RENDERED: OCTOBER 21, 2005; 2:00 P.M.
TO BE PUBLISHED

MODIFIED: FEBRUARY 3, 2006; 10:00 A.M.

Commonwealth Of Kentucky

Court Of Appeals

NO. 2004-CA-001536-MR

SANDOZ PHARMACEUTICALS CORPORATION N/K/A NOVARTIS PHARMACEUTICALS CORPORATION — APPELLANT

APPEAL FROM JEFFERSON CIRCUIT COURT
v. HONORABLE BARRY WILLETT, JUDGE
ACTION NO. 94-CI-004680

RONALD GUNDERSON, AS ADMINISTRATOR OF THE ESTATE OF MARY MARGARET GUNDERSON, AND NICHOLAS GUNDERSON, A MINOR, AND WESLEY GUNDERSON, A MINOR, BY THEIR CONSERVATOR, JOHN J. FORD — APPELLEES

AND NO. 2004-CA-001537-MR

HYMAN & ARMSTRONG, P.S.C., AND KAREN ARMSTRONG, AS EXECUTRIX OF THE ESTATE OF LYMAN ARMSTRONG, M.D. — APPELLANTS

APPEAL FROM JEFFERSON CIRCUIT COURT
v. HONORABLE BARRY WILLETT, JUDGE
ACTION NO. 94-CI-004680

RONALD GUNDERSON, AS ADMINISTRATOR OF THE ESTATE OF MARY MARGARET GUNDERSON, AND NICHOLAS GUNDERSON, A MINOR, AND WESLEY GUNDERSON, A MINOR, BY THEIR CONSERVATOR, JOHN J. FORD — APPELLEES

OPINION
AFFIRMING IN PART,
VACATING IN PART,
AND REMANDING

** ** ** ** **

BEFORE: KNOPF AND TACKETT, JUDGES; ROSENBLUM, SENIOR JUDGE.[1]

KNOPF, JUDGE: On September 28, 1993, Mary Margaret Gunderson gave birth by Caesarean section to her and her husband's, Ronald Gunderson's, second child. Tragically, seven days later, Mary died. Mary's estate blamed her death on the medication, Parlodel®, which Mary had taken to suppress postpartum lactation. The estate, represented by Ronald, and Mary's two children, Nicholas and Wesley Gunderson, sued Parlodel's® manufacturer, Sandoz Pharmaceuticals Corporation,[2] and Mary's obstetrician, Lyman Armstrong, M.D.,[3] in Jefferson Circuit Court under theories of products liability and medical malpractice. The case came to trial in February and March 2004, and resulted in a judgment for the plaintiffs of more than nineteen million dollars. The estate was awarded compensatory damages for the

[1] Senior Judge Paul W. Rosenblum sitting as Special Judge by assignment of the Chief Justice pursuant to Section 110(5)(b) of the Kentucky Constitution and KRS 21.580.

[2] Sandoz has since changed its name to Novartis Pharmaceuticals Corporation.

[3] Dr. Armstrong died in 1997 and his estate was substituted as a party. The Gundersons also sued Dr. Armstrong's practice, Hyman and Armstrong, P.S.C. We shall refer to the estate and the practice as "Armstrong."

loss of Mary's services and earning power in the amount of $1,848,263.00, and Nicholas and Wesley were awarded compensatory damages of $3,000,000.00 apiece for the loss of their mother's consortium. These compensatory awards were apportioned 90% to Sandoz and 10% to Armstrong. Sandoz was also found liable for $11,250,000.00 in punitive damages. Sandoz and Armstrong now appeal. They both contend that the trial court abused its discretion by failing to exclude unreliable expert causation testimony as required by Daubert v. Merrell Dow Pharmaceuticals, Inc.[4] and Mitchell v. Commonwealth.[5] Both appellants also claim to have been entitled to directed verdicts on the issues of strict products liability and medical negligence, respectively. They both challenge certain evidentiary rulings. And Sandoz alleges errors with respect to the award of punitive damages including a claim that the jury was improperly instructed. Except for this last claim, we reject all of the appellants' contentions. Because we agree with Sandoz, however, that the punitive damages instruction was fatally flawed, we must vacate the award of punitive damages and remand the matter for additional proceedings.

[4] 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993).

[5] 908 S.W.2d 100 (Ky. 1995).

BACKGROUND.

The Food and Drug Administration (FDA) originally approved the use of Parlodel® for the prevention of postpartum lactation (PPL) in 1980. By 1983, reports of adverse reactions, including seizures, strokes, and heart attacks, led the FDA to request that Sandoz place a warning of the adverse experiences on its labeling. Sandoz initially resisted the request, but in 1984, and again in 1987, it agreed to make labeling changes, and in conjunction with the 1987 changes it agreed to notify doctors by letter of the potential hazards of using Parlodel® for lactation suppression.

Sandoz also undertook a comprehensive study of the drug. The study, carried out by Epidemiology Resources, Inc. (ERI) and published in 1988, did not conclusively show a relationship between Parlodel® and either stroke or seizure, but because of flaws in the study and its small size, the FDA determined that it did not allay concerns about those potential hazards. Because of different but also serious concerns with respect to other lactation suppressing drugs, the FDA's Fertility and Maternal Health Drugs Advisory Committee recommended that no drug, including Parlodel®, be routinely used to suppress lactation. Agreeing with the committee's recommendation, the FDA in 1989 informally requested that all manufacturers voluntarily withdraw the lactation suppression

indication from their drug products. Again, Sandoz resisted the request until 1994 when, in the face of FDA proceedings to withdraw approval for the indication, Sandoz voluntarily withdrew the Parlodel® indication for the prevention of lactation. Approximately ten million women in the United States had taken the drug for that purpose.

Mary Gunderson was thirty-two years old and in good health at the time of her second son, Wesley's, birth in 1993. Her pregnancy and the delivery at Suburban Hospital in Louisville were uneventful, although during her hospitalization she had periods of slight hypertension both before and after the birth. Because Mary intended a prompt return to work she decided against breast feeding, and Dr. Armstrong prescribed a two-week course of Parlodel® to suppress lactation. Mary had taken Parlodel® for similar reasons following the birth of the couple's first child, Nicholas, in 1989. Mary returned home from the hospital on October 1. On October 4 she complained to family members of a severe headache and of pain in her back. The next morning her mother discovered her dead in her bed.

Initially, the state medical examiner could not determine the cause of Mary's death. The autopsy revealed no evidence of brain or pulmonary abnormalities and though Mary's heart was somewhat enlarged, the examiner found no other cardiac abnormality and did not think the enlargement significant.

There was evidence that Mary may have taken as many as twenty-eight Percocet tablets during the three days leading up to her death, but the toxicology screen indicated no more than a therapeutic level of that drug's ingredients. Although Mary smoked and was somewhat overweight, the examiner found no evidence that smoking or obesity had caused her death. No other cause appearing, the examiner referred to FDA warnings and to case reports of women who had suffered seizures and strokes while taking Parlodel®, noted that in many of those reports the harmful event had been preceded by a severe headache, and concluded that Mary had probably suffered a primary seizure due to Parlodel® that had led to heart failure.

EXPERT CAUSATION TESTIMONY.

The Gundersons filed their suit in 1994. In addition to the testimony of the chief state medical examiner, George Nichols, M.D., a physician board certified in forensic pathology with twenty years' experience as chief of the examiner's office, they supported their allegation that Parlodel® caused Mary's death by proffering two other experts, Denis Petro, M.D. and Kenneth Kulig, M.D. Dr. Petro is a board-certified neurologist with extensive experience in both the development and the regulation of neurologic drugs. He has published at least twenty peer-reviewed journal articles. Dr. Kulig is board certified in toxicology and emergency medicine and has more than

twenty years' experience in those fields, both as a practitioner and as a professor. He has published in excess of 145 journal articles.

The opinion of these experts was that Parlodel® caused a seizure in Mary Gunderson which in turn caused a sudden death syndrome such as apnea (the absence of breathing) or cardiac arrhythmia (irregularity of the heartbeat). Underlying this conclusion is the experts' additional opinion that Parlodel®, the active ingredient of which is bromocriptine, can cause seizures by causing vasoconstriction (narrowing of blood vessels) in the brain. Sandoz and Armstrong moved to exclude this expert testimony on the ground that it is not scientifically reliable and thus not admissible under KRE 702. They also moved for directed verdicts on essentially the same ground: that the expert causation evidence was unreliable and hence insufficient. The trial court abused its discretion, they maintain, by denying those motions.

KRE 702 provides that

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert . . . may testify thereto in the form of an opinion or otherwise.

To be admissible, then, expert testimony must concern specialized knowledge and must aid the trier of fact. The first

requirement is one of reliability. The expert's opinion must be sufficiently validated, by sound reason and method, to be trustworthy.[6] The second requirement is one of relevance. The opinion must be relevant to the facts at issue. Thus, an expert's testimony is admissible under KRE 702 only if it "both rests on a reliable foundation and is relevant to the task at hand."[7] Because there is no dispute that causation evidence is relevant to the Gundersons' claim, the issue before the trial court was whether that evidence was reliable.

Under KRE 702, the assessment of reliability is meant to be flexible and concerned more with the "principles and methodology" the expert employs than with his or her conclusions.[8] Factors bearing on the reliability of expert testimony include

> (1) whether a theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether, with respect to a particular technique, there is a high known or potential rate of error and whether there are standards controlling the technique's operation; and (4) whether the

[6] Mitchell v. Commonwealth, 908 S.W.2d 100 (Ky. 1995) (adopting Daubert v. Merrell Dow Pharmaceuticals., Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993)).

[7] Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141, 119 S. Ct. 1167, 1171, 143 L.Ed.2d 238 (1999) (internal quotation marks omitted); Goodyear Tire and Rubber Company v. Thompson, 11 S.W.3d 575 (Ky. 2000).

[8] Daubert v. Merrell Dow Pharmaceuticals., Inc., *supra.*

> theory or technique enjoys general acceptance within the relevant scientific, technical, or other specialized community.[9]

These factors are not the only ones that may indicate reliability, and the court has broad discretion to consider others suggested by the unique circumstances of the expert testimony involved.[10]

The court should, however,

> be conscious of two guiding, and sometimes competing, principles. On the one hand, the court should be mindful that Rule 702 was intended to liberalize the introduction of relevant expert evidence. . . . And, the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct. . . . As with all other admissible evidence, expert testimony is subject to being tested by "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596, 113 S.Ct. 2786. On the other hand, the court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to "be both powerful and quite misleading." *Id.* at 595, 113 S.Ct. 2786 (internal quotation marks omitted). And, given the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.[11]

---

[9] Miller v. Eldridge, 146 S.W.3d 909, 914 (Ky. 2004).

[10] Kumho Tire Co. v. Carmichael, *supra.*

[11] Westberry v. Gislaved Gummi AB, 178 F3d 257, 261 (4th Cir. 1999).

Where, as in this case, the experts' qualifications have not been challenged and are not in doubt, the trial court must determine whether the proffered testimony falls "outside the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is 'shaky.'"[12] Although experts are not permitted merely to speculate,[13] if their opinions are supported by good grounds based on what is known, it is for the fact finder to decide if they are deserving of credence.[14]

This Court reviews the trial court's decision to admit or exclude evidence for an abuse of discretion.[15] "The test for abuse of discretion is whether the trial judge's decision was arbitrary, unreasonable, unfair, or unsupported by sound legal principles."[16]

The appellants first contend that the trial court abused its discretion by failing to hold a Daubert hearing prior

---

[12] Kumho Tire Company, LTD., v. Carmichael, 526 U.S. at 153, 119 S.Ct. at 1177.

[13] Mondie v. Commonwealth, 158 S.W.3d 203 (Ky. 2005); Rosen v. Ciba-Geigy Corporation, 78 F.3d 316 (7th Cir. 1996).

[14] Daubert v. Merrell Dow Pharms., Inc., *supra.*

[15] Toyota Motor Corporation v. Gregory, 136 S.W.3d 35 (Ky. 2004).

[16] Goodyear Tire and Rubber Company v. Thompson, 11 S.W.3d at 581.

to ruling on the admissibility of the experts' causation opinions and by failing to enter findings in support of its ruling. Our Supreme Court has held, however, that the trial court need not conduct a Daubert hearing if the record before it

> is complete enough to measure the proffered testimony against the proper standards of reliability and relevance. . . . [T]he record upon which a trial court can make an admissibility decision without a hearing usually will consist of 'the proposed expert's reports, affidavits, deposition testimony, and existing precedent.[17]

The voluminous record in this case, which included the experts' depositions and affidavits, much of the material upon which they relied, extensive briefing by the parties, and precedent from other Parlodel® litigation, satisfied that standard. The trial court did not abuse its discretion by forgoing a Daubert hearing.

City of Owensboro v. Adams,[18] on which the appellants rely, is not to the contrary. In Adams our Supreme Court emphasized the importance of the trial court's gate-keeping function in assessing the reliability of proffered expert testimony and noted that

> [t]he trial court's broad latitude to make the reliability determination does *not* include the discretion to abdicate completely its responsibility to do so

[17] Dixon v. Commonwealth, 149 S.W.3d 426, 430 (Ky. 2004).

[18] 136 S.W.3d 446 (Ky. 2004).

> . . . . A trial court must, at least, state on the record its Daubert conclusion with respect to reliability.[19]

Here, however, there is absolutely no suggestion that the trial court abdicated its gate-keeping responsibility under Daubert. On the contrary, as the court stated, it spent weeks studying the parties' extensive submissions on this question and then concluded, on the record, that the plaintiff's expert evidence was reliable.

Nor did the court abuse its discretion by failing to enter findings of fact in support of its Daubert ruling. While it is certainly preferable for a trial court to make such findings,[20] our Supreme Court has recently held that "[w]here the trial court fails to make express [Daubert] findings of fact, . . . an appellate court should engage in [a] clear error review by looking at the record to see if there is substantial evidence to support the trial court's ruling."[21] Our review is thus highly deferential. We do not ask whether we agree with the trial court's ruling, but only whether the record includes substantial evidence to support it.[22]

---

[19] *Id.* at 451 (emphasis in original; citation and internal quotation marks omitted).

[20] Miller v. Eldridge, 146 S.W.3d at 921-22.

[21] Miller v. Eldridge, 146 S.W.3d at 917.

[22] *Id.*

As the appellants note, the appellees bore the burden of proving both that Parlodel® is capable of causing seizures and that it probably did so in this case. With respect to the first question, whether Parlodel® is a possible cause of seizures, the appellees' experts adduced extensive evidence along two fronts. They sought to show that bromocriptine, the active ingredient in Parlodel®, can have vasoconstrictive effects, vasoconstriction being a recognized cause of hypertension and seizure. And they sought to show that Parlodel® itself has been meaningfully associated with cerebral vascular problems such as headache, hypertension, seizure, and stroke.

The first sort of evidence includes the fact that bromocriptine is a semi-synthetic ergot alkaloid, a family of chemicals which includes many members known to cause vasoconstriction. Notwithstanding the fact that bromocriptine typically lowers blood pressure by dilating blood vessels, the Gundersons' experts cited animal studies and a human hand-vein study indicating that in some circumstances bromocriptine can cause the paradoxical effect of vasoconstriction. One study suggests that low initial vascular resistance permits vasoconstriction, and, as the Gundersons' experts argue, a woman's vascular resistance is low during the postpartum period.

This evidence, the experts contend, lends substantial support to numerous adverse drug events and case reports, internal Sandoz documents acknowledging a possible causal relation between bromocriptine and adverse cerebral events, and an epidemiological study allegedly linking Parlodel® to seizures. The Sandoz package insert for Parlodel® lists eighty-nine cases of hypertension, seventy-two seizures, and thirty strokes when the drug was used during the postpartum period. Although these numbers are not overwhelming given the fact that as many as ten million women used Parlodel® to suppress lactation, they were sufficient to induce the FDA to initiate proceedings to withdraw Parlodel's® lactation suppression indication. Case reports have also appeared in the peer-reviewed medical literature to support statements to the effect that Parlodel® can cause vasoconstriction and possibly seizure, stroke, and heart attack.

A very few of the case reports indicate that the adverse symptoms disappeared when Parlodel® was withdrawn and then reappeared when Parlodel® was reintroduced. These "de-challenge, re-challenge" experiments are generally regarded as offering substantially better evidence of a causal relationship than an adverse reaction alone.

Finally, the experts all cited a 1986-88 epidemiological study sponsored by Sandoz and performed by

Epidemiology Resources, Inc. (ERI) that initially reported that women taking Parlodel® in the late postpartum period (more than seventy-two hours after delivery) were more than twice as likely to suffer seizures than such women not exposed to Parlodel®. In the final report, however, the author reclassified some of the late postpartum data to account, he said, for seizure history and the concomitant presence of another drug (ergonovine). He thus arrived at a relative risk figure suggesting that for women, such as Mary, with no history of seizure and who had not been exposed to ergonovine, Parlodel® actually reduced the risk of seizure. The appellees, of course, rely on the initial report, and contend that the modification was undertaken at the behest of Sandoz. Although the experts concede that the ERI study was significantly flawed (several peer-reviewed journals declined to publish it) and does not by itself establish a causal relationship between Parlodel® and seizure, it is nevertheless, they contend, substantial evidence of such a relationship, which, in conjunction with the other evidence linking Parlodel® both with vasoconstriction and adverse cerebral events, permits a reasonable inference that Parlodel® can cause seizures.

The trial court ruled that this inference was reliable; that is, not that it was necessarily correct but that it was sufficiently based on good grounds and sound scientific

methodology to be admissible. As Sandoz and Armstrong note, several federal district courts have considered very similar evidence in other Parlodel® cases and have reached the opposite conclusion.[23] Three federal circuit courts have upheld that result.[24] Generally, those courts have discounted the ERI study as not statistically meaningful, dismissed case studies and adverse drug reports as showing merely a temporal but not a causal relationship, objected to the animal studies as involving doses and processes removed by too great an analytical gap from the plaintiff's ingestion of Parlodel®, and noted that the FDA expressly disavowed having established a causal relationship between Parlodel® and any serious adverse event, but merely determined that the limited utility of lactation suppression was outweighed by the possible risk of serious side effects.

As noted above, however, the question before us is not whether we or other courts agree with the trial court's reliability finding, but only whether substantial evidence

[23] Dunn v. Sandoz, 275 F.Supp.2d 672 (M.D.N.C. 2003); Soldo v. Sandoz, 244 F.Supp.2d 434 (W.D.Pa. 2003); Caraker v. Sandoz, 188 F.Supp.2d 1026 (S.D.Ill. 2001); Siharath v. Sandoz, 131 F.Supp.2d 1347 (N.D.Ga. 2001); Glastetter v. Novartis, 107 F.Supp.2d 1015 (E.D.Mo. 2000); Hollander v. Sandoz, 95 F.Supp.2d 1230 (W.D.Okla. 2000); Brumbaugh v. Sandoz, 77 F.Supp.2d 1153 (D.Mont. 1999).

[24] Rider v. Sandoz, 295 F.3d 1194 (11th Cir. 2002) (affirming Siharath); Hollander v. Sandoz, 289 F.3d 1193 (10th Cir. 2002); Glastetter v. Novartis, 252 F.3d 986 (8th Cir. 2001).

supports it. Indeed, as the Tenth Circuit observed, given the deferential standard of review for Daubert rulings,

> [i]n theory judges are free to select different procedures and apply different factors to a particular expert or type of expertise than their colleagues do . . . and . . . as a consequence, similar cases could be resolved differently on the basis of inconsistent determinations about admissibility.[25]

Nor is the trial court alone in its determination to admit this evidence. In two cases a federal district court has rejected Sandoz's Daubert arguments,[26] and the Supreme Court of Kansas has ruled in another Parlodel® seizure case that, under that state's rules of evidence (Kansas has not adopted Daubert), the plaintiff's causation evidence raised material issues of fact sufficient to withstand a motion for summary judgment.[27] As one of the federal courts observed,

> animal studies, the medical literature reviews, the ADRs reported to the FDA, the "general acceptance" of the association [between Parlodel® and adverse cerebral events] reflected in several medical texts, . . . [and] the [de-challenge, re-challenge] experiment[s] . . . are recognized and accepted scientific methodologies, used for

---

[25] Hollander v. Sandoz, 289 F.3d 1193, 1206-07 (citation and internal quotation marks omitted).

[26] Brasher v. Sandoz, 160 F.Supp.2d 1291 (N.D.Alab. 2001); Globetti v. Sandoz, 111 F.Supp.2d 1774 (N.D.Alab. 2000).

[27] Kuhn v. Sandoz, 14 P.3d 1170 (Kan. 2000).

> assessing the possible side-effects and hazards associated with particular drugs.[28]

We cannot say that the trial court either abused its discretion or clearly erred by ruling that the plaintiffs' experts' general causation opinion based on these methods was sufficiently reliable to be admitted into evidence and tested in the usual way by cross examination and the presentation of contrary evidence.

Nor did the trial court abuse its discretion or clearly err by admitting the experts' special causation opinion that Parlodel® caused Mary's seizure and death. The method employed by all the experts to arrive at this conclusion was the differential diagnosis, a well-recognized, peer-reviewed technique whereby medical clinicians identify medical conditions and their causes.[29] The physician lists the possible diseases or causes of the condition, then engages in a process of elimination by performing diagnostic tests until he or she is left with the most likely diagnosis.

In this case the experts relied upon a thorough autopsy, including microscopic studies of the lung, heart, and brain tissues, a toxicology report, and Mary's family and

---

[28] Globetti v. Sandoz, 111 F.Supp.2d at 1179.

[29] Kennedy v. Collagen Corp., 161 F.3d 1226 (9th Cir. 1998); Glaser v. Thompson Medical Company, Inc., 32 F.3d 969 (6th Cir. 1994) Perkins v. Origin Medsystems Inc., 299 F.Supp.2d 45 (D.Conn. 2004).

medical history. This evidence, they testified, eliminated all possible causes of Mary's death (pulmonary embolism, stroke, or heart attack, for example) except some form of sudden death syndrome, essentially a negative diagnosis. Because of the position in which Mary's body was found, which was consistent with her having suffered a seizure; her exposure to Parlodel®; and the facts that, like other adverse events associated with Parlodel®, Mary's death occurred during the late postpartum period and was preceded by a severe headache, the experts concluded that the most likely cause of death was a Parlodel®-induced seizure followed by heart or lung failure. All of these analyses are standard, well established autopsy and differential diagnosis techniques. The trial court did not clearly err by deeming the opinion based on them reliable.

The appellants argue that the differential diagnosis was not reliable in this case because the experts did not adequately account for the fact that the postpartum period itself is associated with seizures, strokes, and heart attacks. The appellees' experts opined that late postpartum events such as Mary's seizure are rare, however, making it likely that Parlodel® was involved. The trial court did not clearly err by regarding this question as one involving the weight of the experts' testimony, not its admissibility.

Finally, the appellants complain that the trial court unfairly prevented them from cross-examining the Gundersons' experts with respect to certain studies allegedly contrary to their opinions. Because the appellants did not preserve the excluded cross-examination by avowal, however, this issue is not subject to our review.[30]

In sum, the trial court's finding that the plaintiffs' experts' causation testimony was reliable, that it represented "good grounds based on what is known," is not clearly erroneous. There is substantial evidence that the methods the experts employed are well established in their fields and yielded genuinely scientific results within "the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts."[31] Nor, for the same reasons, did the court abuse its discretion by deeming the experts' causation testimony sufficient to withstand the appellants' motions for directed verdicts. On the basis of that testimony, a rational juror could conclude that Parlodel® caused Mary's seizure and death. Accordingly, Sandoz and Armstrong are not entitled to relief on this ground.

THE ADEQUACY OF SANDOZ'S WARNINGS.

[30] Noel v. Commonwealth, 76 S.W.3d 923 (Ky. 2002).

[31] Kumho Tire Company, LTD., v. Carmichael, *supra,* note 11.

Kentucky law provides for strict product liability in tort for sellers of any product "in a defective condition unreasonably dangerous to the user."[32] A product may be "defective because of inadequate instructions or warnings."[33] The Gundersons allege that the warnings accompanying the Parlodel® Mary received were inadequate and that adequate warnings would have prevented her death. As Sandoz notes, under the learned intermediary doctrine, manufacturers of prescription drugs generally need not warn consumers directly of the risks associated with a medication as long as they adequately instruct and warn physicians who prescribe it. Among the rationales for this doctrine, as our Supreme Court has recently explained, is the fact that generally "the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient."[34]

> Although the manufacturer's duty to warn
>
> > runs only to the learned intermediary, that warning must still be adequate. . . . If the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer. . . . An adequate warning has been defined as one

[32] Ford Motor Company v. Fulkerson, 812 S.W.2d 119, 122 (Ky. 1991) (citation and internal quotation marks omitted).

[33] *Restatement (Third) of Torts: Prod. Liab.* § 2(c) (1998).

[34] Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (Ky. 2004).

> sufficient to apprise the general practitioner as well as the unusually sophisticated medical man of the dangerous propensities of the drug. . . . It is incumbent upon the manufacturer to bring the warning home to the doctor. . . . Several cases have held that a package insert may be sufficient for the warning to be adequate as a matter of law. . . . The warning may also be adequate if posted in the Physician's Desk Reference. . . . Thus, providing an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the patient.[35]

The package insert that accompanied Parlodel® at the time of Mary's prescription and the Physician's Desk Reference (PDR) listing both provided the following warning:

> While hypotension during the start of therapy with Parlodel® . . . occurs in some patients, 50 cases of hypertension have been reported, sometimes at the initiation of therapy, but often developing in the second week of therapy. Seizures have been reported in 38 cases (including 4 cases of status epilepticus), both with and without the prior development of hypertension occurring mostly in postpartum patients up to 14 days after initiation of treatment. Fifteen cases of stroke during Parlodel® ... therapy have been reported mostly in postpartum patients whose prenatal and obstetric courses had been uncomplicated. Many of these patients experiencing seizures and or strokes reported developing a constant and often progressively severe headache hours to days prior to the acute event. Some cases of strokes and seizures during therapy with Parlodel® . . . were also preceded by visual disturbances (blurred vision and transient cortical

[35] *Id.* at 764-65 (citations and internal quotation marks omitted).

> blindness). Four cases of acute myocardial infarction have been reported, including 3 cases receiving Parlodel® . . . for the prevention of physiologic lactation. The relationship of these adverse reactions to Parlodel® . . . administration is not certain. The use of Parlodel® . . . is not recommended for patients with uncontrolled hypertension or toxemia of pregnancy. Although there is no conclusive evidence which demonstrates the interaction between Parlodel® . . . and other ergot alkaloids, the concomitant use of these medications is not recommended. Particular attention should be paid to patients who have recently received other drugs that can alter the blood pressure.

This warning was approved by the FDA in 1987. In conjunction with the then new warning, the FDA required Sandoz to send a "Dear Doctor" letter to obstetricians noting the changes and calling attention to the adverse reactions. The estate presented evidence tending to show that Sandoz attempted to undermine the heightened warning by failing to send the "Dear Doctor" letter to more than a small fraction of the doctors registered in the college of obstetricians and gynecologists.

Because of its concern that so few doctors had received the letter, in 1988 the FDA required Sandoz to send the letter again to a wider audience and decided to include consideration of Parlodel® as a lactation suppressant at a 1988 meeting of its Fertility and Maternal Health Drugs Advisory Committee. In the fall of that year the ERI study was published. Following its review of that study and the other

available data, the advisory committee determined that the relatively minor discomfort and inconvenience of postpartum lactation did not justify the potentially serious risks associated with drug therapies, including Parlodel®. The committee recommended that that condition be treated conservatively, as it traditionally had been, with breast binding and analgesics, and that the indications of all drugs for that purpose be withdrawn. The FDA adopted the committee's recommendation in 1989 and asked manufacturers to voluntarily withdraw their drugs' lactation-suppression indications. With the exception of Sandoz, all manufacturers complied with the FDA's request.

Sandoz, however, continued to market Parlodel® for the suppression of postpartum lactation. In a May 1990 "Dear Doctor" letter acknowledging the FDA's request, the company wrote,

> Sandoz considers this request [to voluntarily withdraw the PPL indication] inappropriate for the following reasons: The question of need is one that should be determined between an informed patient and her physician and not by a governmental agency.
>
> There is strong disagreement with the conclusion that there is no need for a drug to prevent lactation in the postpartum period. Although not all women who elect not to breast feed may require therapy to prevent lactation, a significant number will benefit from such therapy.

> As demonstrated in controlled trials, the use of Parlodel® therapy to prevent the engorgement and pain that occur in many women who elect not to breast feed is a more effective approach than treating the engorgement and pain once they occur with analgesics and ice packs.

The estate presented evidence tending to show that Sandoz instructed its sales force not to mention the associated risks or the FDA's concerns unless questioned by the doctor and then to downplay those concerns. Instead, the sales representatives were to continue to urge that Parlodel® be included on standing orders as a routine therapy for postpartum lactation. In 1994, after the FDA had initiated procedures to withdraw its approval of Parlodel® for PPL, Sandoz withdrew that indication voluntarily.

The estate also presented evidence that well before the time of Mary's prescription in 1993 Sandoz knew of at least ninety-eight cases of hypertension, eighty-six cases of seizure, and thirty-three cases of stroke associated with Parlodel®, but had made no effort to provide doctors with updated figures after the 1987 revision to the package insert. Sandoz also knew that, in light of these potential risks, the FDA had determined that PPL did not require routine drug therapy. Nevertheless, Sandoz withheld those concerns from doctors and continued to market Parlodel® as a routine drug. Dr. Armstrong, a member of the college of obstetricians and gynecologists, testified that he

had not been made aware of increased concerns about Parlodel®. He admitted that he had not read the 1987 package insert or PDR entry, but testified that neither had he seen any of the "Dear Doctor" letters. Had he done so, he said, he would not have prescribed Parlodel® for Mary.

Because the 1987 package insert refers expressly to a possible risk of seizure, Sandoz contends that the warning should be deemed adequate as a matter of law and thus that the trial court should have granted its motion for directed verdict. Giving the Gundersons' evidence its most favorable inferences, however, as we must when reviewing the denial of a directed verdict motion,[36] that evidence can reasonably be thought to establish that by 1993 the 1987 package insert did not bring home to a reasonable physician an adequate warning of the drug's dangerous propensities, and that nothing Sandoz had done in the interim had made up for that inadequacy. On the contrary, the company had made no effort to update the adverse reaction figures, the company's warning letters were not widely distributed, and its sales representatives did not discuss risks

[36] Sand Hill Energy, Inc. v. Ford Motor Company, 83 S.W.3d 483 (Ky. 2002) (citing Lewis v. Bledsoe Surface Mining, 798 S.W.2d 459 (Ky. 1990).

except to discount them. The trial court, therefore, properly refused to direct a verdict against the Gundersons.[37]

Sandoz next contends that the Gundersons' Kentucky-law inadequate-warning claim has been impliedly preempted by federal law. As the company notes, warnings reviewed and approved by the FDA are not to be second-guessed by state courts even where the claim is that FDA approval was procured by fraud upon the agency.[38] Such claims "would open a pandora's box of judicial scrutiny of FDA decision-making," which would not comport with Congress's delegation of broad authority to the FDA to regulate drug labeling.[39]

Several courts have held, however, that FDA approval of a drug label does not relieve a manufacturer of its continuing duty to apprise consumers through their learned intermediaries of new information bearing upon the drug's risks

---

[37] *Cf.* Hill v. Searle Laboratories, 884 F.2d 1064 (8th Cir. 1989) (noting that over-promotion by a drug manufacturer can undermine an otherwise adequate warning); Baldino v. Castagna, 478 A.2d 807 (Pa. 1984) (same); Stevens v. Parke, Davis & Company, 507 P.2d 653 (Cal. 1973) (same).

[38] Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Ehlis v. Shire Richwood, Inc., 233 F.Supp.2d 1189 (D.N.D. 2002); Bouchard v. American Home Products Corp., 213 F.Supp.2d 802 (N.D.Ohio 2002).

[39] Kemp v. Medtronic, Inc., 231 F.3d at 234. *Cf.* Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341, 350, 121 S.Ct. 1012, 1018, 148 L.Ed.2d 854 (2001) ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives").

and that state-law claims based on breach of that duty are not preempted.[40] As one of the federal courts involved with Parlodel® litigation explained,

> [T]he [federal] regulations specifically contemplate that the FDA determination of drug safety given the warnings existing at the time of application would not always be accurate after additional post-application information surfaces. . . . Sandoz may have a federal duty to supplement the information before the FDA, but Sandoz is not prohibited from unilaterally strengthening the warnings before FDA approval. It is exactly in this situation that the State common law duty would attach. That duty would require Sandoz to *timely* alert patients (through their learned intermediaries) of an increased risk associated with Parlodel®. The common law duty to promptly alert physicians prescribing Parlodel® of an elevation in the risk of taking Parlodel® stands as no obstacle to the accomplishment and execution of the full purposes and objectives of the regulations.[41]

Although the Gundersons did offer proof that Sandoz had not been completely forthcoming with the FDA as the 1987 package insert was being considered, and though any claim based on that proof that the 1987 warning was inadequate when approved would be preempted, the gravamen of the Gundersons' claim is that between 1987 and 1993 Sandoz failed to apprise physicians

[40] Bell v. Lollar, 791 N.E.2d 849 (Ind.App. 2003); Caraker v. Sandoz Pharmaceuticals Corp., 172 F.Supp.2d 1018 (S.D.Ill. 2001); Kemp v. Medtronic, Inc., *supra* (medical device case in which the proposition was noted rather than held); Motus v. Pfizer, Inc., 127 F.Supp.2d 1085 (C.D.Cal. 2000).

[41] Caraker v. Sandoz Pharmaceuticals Corp., 172 F.Supp.2d 1018, 1037 (S.D.Ill. 2001) (emphasis in original).

of additional adverse reaction reports and of the FDA's determination that drug therapy for postpartum lactation was not necessary in light of the potentially serious risks. We agree with those courts that have found such claims not to be in conflict with the federal regulations and therefore not preempted. Sandoz was not entitled to a directed verdict on this ground.

The trial court's product liability instruction provided as follows:

> It is the plaintiff's claim that Parlodel® was in a defective condition unreasonably dangerous, resulting in the death of Mary Margaret Gunderson.
>
> You will find for the Plaintiffs, . . . if you are satisfied from the evidence as follows:
>
> A. As manufactured by Defendant Sandoz, the drug Parlodel® was unreasonably dangerous for the use of the drug's ultimate users, including Plaintiffs' decedent, ... A product is "unreasonably dangerous" if it creates such a risk of injury to a potential user that an ordinarily prudent manufacturer of pharmaceutical products, being fully aware of the risks, would not have placed or kept the product on the market; and
>
> B. The unreasonably dangerous condition of the drug Parlodel® was a substantial factor in causing Mary Margaret Gunderson's death.
>
> Otherwise you will find for Defendant Sandoz.

Sandoz contends that this instruction was erroneous because it did not specify that an adequate warning to the prescribing doctor is a defense. In Ford Motor Company v.

Fulkerson,[42] however, our Supreme Court endorsed the bare-bones products-liability instruction the trial court employed and cautioned against instructions getting into evidentiary matters, such as warnings, "which better practice suggests should be omitted from the instructions and left to the lawyers to flesh out in closing arguments."[43] While a more specific instruction would not necessarily have been erroneous, the trial court did not err or abuse its discretion by using a less specific but well-established instruction which gave Sandoz a fair opportunity to argue its theory of the case.

DR. ARMSTRONG'S NEGLIGENCE.

In medical malpractice actions, "the plaintiff must prove that the treatment given was below the degree of care and skill expected of a reasonably competent practitioner and that the negligence proximately caused injury or death."[44] Armstrong contends that there was insufficient evidence of his negligence to submit the plaintiffs' case to the jury. Armstrong notes that at the time of Mary's prescription, Parlodel® still technically enjoyed FDA approval for PPL as well as the approval of the standing order committee at Suburban Hospital. He also

[42] 812 S.W.2d 119 (Ky. 1991).

[43] *Id.* at 123.

[44] Reams v. Stutler, 642 S.W.2d 586, 588 (Ky. 1982); See Mitchell v. Hadl, 816 S.W.2d 183 (Ky. 1991).

notes that he had been using Parlodel® for years with good effect and no serious adverse reactions, including successful treatment of Mary's PPL following her delivery of Nicholas in 1989. This evidence, Armstrong maintains, precludes a finding that he deviated from the care and skill expected of a reasonably competent practitioner.

The Gundersons presented the expert testimony of Dr. Patrick Lavery, however, an OB-GYN with experience in Louisville. Dr. Lavery testified that by 1993 a reasonably competent practitioner would have learned through the medical literature, if not through the PDR and Sandoz, that serious concerns had been raised about Parlodel®, particularly in conjunction with hypertension. Because Mary had exhibited slight hypertension both before and after her delivery, such a practitioner, in Dr. Lavery's opinion, would not have prescribed that drug. Dr. Armstrong himself testified that had he been aware of the serious adverse reactions reported in the package insert and the PDR and of the FDA's determination that Parlodel® was not needed for PPL, he would not have prescribed Parlodel® for Mary. Given the favorable inferences required by our standard of review,[45] this evidence can reasonably be thought to show that Dr. Armstrong's failure to keep abreast of the concerns about Parlodel® was negligent and that the negligence

[45] Sand Hill Energy, Inc. v. Ford Motor Company, 83 S.W.3d 483 (Ky. 2002); Reams v. Stutler, *supra.*

caused Mary's exposure to that drug and her death. The trial court did not err, then, by denying Armstrong's motion for a directed verdict.

CROSS-CLAIM AS EVIDENCE.

In September 1998, Armstrong filed a cross-claim against Sandoz alleging fraudulent misrepresentation and gross negligence in Sandoz's marketing of Parlodel® and seeking both damages for injury to Dr. Armstrong's reputation and indemnification should Armstrong be found liable for Mary's death. Prior to trial Sandoz entered into an indemnification agreement with Armstrong whereby his claims were settled and Sandoz took over his defense of the Gundersons' claims against him. Accordingly, the cross-claim was dismissed and at trial Armstrong presented no evidence critical of Sandoz. The trial court permitted the Gundersons to introduce Armstrong's cross-claim as evidence of the defendants' non-adverse relationship and as relevant to the credibility of Armstrong's evidence. Sandoz contends that Armstrong's allegations were actually introduced against it to bolster the Gundersons' similar allegations and that for that purpose the cross-claim was inadmissible hearsay.

KRE 801A(b) permits the introduction as non-hearsay of an adverse party's admissions, including admissions contained in superseded or abandoned pleadings, but only against the

declaring party. "Admissions are not admissible against a declarant's coparty."[46] As Sandoz points out, moreover, several courts have excepted third-party pleadings from the general rule of admissibility because

> [s]trictly applied . . . (the general) rule would place a litigant at his peril in (that) . . . the allegations in third-party complaints and cross-claims seeking recovery over in the event of liability in the principal action could be used in that action as admissions establishing liability. Thus, as a necessary exception to the general rule, there is ample authority that one of two inconsistent pleas cannot be used as evidence in the trial of the other.[47]

Thus, according to Sandoz, Armstrong's cross-claim was not admissible against it as a co-party and was not admissible against Armstrong because the cross-claim was a third-party pleading.

On the other hand, as our Supreme Court has recently made clear, evidence of a settlement that renders formerly adverse parties no longer adverse will frequently be relevant to expose the potential bias of the former adversaries, who now may be motivated to downplay each other's fault. KRE 408 permits

---

[46] Fisher v. Duckworth, 738 S.W.2d 810, 813 (Ky. 1987).
[47] Schneider v. Lockheed Aircraft Corporation, 658 F.2d 835, 843 (D.C.Cir. 1981) (quoting Continental Insurance Co. v. Sherman, 439 F.2d 1294 (5th Cir. 1971), citations and internal quotation marks omitted).

the introduction of settlement evidence for that purpose.[48] Thus, although the cross-claim may not have been admissible under KRE 801A, we do not believe the trial court abused its discretion by admitting it under KRE 408 as evidence tending to show that following the indemnity agreement Sandoz and Armstrong had a potential motive to downplay each other's wrong doing.

Even if the trial court erred by admitting the cross-claim, moreover, we are convinced that the error was harmless.[49] The cross-claim was merely one exhibit out of 172; it was introduced not through a witness but simply through a house-keeping motion after a recess; it occupied only three minutes of an opening argument that was nearly two hours long and comparable portions of lengthy voir dire proceedings and closing argument. The jury is thus not apt to have given it undue weight. It contributed no new facts but only reiterated allegations the Gundersons had already made. It was cumulative even with respect to the facts that Sandoz was footing the bill for Armstrong's defense and had agreed to indemnify him. There is no reasonable possibility that had the cross-claim been

[48] Miller ex. rel. Monticello Banking Company v. Marymount Medical Center, 125 S.W.3d 274 (Ky. 2004); *cf.* Brocklesby v. United States, 767 F.2d 1288 (9th Cir. 1985) (indemnity agreement admissible to show that agreeing parties were no longer adverse and to attack the credibility of their witnesses).
[49] KRE 103(a).

excluded the result would have been different.[50] Sandoz, therefore, is not entitled to relief on this ground.

[50] Heilman v. Snyder, 520 S.W.2d 321 (Ky. 1975) (erroneous admission of cumulative evidence was harmless).

PUNITIVE DAMAGES.

Sandoz next contends that it was entitled to a directed verdict on the issue of punitive damages. Under Kentucky law, punitive damages may be awarded for gross negligence, which our Supreme Court has defined for this purpose alternatively as "wanton or reckless disregard for the lives, safety or property of other [persons]" or conduct "so outrageous that malice could be implied [sic] from the facts of the situation."[51] Sandoz maintains that even if its marketing of Parlodel® be deemed negligent it cannot be deemed grossly negligent, as thus defined, because Parlodel's® ability to cause seizures had not (and still has not) been conclusively established; because the Parlodel® package insert warned expressly of a potential risk of hypertension and seizures; and because the Gundersons offered no evidence that Sandoz representatives over-promoted Parlodel® directly to Dr. Armstrong, who testified that Sandoz representatives rarely visited him and that he based his prescription to Mary not on the company's representations concerning the drug but on his experience with it.

The Gundersons presented evidence, however, tending to show that by 1985 Sandoz officials knew of a likely causal link

[51] Phelps v. Louisville Water Company, 103 S.W.3d 46, 52 (Ky. 2003) (citing Horton v. Union Light, Heat & Power Co., 690 S.W.2d 382 (Ky. 1985) and Cooper v. Barth, 464 S.W.2d 233 (Ky. 1971); internal quotation marks omitted).

between Parlodel® and hypertension and seizures and by 1988 knew that the FDA had determined that Parlodel® should not be prescribed routinely as a prophylactic for PPL. Nevertheless, the company not only continued to market the drug aggressively for routine use, such as its inclusion on the standing order at Suburban Hospital, but sought to keep concerns about the drug from coming to the attention of doctors. It did so by engaging in such practices as denying the existence of adverse reaction reports to physicians who inquired about them, misrepresenting such reports to the FDA, publishing a false advertisement, failing to ensure that the "dear doctor" letters calling attention to the revised 1987 package insert reached its intended audience, attempting to manipulate the ERI report, and instructing its sales force not to mention those concerns unless physicians inquired and then to minimize them. This deliberate policy of obfuscation and misrepresentation has a nexus with this case in as much as Dr. Armstrong testified that had he known of the mounting concerns about Parlodel® or the FDA's position he would not have prescribed the drug to Mary notwithstanding his favorable experience with it. The company's alleged misconduct could reasonably be thought to betray such a wanton or reckless disregard for the safety of women such as Mary as to be outrageous and implicitly malicious. The trial

court did not err, therefore, by submitting the issue of punitive damages to the jury.

Alternatively, Sandoz contends that it was entitled to a directed verdict with respect to punitive damages because that claim was preempted by federal law. It characterizes the claim as based on the fact that it continued to market Parlodel® for PPL even after 1989 when the FDA requested that that indication be withdrawn. Under federal law, the company notes, it was entitled to seek reconsideration of the FDA's request and to continue marketing the drug pending that reconsideration. Kentucky may not punish it, it insists, for conduct that federal law expressly allows.

As discussed above, however, the punitive damages claim was not based on the fact that Sandoz refused to withdraw the PPL indication or that it contested the FDA's determination that prophylactic lactation suppression was not needed. It was based on the fact that Sandoz continued to market Parlodel® without adequately advising physicians of the concerns the drug had aroused and of the FDA's position. Indeed, as just noted, the Gundersons presented evidence tending to show that Sandoz engaged in a systematic campaign to keep that information from physicians. Federal law does not sanction such conduct, and therefore the Gundersons' punitive damages claim was not preempted.

Finally with respect to punitive damages, Sandoz contends that the trial court erred by failing to instruct the jury that it was not to award punitive damages to punish Sandoz for conduct that occurred outside Kentucky. We agree, and so must vacate the punitive damages award and remand.

In Sand Hill Energy, Inc. v. Smith,[52] our Supreme Court reconsidered a punitive damages award in light of the recent United States Supreme Court opinion in State Farm Mutual Insurance Co. v. Campbell.[53] Our Supreme Court held that, under Campbell, the jury could, with respect to a claim for punitive damages, consider evidence of a defendant's extraterritorial conduct to determine whether and to what degree the defendant's conduct within Kentucky had been reprehensible, but it must be instructed not to use out-of-state evidence to award punitive damages for conduct that occurred outside Kentucky. The defendant had adequately requested such an instruction, the Court noted, and thus the trial court's failure to give one was an error requiring vacation of the punitive damages award and remand for a new determination of the amount of punitive damages.

As did the plaintiff in Smith, in this case the Gundersons relied heavily on evidence of conduct that did not

[52] 142 S.W.3d 153 (Ky. 2004).

[53] 538 U.S. 408, 123 S. Ct. 1513, 155 L.Ed.2d 585 (2003).

occur in Kentucky at all (for example Sandoz's alleged misrepresentations to a Texas physician and to the FDA) or that occurred nationwide (such as the false advertisement that appeared in a national medical journal or the alleged nationwide sales tactics). The estate also emphasized other serious adverse reactions associated with Parlodel® almost all of which occurred outside Kentucky. Given this extra-territorial evidence, much of which was introduced to prove that Sandoz had conducted itself reprehensibly, we agree with Sandoz that, under Campbell and Smith, it was entitled to an instruction limiting punitive damages to its conduct within Kentucky.[54]

Although the trial court is not to be faulted much for relying on what, until Campbell, had been a standard punitive damages instruction in Kentucky, the trial court's failure to give the instruction required by Campbell was nevertheless an error requiring that the punitive damages award be vacated and the matter remanded for a new determination of the amount of punitive damages by a properly instructed jury. The court should use an instruction substantially similar to the one our Supreme Court suggested in Smith.[55]

---

[54] The Gundersons do not dispute that Sandoz preserved this issue by tendering an adequately accurate version of such an instruction and by arguing during discussion of the instructions for its use.

[55] Sandoz contends that it was also entitled to an instruction distinguishing the purposes of compensatory and punitive

LOSS OF CONSORTIUM EVIDENCE.

Both Armstrong and Sandoz contend that the trial court made erroneous evidentiary rulings with respect to the claims by Nicholas and Wesley Gunderson for damages to compensate them for the loss of their mother's consortium. "Consortium" in this context means the fundamental benefits, such as the society, love, guidance, care, comfort, and protection, of the children's relationship with their mother. Our Supreme Court first recognized a minor child's right to seek a remedy for the loss of his or her parent's consortium in Giuliani v. Guiler,[56] which, like this case, was a wrongful death action. As noted above, the jury awarded Nicholas and Wesley three million dollars each on their loss of consortium claims. The appellants maintain that the trial court erred by excluding evidence of the boys' father's relationship with Janice Hays, his girlfriend of about four years at the time of trial who often stayed overnight at the Gunderson residence, fixed breakfast, made the boys' school lunches, helped care for them when the father was out of town,

---

damages. Although neither Campbell nor Smith requires such an instruction as they do the instruction limiting punitive damages to conduct within the jurisdiction, our Supreme Court's sample instruction includes a provision on the purpose of punitive damages. We agree with Sandoz, therefore, that on remand it will be entitled to a similar provision.

[56] 951 S.W.2d 318 (Ky. 1997).

and assisted with their schooling. This was evidence, the appellants insist, that the boys' loss had been mitigated to some extent, and was a factor the jury was entitled to consider.

As several courts, including our Supreme Court, have noted, damages for the loss of consortium are not compensatory in the way that damages for, say, lost wages are.[57] Damages can replace lost wages, but they cannot replace a relationship that has been destroyed. Assigning a monetary value to lost consortium is thus notoriously difficult, but, as those same courts have also noted, no more so than assigning a value to pain and suffering or other intangible harms the law attempts to remedy.

In an effort to provide some guidance to the trial court and the finder of fact, other courts have observed that the following factors are relevant in determining the amount of damages to award the child who has suffered a compensable loss of consortium: "the child's age, the nature of the child's relationship with the parent, the child's emotional and physical characteristics, and whether other consortium-giving

[57] Giuliani v. Guiler, *supra;* Pence v. Fox, 813 P.2d 429 (Mont. 1991); Williams v. Hook, 804 P.2d 1131 (Okla. 1990); Ueland v. Reynolds Metals Company, 691 P.2d 190 (Wash. 1984). *See* Dan B. Dobbs, *The Law of Torts* § 302 (2001) (discussing claims for stand-alone emotional harm).

relationships are available for the child."[58] Seizing on the last factor, the appellants contend that Janice Hays's care of and concern for Nicholas and Wesley were consortium-like benefits and thus that their relationship with her was a fact the jury should have been allowed to consider.

We are convinced, however, that "consortium-giving relationship" does not refer to any and all relationships from which a child might derive some measure of love, society, or guidance, but that to be relevant to a child's lost consortium claim the other relationship must be sufficiently close and intimate truly to compare to the relationship with a parent. It must have been of a significant duration and stability and to have involved day-to-day emotional interdependence as well as the child's substantial physical, and financial dependence.[59] Otherwise, the child's claim is apt to be swamped by collateral evidence of the surviving parent's relationships.

Without denigrating the boys' relationship with Janice Hays, we do not think the trial court abused its discretion by excluding that relationship from evidence. The avowal testimony indicated that Ms. Hays had known Mr. Gunderson for only about

[58] Villareal v. State, Department of Transportation, 774 P.2d 213, 220-221 (Ariz. 1989); Reagan v. Vaughn, 804 S.W.2d 463 (Tex. 1990); Belcher v. Goins, 400 S.E.2d 830 (W.Va. 1990).

[59] *Cf.* Fitzjerrell v. City of Gallup ex rel. Gallup Police, 79 P.3d 836 (N.M.App. 2003) (discussing elements of a consortium-giving relationship).

four years, and that while she had to a considerable extent been accepted in the Gunderson household, she did not live there exclusively but still maintained her own residence. She was, in a word, Mr. Gunderson's girlfriend whose relationship with the boys was still derived from him and had not become so stable or so mutually dependant and supportive as to be deemed consortium-giving.

Not only was that relationship thus irrelevant, but its admission into evidence would likely have necessitated the admission of evidence of another of Mr. Gunderson's relationships of comparable duration. The trial court could rightly determine that the multiplication of such collateral evidence was likely to confuse the jury and distract it from the real issues in the case.[60] The trial court did not abuse its discretion, therefore, by excluding evidence of the boys' relationship with Janice Hays.

Nor is this result affected by Justice Cooper's aside in Miller ex. rel. Monticello Banking Company v. Marymount Medical Center,[61] that whether the appellant in that case had been living with his girlfriend was "a fact relevant to his claim for loss [of spousal] consortium."[62] We do not understand

[60] KRE 403.

[61] 125 S.W.3d 274 (Ky. 2004).

[62] *Id.* at 285.

Justice Cooper's remark to imply that all of a claimant's subsequent relationships will, without more, be relevant to a lost consortium claim.

Finally, Armstrong and Sandoz also contend that the trial court abused its discretion by admitting the expert testimony of Dr. Barbara Bower. Dr. Bower's doctorate is in education, and she is licensed as a psychological counselor. She testified to extensive experience as a guidance counselor, as a university teacher, and as a private children's counselor. Trial counsel hired her in 2000 to perform an assessment of Nicholas and Wesley. She met with the boys eight times during 2000 and 2001 and attempted through conversations, drawings, and writing assignments to elicit their feelings about themselves and the loss of their mother. She did not attempt to diagnose or treat the boys, only to observe them, and her testimony was largely limited to reporting her observations and showing the jury the boys' drawings and writings. She testified, not surprisingly, that the absence of their mother loomed large in the boys' lives; that Nicholas, the elder, remembered a good and loving relationship with his mother; and that both boys would be at some increased risk for developmental issues, risk taking behaviors, and depression. She interpreted certain "happy" drawings by Nicholas, not, as appellants contend, as expressions of a sense of abandonment, but rather as expressions of

Nicholas's need, in the wake of his abandonment, to be reassured that it was possible and acceptable for him to feel happy—the implication clearly being that he often did feel happy.

Appellants maintain that Dr. Bower's testimony was not sufficiently objective and scientific to pass muster under Daubert. They note that in Staggs v. Commonwealth,[63] our Supreme Court rejected testimony by an art therapist who purported to characterize a child's drawings as abnormal and indicative of sexual abuse. And they complain that Dr. Bower's testimony appealed unduly to the jury's emotions.

Daubert and KRE 702 are not limited to scientific testimony, however, but also apply to "other specialized knowledge" that is reliable, relevant, and likely to be helpful to the trier of fact.[64] The trial court did not abuse its discretion by determining that by virtue of her training and experience Dr. Bower had specialized knowledge about children dealing with emotional problems and about ways to help such children express emotions they may not be able otherwise to articulate.

Although "art therapy" may be of dubious value as a diagnostic tool, Dr. Bower did not purport to diagnose Nicholas and Wesley. She merely used their drawings, as she did their

[63] 877 S.W.2d 604 (Ky. 1993).

[64] The Goodyear Tire and Rubber Company v. Thompson, 11 S.W.3d 575 (Ky. 2000).

writings, to give some idea of how the boys were conscious of and hurt by their mother's loss. The trial court did not abuse its discretion by determining that Dr. Bower's methods and results were reliable for this modest purpose.

Nor did the trial court abuse its discretion by deeming Dr. Bower's testimony relevant. It shed light on the boys' relationships to their mother and on their emotional characteristics, both of which are among the factors listed above as relevant to valuation.

Finally, although Dr. Bower's testimony dealt with the boys' emotions, and though she presented Nicholas and Wesley as unique individuals coping with a difficult loss, her testimony was not inflammatory. It consisted primarily of what the boys themselves said, drew, and wrote, and as noted it included evidence that the boys were adjusting to their grief in normal ways. We are convinced that this testimony was not unduly prejudicial and was sufficiently likely to be helpful to the jury to be admissible. The trial court, in sum, did not abuse its discretion by admitting the testimony of Dr. Bower.

We reject, thus, Armstrong's argument that the size of the boys' awards indicates that Dr. Bower's testimony was inflammatory. The jury was instructed that the damages for lost consortium were not to exceed $10,000,000.00. The $3,000.000.00 awards were well within that limit, suggesting that the jury's

decision was a deliberate one, not one overborne by passion. The appellants' assertion that the boys' awards were excessive as a matter of law was not sufficiently developed to permit review.[65]

In sum, it was not the Gundersons' burden to establish conclusively that Parlodel® causes such serious side effects as the seizure that led to Mary's death. They were required to show only that Parlodel® is a likely cause of such effects. Their experts' conclusion that it is, based on standard and the best available scientific studies and techniques, was sufficiently reliable under Daubert and KRE 702 to be admissible. That evidence together with Dr. Nichols's differential diagnosis adequately support the jury's finding that Parlodel® caused Mary's death.

There was substantial evidence, moreover, that by the time of Mary's prescription Sandoz knew of concerns about Parlodel's® serious side effects and yet not only failed to convey those concerns to the doctors, such as Dr. Armstrong, who were routinely prescribing the drug for postpartum lactation, but actively and at times dishonestly endeavored to keep the concerns from being seriously considered. Such an egregious failure to warn justifies the jury's award against Sandoz of both compensatory and punitive damages.

[65] CR 76.12.

The judgment against Dr. Armstrong was also adequately supported. Dr. Lasker's testimony that by 1993 a reasonably cautious obstetrician would have known not to prescribe Parlodel® in the face of even slight hypertension was substantial evidence of Dr. Armstrong's negligence, without which, by Dr. Armstrong's own testimony, he would not have prescribed the drug to Mary.

These results were not rendered unfair by the admission into evidence of Dr. Armstrong's counter-claim or the testimony of Dr. Bower, or by the exclusion of evidence concerning Nicholas and Wesley's relationship with their father's girlfriend.

The award of punitive damages against Sandoz, however, was rendered unfair by the omission from the jury instructions of a provision directing the jury not to punish Sandoz for its conduct outside Kentucky.

Accordingly, we affirm the March 11, 2004, judgment of the Jefferson Circuit Court in all respects except its provision awarding punitive damages. That portion of the judgment is vacated, and the matter is remanded for a new trial on the amount of Sandoz's punitive damages liability.

TACKETT, JUDGE, CONCURS.

ROSENBLUM, SENIOR JUDGE, CONCURS IN PART, DISSENTS IN PART, AND FILES SEPARATE OPINION.

ROSENBLUM, SENIOR JUDGE, CONCURRING IN PART AND DISSENTING IN PART: I respectfully dissent in part with respect to two issues. First, the trial court, despite acknowledging its relevance to the quantum of loss of consortium damages, excluded all evidence that the minor plaintiffs, Nicholas and Wesley, were living with and had been cared for over a number of years by their father's girlfriend, Janice Hays. Through avowal testimony, appellants demonstrated that Ms. Hays has developed a loving relationship with Nicholas and Wesley. Ms. Hays "splits up" the parenting duties with Mr. Gunderson. Whether other consortium-giving relationships are available to a child is a factor which juries should consider in determining the amount of damages. The exclusion of this evidence entitles the appellants to a new trial.

Second, the trial court's ruling allowing appellees to introduce the cross-claim filed by Dr. Armstrong's estate as affirmative evidence against Sandoz was prejudicial error. The cross-claim is hearsay for which no exception exists. Although pleadings may be admissions of a party that filed them, they are not admissions of parties against whom they are filed. Here, the Armstrong cross-claim against Sandoz was not introduced against Armstrong – it was completely exculpatory as to Armstrong — but against Sandoz. That pleading was not Sandoz's admission. The cross-claim was particularly egregious hearsay

in that, crafted after Dr. Armstrong's death, it contradicted his testimony that he had not been persuaded by Sandoz to prescribe Parlodel®. Because the cross-claim is hearsay as to Sandoz, it was improperly and prejudicially admitted. Sandoz is entitled to a new trial based upon this prejudicial error. In all other respects, I concur with the majority opinion of this Court.

BRIEFS FOR APPELLANT SANDOZ:

Joe G. Hollingsworth
Katharine R. Latimer
Bruce J. Berger
Spriggs & Hollingsworth
Washington, DC

Virginia Hamilton Snell
Deborah H. Patterson
Wyatt, Tarrant & Combs
Louisville, Kentucky

BRIEFS FOR APPELLANTS HYMAN & ARMSTRONG, P.S.C., AND KAREN ARMSTRONG:

Edward H. Stopher
Rod D. Payne
Boehl Stopher & Graves, LLP
Louisville, Kentucky

ORAL ARGUMENT FOR APPELLANT SANDOZ:

Bruce J. Berger
Washington, DC

BRIEFS AND ORAL ARGUMENT FOR APPELLEE:

Larry Franklin
Michael R. Hance
Franklin & Hance, P.S.C.
Louisville, Kentucky