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APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-3984-08T1

KIMBERLY ZUNDEL and CHARLES ZUNDEL, Individually, and on behalf of their minor child, STEPHANIE ZUNDEL,

Plaintiffs-Appellants,

v.

JOHNSON & JOHNSON,

Defendant,

and

MCNEIL CONSUMER HEALTHCARE, a Division of McNeil-PPC, Inc., and MCNEIL-PPC, INC.,

Defendants-Respondents.

Argued January 5, 2011 – Decided August 5, 2011

Before Judges Fuentes, Gilroy and Ashrafi.

On appeal from the Superior Court of New Jersey, Law Division, Middlesex County, Docket No. L-6854-05.

Greg D. Shaffer argued the cause for appellants (Wilentz, Goldman & Spitzer, attorneys; Alfred M. Anthony, of counsel; Mr. Shaffer, on the briefs).

Charles C. Lifland (O'Melveny & Myers) of the California bar, admitted pro hac vice, argued the cause for respondents (Drinker, Biddle & Reath, attorneys; Mr. Lifland, Thomas W. Pulliam, Jr., of the California bar, admitted pro hac vice,

Vernon I. Zvoleff of the California bar, admitted pro hac vice, Kenneth P. Conour of the California bar, admitted pro hac vice, and Daniel B. Carroll, on the brief).

PER CURIUM

Plaintiffs Kimberly and Charles Zundel, individually and on behalf of their minor daughter, Stephanie Zundel, filed a complaint against defendants Johnson & Johnson,[1] McNeil Consumer Healthcare, and McNeil's corporate parent, McNeil-PPC, Inc., asserting various claims, including a count alleging products liability based on defendants' failure to warn about "all possible adverse side effects and reactions and complications associated with the use of Children's Motrin." Plaintiffs alleged that when Stephanie was given Children's Motrin in December 1997 and January 1998, she contracted Toxic Epidermal Necrolysis, a rare disease that caused her severe injuries, including blindness.

The case was tried before a jury that found Stephanie's illness and resulting injuries were not caused by her ingestion of Children's Motrin. The trial court denied plaintiffs' motion seeking to set aside the verdict because it was against the weight of the evidence.

[1] Plaintiffs voluntarily dismissed their claims against Johnson & Johnson before the commencement of trial.

Plaintiffs now appeal, arguing the trial court erred in denying their motion for a new trial. Plaintiffs also challenge a number of evidential rulings made by the trial court that: (1) excluded certain documentary evidence; (2) limited the scope of testimony of plaintiffs' expert witnesses; and (3) permitted defendants' medical expert to testify concerning the cause of Stephanie's illness.

We reject these arguments and affirm. We gather the following facts from the record developed before the trial court.

I

Before we recite the events that led to this litigation, a brief description of the pharmacological history of the medication at issue is warranted.

At all times relevant to this litigation McNeil Consumer Healthcare (McNeil) manufactured Children's Motrin, an over-the-counter (OTC) medication intended to reduce fever and relieve pain for children ages six months or older. The United States Food and Drug Administration (FDA) first approved this medication for use as a prescription drug in 1989, and for OTC use in 1995. Before approving the OTC sale of Children's Motrin, the FDA required McNeil to conduct a large-scale

clinical study to demonstrate that the product's active ingredient, ibuprofen, was safe for OTC pediatric use.

McNeil retained the Boston University School of Medicine's Slone Epidemiology Center to conduct what was denoted as the "Boston University Fever Study" (BUFS). The BUFS protocol approved by the FDA examined whether ibuprofen was more likely than acetaminophen to result in four specific adverse events that required either hospitalization or follow-up visits to a physician by a pediatric patient. The BUFS results indicated that "there seems to be no increase of risk factors [presented by ibuprofen] when compared to acetaminophen." Significantly, however, BUFS did not include Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) among the four adverse events looked for in the study.

SJS and TEN are acute life-threatening conditions which cause the patient's skin to erode and detach itself from the underlying tissues. According to plaintiffs' expert witness, ophthalmologist Dr. Charles Steven Foster, TEN manifests as a "very odd attack by the immune system on the patient's epithelial cells and the substratum under the epithelium."[2]

[2] The epithelium is "[t]he purely cellular avascular layer covering all the free surfaces . . . including the glands and other structures derived therefrom." Stedman's Medical Dictionary 527 (25th ed. 1990).

Further, according to plaintiffs' expert witness, burn victim specialist Dr. Michael Marino, patients diagnosed with SJS are affected over "less than ten percent of [their] body surface area," while patients afflicted with TEN are affected over a greater percentage of their skin area.

SJS and TEN are rare diseases, with an estimated incidence rate of less than 5 persons per million per year in the general population. SJS has an estimated incidence rate of 1.2 to 6 persons per million per year. The even rarer TEN has an estimated incidence rate of .4 to 1.2 persons per million per year. Eighty to ninety percent of cases of TEN are triggered by exposure to various drugs; ten to twenty percent of SJS and TEN cases have no identified cause.

BUFS identified two reported cases of SJS in children who had received ibuprofen. BUFS did not draw a significant connection between the drug and the disease, however, because the reports were based on responses given by parents to questionnaires and the children involved were not hospitalized or did not have a follow-up visit with a physician after receiving ibuprofen.

There have been two large-scale epidemiological studies to determine whether there is an association between the use of certain drugs, including ibuprofen, and the onset of SJS or TEN:

the Study on Severe Cutaneous Adverse Reactions (SCAR Study), conducted between 1989 and 1995, and the much larger EuroSCAR-Study, conducted from 1997 to 2001. The SCAR Study was the subject of two medical journal articles that were relied upon by the parties' experts at trial: the "Roujeau 1995" article, published on December 14, 1995, and the "Mockenhaupt 2003" article, published on October 13, 2003. The EuroSCAR-Study was the subject of the "Mockenhaupt 2007" article published in 2007, which was also relied upon by the parties' experts.

The Roujeau 1995 article examined partial SCAR Study data concerning the risk of contracting SJS/TEN presented by a class of drugs known as non-steroidal anti-inflammatory drugs (NSAIDs). Of particular relevance here, the article distinguished between NSAIDs derived from oxicam and those derived from propionic acid; ibuprofen is an NSAID derived from propionic acid.

The Roujeau 1995 article concluded that the use of oxicam-derived NSAIDs presented a significantly increased risk of contracting SJS/TEN. However, the "confidence limits" for the data dealing with propionic-acid-derived NSAIDs (including ibuprofen) were such that an increase in risk could neither be confirmed nor denied.

The Mockenhaupt 2003 article examined the complete SCAR Study data and arrived at a materially different conclusion. The article pertinently concluded that "[a]mong the NSAID[s], the oxicams . . . were associated with the greatest increase in risk of SJS and TEN . . . . Of the non-oxicam NSAID[s] with sufficient numbers of exposed cases, only diclofenac and ibuprofen had significantly increased risks of SJS and TEN[.]"

By contrast, the Mockenhaupt 2007 article examined the more expansive EuroSCAR-Study data and concluded that "[c]oncerning NSAIDs there were variable levels of risks. As already suspected, oxicam derivatives were associated with a high risk and acetic acid derivatives with a lower risk for SCAR (Mockenhaupt et al., 2003), whereas for propionic acid derivatives including ibuprofen we did not find a significant risk [of SJS/TEN]."

II

We now address the particular facts that led to this litigation.

Stephanie was born in January 1995. In September 1996, her mother gave her Children's Motrin to treat the associated pain and fever caused by teething. Stephanie did not have an adverse reaction to the medication at that time. On December 25, 1997, Stephanie and her parents visited Stephanie's maternal

grandmother, Diane Thompson Frangipane, and other family members at Frangipane's townhouse for a holiday party. According to Frangipane, at some point that evening she took Stephanie upstairs to change her diaper and noticed that Stephanie "felt warm." Frangipane testified that she "went to the medicine cabinet and [] saw Children's Motrin." After reading the label on the box for dosage instructions, she

> yelled over the balcony to my daughter [Mrs. Zundel] that I was going to give [Stephanie] Cold Formula[3] Children's Motrin and they [the other family members] were all talking and music and everything. I just assumed she heard me and I gave the baby Children's Motrin and brought her downstairs.

Although she could not state with absolute certainty, Frangipane testified that she probably gave Stephanie a second dose of Children's Motrin that day because her daughter's Christmas visit lasted for several hours. Frangipane mentioned this alleged second Christmas Day dose of Children's Motrin for the first time in this litigation during her direct testimony at trial.

Stephanie and her mother next visited Frangipane on December 31, 1997. According to Mrs. Zundel, Stephanie appeared

[3] McNeil did not market a "Children's Motrin cold suspension" until August 7, 2000. When confronted with this, Frangipane explained that she generally referred to any OTC medication for the treatment of the symptoms of children's colds as "cold formulas."

to be somewhat "run down" at that time. After Mrs. Zundel left to return some Christmas gifts, Frangipane noticed that Stephanie "felt warm." Frangipane "gave" Stephanie Children's Motrin and "[s]hortly after that, her fever seemed to go down." When Mrs. Zundel returned later that same day to Frangipane's townhouse to take Stephanie home, she noticed that Stephanie "felt a little warm."[4]

According to Mrs. Zundel, over the next few days Stephanie was "still a little run down," with a "runny nose" and "watery" eyes. On January 5, 1998, Mrs. Zundel took Stephanie to her pediatrician, Dr. Donald Kline, because she had a "higher fever." Dr. Kline noted that Stephanie had an elevated temperature, blisters in her mouth, a rash on her body, and irritated and red eyes. He diagnosed the child as suffering from chicken pox and directed that she be given "Tylenol," along with other medications.

Mrs. Zundel testified that Dr. Kline told her to give Stephanie either Motrin or Tylenol. She decided to purchase Children's Motrin because she believed it lasted longer than Tylenol. Mrs. Zundel gave Stephanie a dose of Children's Motrin

[4] Mrs. Zundel also testified that Frangipane told her that she had given Stephanie a cold formula she believed was Children's Motrin. On defense counsel's objection, this testimony was stricken by the trial court on hearsay grounds.

in the late afternoon of January 5, 1998, and another dose at some point after midnight on January 6, 1998. Stephanie's symptoms did not improve, and by this point she was also vomiting.

According to Mrs. Zundel, when she called Dr. Kline on January 6, 1998, to report her daughter's worsening condition, he first directed her to give Stephanie Pedialyte to prevent dehydration. When the child's condition did not improve, Mrs. Zundel testified that he then told her to take Stephanie directly to a hospital. According to Dr. Kline, Mrs. Zundel and Stephanie came to his office that day; he examined Stephanie and determined that she was feverish and dangerously dehydrated. Dr. Kline testified he then directed that Stephanie be taken to the John F. Kennedy Medical Center (JFKMC) immediately.

Stephanie was admitted to JFKMC on the afternoon of January 6, 1998. She had a high fever, "mouth ulcers," an expanding body rash, and was "unable to drink liquids." Her condition deteriorated and she developed "a lot of blisters" on her body. After consulting with an infectious disease specialist, Dr. Kline decided to transfer Stephanie to Newark Beth Israel Medical Center. Stephanie's stay at Beth Israel lasted for less than two days. On January 8, 1998, Stephanie was transferred

and admitted to the Burn Unit at St. Barnabas Medical Center (SBMC).

The medical staff at SBMC initially diagnosed Stephanie as having SJS. Because her condition continued to deteriorate over the next several days, she was re-diagnosed as suffering from TEN. Following treatment, Stephanie was discharged from SBMC on February 28, 1998. The SBMC discharge summary indicated that about ninety-one percent of her body had been affected by the equivalent of second-degree burns, and noted that she was allergic to "Motrin." As a result of contracting TEN, Stephanie is permanently blind; she is also scarred over much of her body.

III

The case was tried over a period of eighteen days. In response to verdict-sheet interrogatory number one: "Have Plaintiffs proved by a preponderance of the evidence that ingestion of Children's Motrin caused Stephanie Zundel's claimed injuries?" the jury answered: "No." The vote was eight to zero. Plaintiffs' counsel opted not to poll the jury.

Plaintiffs moved for a new trial, arguing the jury's verdict was against the weight of the evidence. The trial court denied the motion. Acknowledging its obligation to give "due regard to the opportunity of the jury to pass upon the credibility of the witnesses," the trial court found plaintiffs

had not shown, by clear and convincing evidence, that the verdict appeared to be "a miscarriage of justice under the law." R. 4:49-1(a).

Our standard of review on appeal from the trial court's denial of a motion for new trial is similar, with one important added element. We must afford "due deference to the trial court's 'feel of the case', with regard to the assessment of intangibles, such as witness credibility." Jastrum ex rel. Jastram v. Kruse, 197 N.J. 216, 230 (2008) (quoting Feldman v. Lederle Labs., 97 N.J. 429, 463 (1984)).

At both the appellate and trial levels, "[o]n a motion for a new trial, all evidence supporting the verdict must be accepted as true, and all reasonable inferences must be drawn in favor of upholding the verdict." Boryszewski v. Burke, 380 N.J. Super. 361, 391 (App. Div. 2005), certif. denied, 186 N.J. 242 (2006). Thus, "[j]ury verdicts should be set aside in favor of new trials only with great reluctance, and only in cases of clear injustice." Ibid.

Applying this standard to the case at hand, we are satisfied the trial court correctly denied plaintiffs' motion for a new trial. The record shows that Stephanie was afflicted with TEN on January 5, 1998, when she was first examined by Dr. Kline, and before she was given Children's Motrin by her mother.

Defense counsel's cross-examination of plaintiffs' expert witness, Dr. Foster, crystallizes this critically important issue:

> DEFENSE COUNSEL: Having had a chance — and Dr. Kline's notes are part of the medical records that you looked at in developing your opinions in this case?
>
> DR. FOSTER: Yes, sir.
>
> DEFENSE COUNSEL: So this note was included among what you looked at in forming your opinions?
>
> DR. FOSTER: That's correct.
>
> DEFENSE COUNSEL: Having seen this, you would now agree with me that on 1/5/98, when Stephanie Zundel was taken to Dr. Kline, she already had blisters in her mouth, a body rash?
>
> DR. FOSTER: Yes, sir, she did.
>
> DEFENSE COUNSEL: And I believe you agreed at your deposition that those symptoms would indicate that her TEN had already started before this visit on 1/5, correct?
>
> DR. FOSTER: Correct, I do agree.
>
> DEFENSE COUNSEL: Now, do you recall that her mother testified and that it's reflected in some written medical records that her mother gave her two doses of Children's Motrin, one on 1/5/98 and one some time late that day or perhaps early in the morning of 1/6/98?
>
> PLAINTIFF'S COUNSEL: Objection, Your Honor. That's an incorrect statement.
>
> THE COURT: I can't hear you.

PLAINTIFF'S COUNSEL: It's an incorrect statement.

DEFENSE COUNSEL: Do you recall -- what do you recall about when the mother gave her doses of Motrin, according to the mother's testimony?

DR. FOSTER: When the mother specifically gave, I think the first time was on January 5, that's my recollection.

DEFENSE COUNSEL: Okay. And then you recall she gave a second dose, you believe that to be on January 6?

DR. FOSTER: Later in the day on the 5th, early on the 6th, I'm not certain.

DEFENSE COUNSEL: So it was either late on the 5th or early on the 6th, correct?

DR. FOSTER: Yes.

DEFENSE COUNSEL: And you agreed with me that those two doses of Children's Motrin by Kimberly Zundel could not have caused Stephanie to have TEN because she already was showing the symptoms of TEN when she went to the pediatrician earlier in the day on 1/5?

DR. FOSTER: That's correct, the timing is not correct.

Plaintiffs' case was thus predicated on the theory that Stephanie contracted TEN as a result of being given Children's Motrin by Frangipane on two or three occasions on December 25 and 31, 1997. The jury could have found otherwise, however,

because there was ample evidence in the record undermining Frangipane's credibility in this regard.

As a starting point, Stephanie's medical records do not mention anyone giving her Children's Motrin in December 1997. This is highly significant because the physicians at the SBMC Burn Unit urgently sought any information of this nature from family members, including Frangipane, when Stephanie was first admitted to that hospital. If Frangipane had mentioned this at that time, it is reasonable to assume these physicians would have recorded and acted on this information. The absence of this critically important information in the medical records documenting the early stages of Stephanie's illness directly and significantly undermines Frangipane's credibility.

For her part, Frangipane testified that she told the physicians at that time that she had given "Cold Formula Children's Motrin" to Stephanie. Frangipane's account was partly corroborated by Dr. Sylvia Petrone, a physician at SBMC. Dr. Petrone testified at a videotaped deposition that another physician treating Stephanie, one Dr. Minnefore, told her that Frangipane had told him that Frangipane had given Stephanie Children's Motrin at some point prior to January 5, 1998. Dr. Petrone's deposition testimony in this regard was ruled inadmissible on hearsay grounds, however, because Dr. Minnefore

died before the start of the trial and therefore could not be called to testify about Frangipane's alleged prior consistent statement. Plaintiffs' counsel implicitly conceded the correctness of this ruling when he advised the court that he did not intend to replay the portion of Dr. Petrone's videotaped deposition pertaining to her conversations with the late Dr. Minnefore.

Ironically, Dr. Minnefore's only written record in this case - his consultation report dated January 9, 1998 - does not mention Frangipane or that Children's Motrin was given to Stephanie prior to January 5, 1998. Indeed, Dr. Minnefore wrote that "[a]fter onset of illness Motrin given." This suggests that the Children's Motrin was administered after January 5, 1998. This evidence supports the trial court's finding that "the jury could have reasonably concluded that Stephanie Zundel did not receive Children's Motrin before her disease began" because "Frangipane never gave Stephanie the Motrin" in December 1997.

Further eroding Frangipane's credibility is the timing of her revelations. According to Mrs. Zundel, she did not discover her mother's role in this case until October 2006, when she noticed the reference to medications given to Stephanie in Dr. Minnefore's consultation report. Frangipane testified that when

her daughter (Mrs. Zundel) called her about this, Frangipane told her: "Don't you remember that I gave [Stephanie] the Children's Motrin on Christmas Day and New Year's Eve Day[?]" Plaintiffs thereafter filed an amended complaint and amended interrogatories, and Mrs. Zundel gave another deposition, imparting this new information.

When Mrs. Zundel and Frangipane were asked at trial why it took more than eight years for them to have discussed and discovered this critically important aspect of Stephanie's medical history, they both responded in a manner that suggested they were legally prevented from doing so. This was not the case. Accordingly, the trial court instructed the jury that, while some testimony may have "created the impression" that Mrs. Zundel had been legally barred from speaking with Frangipane about the litigation, "the court has never imposed a gag order and there was no other legal bar imposed either by the court or by McNeil that would have prevented such conversations."

Another point undermining Frangipane's credibility concerned the number of doses of Children's Motrin she allegedly gave Stephanie on December 25, 1997. At her deposition, Frangipane testified that she had given Stephanie one dose; at trial, she testified that she probably gave her two doses.

The record provides a solid basis to support the jury's

finding of lack of causation. The jury could have reasonably found that Frangipane did not give Stephanie Children's Motrin before the onset of the disease. Defense counsel made this a key part of their summation.

IV

We need only briefly address the remainder of plaintiffs' arguments contesting the trial court's exclusion or admission of certain evidence. Initially, we agree with defendant that these rulings do not affect our ultimate determination concerning the sufficiency of evidence supporting the jury's verdict.

Several of the challenged rulings pertained to whether, as a general matter, Children' Motrin is a cause of TEN. Those issues are rendered moot by this verdict. As we have discussed, the jury's answer to the first verdict interrogatory must be upheld because the jury could have rationally concluded that the evidence was insufficient to find Stephanie was given Children's Motrin before symptoms of her tragic illness manifested. Thus, evidence showing that Children's Motrin can cause TEN does not affect the nature and weight of plaintiff's evidence on the hotly-contested issue of whether Children's Motrin in fact caused Stephanie's condition.

The rulings challenged on appeal that were relevant to specific causation of Stephanie's condition were properly

excluded as inadmissible hearsay. The trial court properly sustained an objection to deposition testimony by Dr. Petrone alleging the late Dr. Minnefore told her that Frangipane had told him she had given Stephanie Children's Motrin in December 1997. Also, Dr. Petrone's deposition testimony included her opinion of the cause of the child's condition. This part of her deposition testimony was correctly excluded because Dr. Petrone had not provided a report as an expert witness. Defendant agreed to the playing of Dr. Petrone's videotaped deposition in lieu of her live testimony at trial, but only to the extent she testified as a treating physician. Defendant did not agree to the admission of her opinion testimony. These out-of-court statements offered for their truth were not admissible in evidence.

We must affirm a trial court's evidentiary rulings unless our examination of the record reveals a mistaken exercise of discretion. See Estate of Hanges v. Met. Prop. & Cas. Ins. Co., 202 N.J. 369, 382 (2010) (collecting appellate cases under several rules of evidence applying the abuse of discretion standard of review); Hisenaj v. Kuehner, 194 N.J. 6, 12 (2008) (appellate court is limited to examining for abuse of discretion trial court's rulings on admission of expert testimony); Abtrax Pharms., Inc. v. Elkins-Sinn, Inc., 139 N.J. 499, 513-14 (1995)

(discretionary authority of trial court to impose sanctions for failure to provide discovery, including exclusion of evidence under Rule 4:23-2(b)(2)).

In addition to excluding evidence as inadmissible hearsay, the trial court made appropriate discretionary rulings in response to discovery objections and disputed arguments on the admissibility of expert testimony. Having considered the parties' arguments, we find no abuse of discretion or other legal error in the trial court's several evidentiary rulings. Although forcefully and passionately argued because of the severity of the child's injuries, the points of evidentiary error argued on appeal do not warrant extensive discussion. We conclude these discretionary rulings were not erroneous.

Affirmed.