Brianna's entire primary care team reached a consensus that the cause of Brianna's TEN was her ingestion of over-the-counter Children's Motrin (ibuprofen). 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 are 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 conclusion of the nine-week 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, 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).

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

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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).

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 McNeil in similar Motrin-induced 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 will continue to suffer throughout the rest of her life. Perhaps recognizing that the

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[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 .

evidence could have justified a far larger award of damages, on appeal McNeil has not challenged 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). Thereafter, a unanimous three-judge panel of the Superior Court of Pennsylvania affirmed the trial court's judgment in full.

III. McNEIL'S PETITION FOR ALLOWANCE OF APPEAL SHOULD BE DENIED

A. The Superior Court Correctly Ruled That 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 appellate ground for a new trial presented to the Superior Court — now repackaged as McNeil's first ground for allowance of appeal — asserted 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."

In its opening Brief for Appellant filed in the Superior Court, McNeil's argument in support of this ground for a new trial consisted of only three paragraphs on about one page of text in a 61-page brief. *See* Exhibit One hereto (copy of relevant argument section from McNeil's Pa. Superior Court Brief for Appellant). McNeil's specific

argument on this point in its opening brief filed in the Pa. Superior Court contained not a single citation to any case law or any legal authority whatsoever. *See* Exhibit One hereto (McNeil's Pa. Super. Ct. Brief for Appellant at 47–48). Accordingly, McNeil already waived the first question presented for this Court's review in its briefing to the Superior Court. *See Wirth* v. *Commonwealth*, 95 A.3d 822, 837 (Pa. 2014) ("[W]here an appellate brief fails to provide any discussion of a claim with citation to relevant authority or fails to develop the issue in any other meaningful fashion capable of review, that claim is waived.") (internal quotations omitted); *Harris* v. *Toys "R" Us–Penn, Inc.*, 880 A.2d 1270, 1279 (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").

Moreover, as the unanimous three-judge Superior Court panel recognized, the trial court's supposed error 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. *See Lance* v. *Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010) (recognizing claim for negligent design defect under Pennsylvania law where the prescription drug in question had been permanently removed from the market by the FDA), *aff'd in relevant part*, 85 A.3d 434 (Pa. 2014).

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. McNeil's assertion that this evidence was somehow relevant to Maya's negligent failure to warn claim is pure sophistry. Rather, as the Superior Court correctly recognized, Maya's argument in support of her successful negligent failure to warn claim was merely that the medication's warning label should have included "rash" and "blisters" among the signs of serious allergic reactions in 2000, as the medication's label now does and has done since 2005.

Because McNeil's challenge to this supposedly erroneous aspect of the jury instructions in this case is both waived and, as the unanimous Superior Court panel recognized, without merit, this issue does not satisfy this Court's stringent criteria for allowance of appeal.

B. McNeil Has Waived, And Was Not Prejudiced By, The Trial Court's Failure To Give A Heeding Presumption Charge To The Jury

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 for whatever reason 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 maintained on appeal that no heeding instruction was appropriate, McNeil nevertheless continues to pursue in its petition for allowance of appeal a rather bizarre demand 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 not have purchased Children's Motrin to administer to Brianna if the medication's warning label contained mention of "rash" and "blisters."

As the unanimous three-judge Superior Court panel correctly recognized, 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*, 881 A.2d 1262 (Pa. 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.

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 A to Petition for Allowance of Appeal (trial court's 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 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 the Superior 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 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. As the Superior Court recognized: "McNeil cannot sit on its hands and now argue that failure to give the instruction was reversible error." Superior Court opinion at 25.

McNeil contends in its petition for allowance of appeal, as McNeil had argued in its Superior Court briefs, that the particular form of heeding instruction that the trial court *did not deliver here* would have *required* the jury to find that plaintiff would have heeded an adequate warning. Even if that were correct, however, it also remains true that the trial court never issued any ruling or oral direction that precluded McNeil's counsel from arguing the issue of inadequate warning causation to the jury in her closing argument. Whether or not McNeil's counsel decided to argue the issue of inadequate warning causation in her closing argument remained entirely within the control and discretion of McNeil's counsel.

Moreover, the particular heeding instruction in question is only proper in a case in which the defendant has produced *no evidence whatsoever* to call into question or cast doubt on whether the plaintiff would indeed have heeded an adequate warning had such an adequate warning in fact been provided. Thus, the trial court's initial decision to deliver the heeding presumption instruction in question confirms that no evidence existed in the trial court record to which counsel for McNeil could refer to call into question plaintiff's explicit testimony that she would not have purchased Children's Motrin had the medication contained an adequate warning that mentioned "blisters" and "rash" as possible side-effects.

The absence of any such evidence to undermine plaintiff's unambiguous testimony that an adequate warning would have been heeded serves to further refute McNeil's purely after-the-fact invention that its counsel supposedly would have presented a different closing argument had delivery of the heeding instruction not been promised. There is no evidence in the record to undermine plaintiff's testimony that she would have heeded an adequate warning, and McNeil has never submitted any evidence (such as an affidavit from its trial counsel in support of McNeil's motion for post-trial relief) to assert under oath that its counsel's closing argument would have been any different on the issue of whether Ms. Maya would have heeded an adequate warning given the absence of any evidence whatsoever to support such a closing argument by McNeil's trial counsel.

Once the trial court finished delivering its legal instructions to the jury without including any heeding presumption instruction, McNeil was put to the following

choice. On the one hand, McNeil could have drawn the instruction's omission to the trial court's attention so that the omission could be corrected. Had the trial court then delivered the instruction, it would have preserved for appellate review McNeil's contention that delivery of a heeding instruction (which, again, the trial court did not deliver here) would have been legally erroneous. McNeil, however, failed to do that. On the other hand, and at a minimum, McNeil had the option of asking the trial court for permission to reopen its counsel's closing argument to the jury in light of the trial court's omission of any heeding instruction. But McNeil failed to do that as well. On balance, McNeil no doubt recognized that the trial court's omission of a binding heeding instruction was likely to help McNeil obtain a verdict in its favor far more than the omission was likely to be of any benefit to the plaintiff.

In any event, McNeil's counsel's failure to ask the trial court to reopen McNeil's closing argument after the trial court did not deliver any heeding instruction served to waive the issue that McNeil now seeks to present for this Court's review, as the Superior Court's unanimous opinion explicitly recognizes. *See* Superior Court opinion at 25 ("McNeil cannot sit on its hands and now argue that failure to give the instruction was reversible error.").

Finally, as the Superior Court's opinion makes clear, more than sufficient evidence exists in the record to establish that an adequate warning would have avoided altogether or significantly limited plaintiff's injuries. McNeil's request for further review on this issue pertains only to the closing argument of counsel, which of course is not evidence. The jury was instructed that it must decide the question of inadequate

warning causation based on the evidence, not based on the mere arguments of counsel. The jury's verdict in favor of plaintiff on her negligent failure to warn claim unambiguously establishes that the jury found for plaintiff on the issue of inadequate warning causation based on the evidence before the jury. McNeil's petition for allowance of appeal fails to address how any argument that defense counsel might have made on this issue would have had any impact on the jury's finding in this regard.

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. In any event, McNeil irrevocably waived this issue when, following the trial court's delivery of jury instructions, McNeil failed either to point out the omission of this instruction or to seek to reopen its closing argument in light of this instruction's omission. For these reasons, the second ground raised in McNeil's petition for allowance of appeal fails to satisfy the stringent criteria for this Court's review.

C. The Superior Court Correctly Recognized That The Trial Court Did Not Abuse Its Discretion In Providing 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 The Injuries

The third ground for allowance of appeal that McNeil seeks to raise 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). Contrary to McNeil's contentions in its petition for allowance of appeal, this testimony represented McNeil's expert's concession, to a reasonable degree of scientific certainty, that both drugs may have combined to cause Brianna's TEN.

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 produce Brianna's damages. *See* Exhibit A to Petition for Allowance of Appeal (trial court's 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.

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 this 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 McNeil's argument would be plainly wrong, just as it is here. *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.").

Whether or not a trial court's jury instructions are erroneous can only be evaluated based on the evidentiary background in a case. In this case, that evidentiary background fully justified the trial court's concurring cause instruction. 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. The unanimous Superior Court panel thus correctly ruled that it was an appropriate exercise of the trial court's discretion for the trial court to provide the jury with a legally correct concurring cause instruction under the facts and circumstances of this case. McNeil's request for allowance of appeal on this third ground fails to satisfy this Court's stringent criteria for review.

D. McNeil's Challenge To "Stop Use" Inadequate Warning Causation Is Moot As The Superior Court Also Affirmed The Trial Court's Ruling On "No Purchase Or Use" Causation, And The Petition Fails To Challenge This Adequate And Independent Ground For Upholding The Judgment

The fourth and final ground for allowance of appeal that McNeil presents is both moot and without merit. The issue is moot because McNeil's petition only takes issue with one of the two adequate and independent grounds on which both the trial court and the Superior Court held inadequate warning causation to exist in this case. In maintaining that the Superior Court supposedly rejected one of the two grounds for the trial court's ruling that more than adequate evidence supported the jury's finding of inadequate warning causation, McNeil simply disregards the actual language of the Superior Court's unanimous opinion in this case.

The only possible reading of the Superior Court's decision, as demonstrated below, is that the unanimous Superior Court panel upheld both alternative grounds on which the trial court found inadequate warning causation to exist in this case. By challenging only one of those two adequate and independent grounds in its petition for

allowance of appeal, McNeil presents for this Court's discretionary review an issue that is moot and academic, because even a ruling in McNeil's favor on that issue would not result in the overturning of the trial court's judgment in plaintiffs' favor.

The unanimous Superior Court panel's rejection of McNeil's challenges to both aspects of the trial court's ruling, on alternate grounds, that sufficient evidence existed to establish inadequate warning causation concluded as follows:

> 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.

Pa. Super. Ct. Opinion at 20–21.

Far from rejecting plaintiffs' argument that the evidence established that an adequate warning of Children's Motrin's risks of "blister" and "rash" would have caused Ms. Maya not to have purchased the medication, the above quotation from the Superior Court's decision in this case confirms beyond any doubt that the Superior Court in fact affirmed that aspect of the trial court's ruling. Moreover, nowhere else in its opinion does the Superior Court suggest or hold that the mother's testimony that she would not have purchased Children's Motrin if the medication contained adequate warnings was insufficient to establish inadequate warning causation. McNeil's failure to accurately present this critical aspect of the Superior Court's ruling constitutes "a

sufficient reason for denying the petition." *See* Pa. R. App. P. 1115(d) (listing "accuracy" as an "essential requisite[]" of a petition for allowance of appeal).

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 inadequate warning 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.*, 963 A.2d 1282 (Pa. 2009), this 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 1288–89 (internal quotations omitted). As this 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 1289.

As this Court 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 in its petition for allowance of appeal McNeil challenges only one of the two alternate grounds for proving inadequate warning causation that both the trial court and the Superior Court upheld as sufficient, the fourth and final issue that McNeil seeks to raise in its petition for allowance of appeal presents a moot question, since even a ruling for McNeil on that issue would not result in any relief in McNeil's favor.

In *Pap's A.M.* v. *City of Erie*, 812 A.2d 591, 599 (Pa. 2002), this Court explained that "This Court generally will not decide moot questions." The recognized exception to that rule, for cases presenting issues capable of repetition yet constantly evading review, does not apply here, because McNeil certainly could have — but elected not to — challenge in its petition for allowance of appeal both grounds on which the Superior Court relied in upholding the trial court's ruling that more than sufficient evidence to establish inadequate warning causation existed here.

Even if the fourth and final ground for allowance of appeal that McNeil has presented were not moot, the issue would nevertheless still not satisfy this Court's rigorous criteria for review on allowance of appeal. The issue is fact-bound, limited in relevance to the specific facts and circumstances of this case. And McNeil's presentation of this issue improperly fails to view the evidence in the light most favorable to plaintiffs, the verdict winners.

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

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

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

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

The fourth and final issue that McNeil seeks to present in its petition for allowance of 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.

McNeil's petition for allowance of 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).

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. Randall 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.

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), the Superior 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*, the Superior 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.*, 72 A.2d 290 (Pa. 1950), this 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 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, this 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.*, 528 A.2d 947 (Pa. 1987). In *Martin*, this 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 949–51. This result was proper, this 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*, 887 A.2d 209, 218–19 (Pa. 2005).

Similarly, the Superior 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.

For all of these reasons, the fourth and final ground for allowance of appeal that McNeil seeks to raise should be rejected as moot and meritless.

IV. CONCLUSION

For all of the foregoing reasons, this Court should deny McNeil's petition for allowance of appeal.

Respectfully submitted,

Dated: November 7, 2014

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EXHIBIT ONE

IN THE SUPERIOR COURT OF PENNSYLVANIA

Nos. 3259 EDA 2011 and 471 EDA 2012 (consolidated)

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

Plaintiffs-Appellees,

v.

MCNEIL-PPC, INC.,

Defendant-Appellant.

PRINCIPAL BRIEF OF APPELLANT MCNEIL-PPC, INC.

Appeal from Judgment entered January 6, 2012
following trial and post-trial motions
by the Court of Common Pleas of Philadelphia County
February Term 2009 No. 002879 (Hon. N. Quinones-Alejandro, J.)

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spillways on their reservoirs/dams, drawn down the water levels of their dams, and instituted and followed with [sic] emergency action plan, damage to [Appellees'] property would not have occurred, or would not have been as severe'" (internal citations omitted)). By contrast, there is no evidence here that Children's Motrin *combined* with another agent to cause Brianna's SJS/TEN and thus there was no basis for this instruction. This prejudicial error also requires a new trial.

C. The Trial Court Prejudiced McNeil by Allowing Plaintiffs to Invite a Verdict Based on the Withdrawal of Drugs Not Marketed by McNeil and Not at Issue Here.

In addition, McNeil is entitled to a new trial because the trial court invited the jury to evaluate McNeil's conduct based on the withdrawal of different drugs sold by different manufacturers. Over McNeil's objection, plaintiffs offered substantial evidence that non-ibuprofen drugs had been withdrawn from the market.[22] And the trial court's instructions expressly invited the jury to consider that evidence in evaluating McNeil's conduct: "[y]ou may consider . . . what happened with other drugs, such as other drugs being taken off the market, when evaluating the defendant's conduct." (Tr. 5/19 AM 42:10-23, R. 2469a.)

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[22] *See* Tr. 3/23 PM 50:2-13, R. 1832a (plaintiffs' counsel arguing in opening about other drugs that were "yanked" from the market); Tr. 3/24 PM 21:22-26:1, R. 1842a-1843a (plaintiffs' counsel attempting to question Dr. Tackett about Zomax); Tr. 4/4 AM 48:15-49:16, R. 1926a; Tr. 4/4 PM 33:19-36:13, R. 1931a (Dr. Tackett testifying about certain other drugs not at issue being taken off the market due to an association between those drugs and SJS/TEN); Tr. 4/19 AM 51:14-52:20, R. 2018a-2019a (plaintiffs' counsel arguing that he personally brought litigation that spurred withdrawals of other drugs); Tr. 5/18 AM 136:7-137:15, R. 2419a (plaintiffs' counsel referring to the withdrawal of other drugs in closing argument); *see also* Tr. 4/15 PM 116:14-129:24, R. 1993a-1997a; *id.* at 133:10-134:9, R. 1998a; *id.* at 136:24-140:8, R. 1998a-1999a (counsel for plaintiffs questioning defense witness about the withdrawal of other NSAIDs despite repeated objections, some sustained); Tr. 4/18 AM 14:4-17:21, R. 2004a-2005a (same).

This was error. The particular circumstances in which other drugs manufactured by other companies were withdrawn have no logical connection to this case. *See* Pa.R.E. 401-403. And McNeil is in no position to litigate the cost and benefits of drugs it does not manufacture. Indeed, the transparent import of this attack was to suggest improperly that no warning would have sufficed and that McNeil was negligent for selling Children's Motrin at all.

Significantly, both at trial and in its Amended Opinion, the trial court's sole justification for inviting the jury to consider the withdrawal of the products of other manufacturers was its belief that McNeil offered the instruction. (*See* Tr. 5/19 AM 69:10-12, R. 2476a ("That was from you. That was your charge."); Am. Op. 110 ("Defendant McNeil cannot take exception to the jury instruction it submitted to this trial judge.").) But the trial court's instructions omitted the key word—"not"—from McNeil's instructions. McNeil asked the court to instruct the jury "[y]ou may *not* base your verdict on the conduct of other pharmaceutical manufacturers or on what happened with other drugs." (Defs.' Sec. Rev. Prop. Jury Instr. No. 41, R. 2172a (emphasis added).) The court earlier approved that instruction over Plaintiffs' objection to the "not." (Tr. 5/5 PM 61:16-63:15, R. 2221a.) But the court ultimately instructed the jury "[y]ou *may* consider . . . ." (Tr. 5/19 AM 42:10-23, R. 2469a (emphasis added).) Omitting "not" reversed the meaning. McNeil called this omission to the Court's attention before the jury retired, but the court refused to correct it. (Tr. 5/19 AM 73:9-74:3, R. 2477a.) This error too requires a new trial.

D. The Verdict Cannot Be Trusted Because the Jury Was Repeatedly Exposed to Irrelevant and Prejudicial Information Throughout the Nine-Week Trial.

More broadly, McNeil is entitled to a new trial because the nine-week trial in this case was so pervaded by evidentiary errors and counsel misconduct that McNeil was denied its right to a fair trial. Indeed, although the jury should have been narrowly focused on whether a change

CERTIFICATE OF SERVICE

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

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