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Supreme Court of Kentucky

2006-SC-000175-DG

HYMAN & ARMSTRONG, P.S.C., ET AL. — APPELLANTS

ON REVIEW FROM COURT OF APPEALS
V. CASE NOS. 2004-CA-001536 & 2004-CA-001537
JEFFERSON CIRCUIT COURT NO. 94-CI-004680

RONALD GUNDERSON
(ADMINISTRATOR OF THE ESTATE OF MARY
MARGARET GUNDERSON), ET AL. — APPELLEES

AND 2006-SC-000179-DG

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

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OPINION OF THE COURT BY JUSTICE SCHRODER

AFFIRMING

While we find it was error in the trial of this products liability/medical malpractice case to allow evidence of the cross-claim to be admitted, we adjudge it to be harmless error. We find no error in the Appellant's other allegations. Hence, we affirm the decision of the Court of Appeals.

FACTS

On September 28, 1993, Mary Gunderson, age thirty-two, gave birth by cesarean section to her second child, Wesley Gunderson. Because Mary did not want to breastfeed, Mary's obstetrician, Dr. Lyman Armstrong, prescribed the drug Parlodel (bromocriptine mesylate) to stop lactation. Mary began taking Parlodel on September 29, and was discharged from the hospital on October 1 to recover at home. Mary's recovery was uneventful until October 4, when Mary complained of a severe headache and pain between her shoulder blades radiating down her back. Mary went to bed that night at around 11:30 p.m. The next morning Mary's mother discovered Mary dead in her bed. Authorities were called and Detective David Burks of the Jeffersontown Police Department began a death scene investigation. Mary was found in bed lying on her back with her arms bent backwards by her head in a gravity-defying position. Mary was also found to have voided from her bladder.

The police report filed on November 23, 1993, listed the cause of death as unknown. In conducting the autopsy, the Kentucky Medical Examiner's Office found no anatomic cause of death. After further investigation of the death and research into the drug Parlodel, the Medical Examiner's report, completed on December 29, 1993, concluded the following:

> Autopsy and toxicologic examinations disclose no cause of death in this case. Review of circumstances, literature and case reports concerning bromocriptine, used in this case for suppression of

> lactation, reveals an association with hypertension, vascular complications, headache[,] convulsive seizure, and death. Death is attributed to seizure, which is expected to provide no findings at autopsy.

On September 8, 1994, Mary's Estate, her husband, Ronald Gunderson, and her two minor children (hereinafter "the Gundersons") filed suit against Sandoz Pharmaceutical Corporation ("Sandoz"), the maker of Parlodel, and Hyman & Armstrong, P.S.C. (hereinafter "Dr. Armstrong"),[1] alleging products liability and medical malpractice in causing Mary's death. The case was tried from February 2, 2004, to February 28, 2004, and resulted in a judgment for the Plaintiffs totaling $19,098,263. Apportioning 90% liability to Sandoz and 10% to Dr. Armstrong, the jury awarded $7,848,263 in compensatory damages ($6,000,000 for loss of parental consortium and $1,848,263 for loss of services and earning power). $11,250,000 in punitive damages was assessed against Sandoz.

On appeal to the Court of Appeals, the court vacated the portion of the judgment awarding punitive damages because the trial court failed to instruct the jury that punitive damages could not be based on conduct that occurred outside of Kentucky. The court thus remanded the action for a new trial "on the amount of Sandoz's punitive damages liability." The judgment was affirmed in all other respects. Sandoz and Dr. Armstrong filed separate motions for discretionary review, which were granted and consolidated for review before this Court.

LACK OF A DAUBERT HEARING

Prior to trial, the Defendants/Appellants moved for a hearing pursuant to Daubert v. Merrrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469

[1] Hyman and Armstrong, P.S.C. was the name of Dr. Armstrong's medical practice. Dr. Armstrong died in February 1997, prior to trial in this case, and his estate was substituted as a defendant in the case.

(1993), to determine the admissibility of the Gundersons' causation experts who were slated to testify that Parlodel causes seizures in women taking the drug for postpartum lactation suppression. Sandoz and Dr. Armstrong argue that the trial court did not satisfy its gatekeeping obligations when it failed to hold a formal Daubert hearing and enter specific findings regarding the testimony of the Gundersons' causation experts. In Commonwealth v. Christie, 98 S.W.3d 485, 488-89 (Ky. 2002), this Court stated the following relative to the proper application of Daubert in Kentucky:

> When faced with a proffer of expert testimony under KRE 702, the trial judge's task is to determine whether the expert is proposing to testify to (1) scientific, technical, or other specialized knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This calls upon the trial court to assess whether the proffered testimony is both relevant and reliable. This assessment does not require a trial court to hold a hearing on the admissibility of the expert's testimony. But a trial court should only rule on the admissibility of expert testimony without first holding a hearing when the record [before it] is complete enough to measure the proffered testimony against the proper standards of reliability and relevance.
>
> Usually, the record upon which a trial court can make an admissibility decision without a hearing will consist of the proposed expert's reports, affidavits, deposition testimony, existing precedent, and the like. Such a record is necessary in order to give a trial court an adequate basis for making its decision on the relevancy and reliability of the proposed expert's testimony and to allow for appellate review of the trial court's decision. Failure to make a determination on the admissibility of expert testimony without an adequate record is an abuse of discretion by the trial court.

(internal quotations and citations omitted).

In the instant case, the trial court had before it a mountain of discovery material, including lengthy depositions of the causation experts, affidavits of the experts, reports of the experts, a voluminous amount of scientific studies, reports and publications relied on by experts, and extensive briefing by the parties. At one point, the judge remarked

on the record that the pre-trial record occupied an entire room in his chambers and that he had spent weeks reading the material. Further, on January 19, 2004, the court devoted an entire day to addressing the parties' motions in limine, many of which related to the admissibility of specific pieces of scientific evidence that were relied on by the Gundersons' causation experts and were challenged as being unreliable and irrelevant. The challenged evidence included case reports, adverse drug experience reports, and animal studies. Although this may not have technically been a Daubert hearing, the court heard lengthy arguments on the reliability and relevancy of the scientific evidence underlying the Gundersons' causation experts' opinions. We adjudge that the trial court did not abuse its discretion in its method of evaluating the reliability and relevancy of the testimony of the Gundersons' causation experts. The court had more than an adequate record before it to make its Daubert ruling, and it was apparent at the January 19, 2004, hearing that the trial judge was well versed on the copious record.

LACK OF EXPRESS FINDINGS OF FACT ON THE DAUBERT RULING

While the trial court may not have entered express findings of fact, the court articulated some basis for its Daubert ruling when it stated the following at the January 19, 2004, hearing:

> I have to make a requisite minimal determination whether or not I believe that the testimony is reliable, whether it is sufficiently trustworthy, and whether it's the general type of data upon which, in this case physicians or scientists, typically rely upon in forming their opinions. And it appears to me that both sides have that. You've got eminently well qualified experts and the subject of the majority of the attack with these experts is going to be on cross-examination in terms of the appropriate weight that the jury ought to afford their testimony and whether it is affected by this data on which they rely.

The trial court affirmatively stated on the record that it had reviewed the material submitted by the parties relative to the testimony of the Gundersons' causation experts and concluded that the testimony was reliable. This is the minimum required for a Daubert ruling. City of Owensboro v. Adams, 136 S.W.3d 446, 451 (Ky. 2004). "In doing so, however, the court need not recite any of the Daubert factors, so long as the record is clear that the court effectively conducted a Daubert inquiry." Id. While this Court would prefer trial courts to include findings of fact in their Daubert rulings, "failure to include those findings and conclusions is not automatically indicative of arbitrariness, unreasonableness, unfairness, or application of the wrong legal standard[,]" and "is not grounds for reversal." Miller v. Eldridge, 146 S.W.3d 909, 921-22 (Ky. 2004). "[T]he proper appellate approach when the trial court fails to make express findings of fact is to engage in a clear error review by looking at the record to see if the trial court's ruling is supported by substantial evidence." Id. at 922. From our review of the record, the trial court conducted an effective Daubert inquiry.

RELIABILITY AND RELEVANCE OF CAUSATION EVIDENCE

An appellate court's standard of review relative to a ruling on the reliability of scientific evidence under Daubert is whether the ruling is supported by substantial evidence. Id. at 917. The ruling as to the relevance of the scientific evidence is reviewed under an abuse of discretion standard. Id. Appellants maintain that the scientific evidence relied on by the Gundersons' causation experts, specifically case reports, animal studies, and chemical analogies, was unreliable and/or not relevant because it did not prove that Parlodel causes seizures in women taking the drug for postpartum lactation suppression ("PPLS"). Appellants argue that such evidence is

merely anecdotal and that the only reliable method of proving that Parlodel causes seizures in such women is an epidemiological study.

It was established at trial that there were two epidemiological studies looking at postpartum women taking Parlodel for PPLS, the HCIA study commissioned by Sandoz, and the ERI study, also commissioned by Sandoz and conducted by Dr. Rothman from Epidemiology Resources, Inc. ("ERI"). The evidence established that the HCIA study had been rejected by the scientific community because some patients were not trackable, and there were apparent misclassifications within the study. Even an epidemiologist from Sandoz conceded that the HCIA study was too flawed to be considered.

Shortly after Parlodel was approved by the FDA for PPLS in 1981, the FDA began receiving a significant amount of adverse drug reports of women experiencing headaches, hypertension, heart attacks, seizures, and strokes after taking the drug for PPLS. The ERI study was commissioned by Sandoz in 1986 to allay concerns of the FDA that Parlodel was responsible for causing strokes and seizures in women taking the drug for PPLS. The final report from the ERI study released in 1988 concluded that women taking Parlodel for PPLS had only a 1.61% greater risk of having a seizure than women not getting the drug, which is considered statistically insignificant. At trial, three of Appellees' experts, Dr. George Nichols, Dr. Kenneth Kulig and Dr. Dennis Petro, seriously criticized the final report from the ERI study because it was apparent to them that the risk rate of seizure for that population had been lowered from 2.86% (which is considered statistically significant) due to changing the data analyzed to exclude women with a history of seizures and women who had also taken a related drug, ergonovine, regardless of whether that drug was known to be in the woman's system at the time of

the adverse event. In fact, the Gundersons offered into evidence a letter to ERI from Sandoz requesting that it "recut the data on late-onset seizures" in the final report on the ERI study. The final report on the ERI study was subsequently rejected for publication by three peer review journals because it was misleading and discounted the positive association between Parlodel and seizures. Dr. Kulig and Dr. Petro testified that the ERI study actually supported their opinion that Parlodel can cause seizures late in the postpartum period (more than seventy-two hours after delivery).

The Gundersons' causation experts also relied on the myriad of case reports of women experiencing postpartum seizures after taking Parlodel for PPLS. The case reports filed with the FDA, known as adverse drug reports ("ADRs"), are filed by many sources, including hospitals, physicians, and the patients who took the drugs. The ADRs are relied on by the FDA after the drug is approved and released into the marketplace to monitor whether there are side effects or adverse reactions to the drug that did not show up in the initial clinical trials of the drug. Under federal regulations, drug companies that receive information about an adverse drug reaction that involves one of their drugs are required to report the reaction to the FDA. The package insert for Parlodel listed eighty-nine cases of hypertension, seventy-two seizures, and thirty strokes when the drug was used for PPLS. Several case reports were contained in peer-reviewed medical literature as support for statements that Parlodel has been known to cause vasoconstriction and possibly seizure, stroke and heart attacks. At least two of the case reports indicated that the adverse symptoms disappeared when Parlodel was withdrawn and then reappeared when Parlodel was reintroduced. Dr. Petro testified that these cases of "de-challenge/re-challenge" were considered substantially better evidence of a causal relationship than an adverse reaction alone.

The Gundersons offered into evidence an internal Sandoz document from 1982 in which Sandoz acknowledged that it had received ten to twelve reports of seizures in patients given Parlodel during the postpartum period and stated, "From our side, we felt that these cases were probably related to episodes of hypertension, which we know can occur under Parlodel in such patients." In another internal Sandoz memorandum from 1982, Dr. William Westlin, Director of the Medical Services Department at Sandoz, responded as follows to reports of adverse reactions to Parlodel:

> In view of my recent conversation with Dr. Weiner at FDA, I think we should give this report serious consideration. I am beginning to think that there is some association between seizures, hypertension, and Parlodel therapy in the postpartum period, even though it is rare and is, at present, unexplainable.

Dr. Petro testified that case reports are some evidence of an association between a drug and a particular reaction, but not definitive evidence.

Although Parlodel is known to lower blood pressure by dilating blood vessels, the Gundersons' causation experts also relied on animal studies wherein Parlodel was shown to cause the paradoxical effect of vasoconstriction. One study in particular, a hind leg study on dogs, indicated that low initial vascular resistance, which women typically experience after giving birth, permits vasoconstriction, which could account for why women in a postpartum state are more susceptible to seizures from Parlodel. Dr. Petro also cited a toxicology study on rats in which the rats experienced seizures when given high doses of Parlodel. Appellants contend that the animal studies offer no proof that Parlodel causes seizures in humans, thus, are scientifically unreliable under Daubert. Dr. Nichols, Dr. Petro and Dr. Kulig all testified that they looked at animal studies on Parlodel and found them insightful on the issue of causation. Dr. Kulig

testified that animal reactions to drugs are relevant because they reflect a reaction that a human may have to the drug.

Appellants also assert that evidence of the properties of the general class of drugs within which Parlodel is contained, ergot alkaloids, was not scientifically relevant or reliable. Dr. Kulig, a physician specializing in emergency medicine and medical toxicology, testified that it is a well known and proven fact that ergot alkaloid drugs can cause vasoconstriction, hypertension, and convulsive seizures, which supported his opinion that the Parlodel caused the hypertensive episode which resulted in Mary Gunderson's fatal seizure. Appellants maintain that the general propensities of the broad class of ergot alkaloid drugs cannot be analogized to Parlodel because of the diversity amongst the different ergot drugs.

The trial court ruled at the January 19, 2004 hearing that although the individual pieces of evidence at issue (case reports, ADRs, animal studies and chemical analogies, articles in medical textbooks and scientific publications) may not by themselves definitively prove that Parlodel causes postpartum seizures in women, when considered together as an aggregate body of evidence with scientific underpinnings, it is reliable enough evidence to put before the jury in this case. We agree.

The four factors that a court may look at in determining the reliability of an expert's testimony include, but are not limited to:

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

Goodyear Tire and Rubber Co. v. Thompson, 11 S.W.3d 575, 578-79 (Ky. 2000) (citing Daubert, 509 U.S. at 592-94, 113 S. Ct. at 2796-97, 125 L. Ed. 2d at 482-83). A trial court's reliability analysis under Daubert is not limited to the above factors and should be tailored to the particular facts and science in the case. Miller, 146 S.W.3d at 918-19. The Daubert factors are simply a way of distinguishing "between science and pseudo-science." Id. at 919.

In applying Daubert to the type of evidence relied on by the causation experts in the instant case, a number of courts in Parlodel cases from other jurisdictions have rejected the evidence other than epidemiological studies (case reports, ADRs, animal studies, temporal association between ingestion of Parlodel and adverse event, hypertensive properties of ergot alkaloids, FDA withdrawal of approval of Parlodel's indication for PPLS) as scientifically unreliable. Rider v. Sandoz Pharm. Corp., 295 F.3d 1194 (11th Cir. 2002) (postpartum stroke case); Glastetter v. Novartis Pharm. Corp., 252 F.3d 986 (8th Cir. 2001) (postpartum stroke case); Dunn v. Sandoz Pharm. Corp., 275 F. Supp. 2d 672 (M.D.N.C. 2003) (postpartum stroke case); Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434 (W.D. Pa. 2003) (postpartum stroke case); Caraker v. Sandoz Pharm. Corp., 188 F. Supp. 2d 1026 (S.D. Ill. 2001) (postpartum stroke case); Hollander v. Sandoz Pharm. Corp., 95 F. Supp. 2d 1230 (W.D. Okla. 2000), affirmed and remanded on other grounds, 289 F.3d 1193 (10th Cir. 2002) (causation expert's testimony rejected in postpartum stroke case); Brumbaugh v. Sandoz Pharm. Corp., 77 F. Supp. 2d 1153 (D. Mont. 1999) (causation expert's testimony rejected in postpartum seizure case). However, we view those cases, as the court did in Globetti v. Sandoz Pharmaceuticals Corporation, 111 F. Supp. 2d 1174, 1180 (N.D. Ala. 2000) (expert testimony that Parlodel caused plaintiff's acute postpartum heart attack found to

be sufficiently reliable), as incorrectly requiring scientific certainty, which was not intended by Daubert.

> The court believes that in those cases the Daubert standard was applied incorrectly, creating too high a standard of admissibility. Both of these cases seem to equate Daubert's reliability with scientific certainty, which is far from what the Supreme Court intended in Daubert. Science, like many other human endeavors, draws conclusions from circumstantial evidence when other, better forms of evidence is not available. . . . [O]ne cannot practically conduct an epidemiological study of the association of Parlodel with postpartum AMI. Moreover, one cannot ethically experiment on human beings, exposing them to the near certainty of some number of deaths, simply to satisfy some evidentiary standard.

Id. at 1180. The Globetti court adjudged that much of the same type of evidence relied on by the causation experts in the instant case was scientifically reliable under Daubert.

> Although defendant is correct that there is no epidemiological study showing an increased risk of AMI [acute myocardial infarction] associated with bromocriptine, there is more than adequate evidence of a scientific nature from which a reliable conclusion can be drawn about the association. While an epidemiological study may be the best evidence, Daubert requires only that reliable evidence be presented, and that evidence here consists of animal studies, the medical literature reviews, the ADRs reported to the FDA, the "general acceptance" of the association reflected in several medical texts, the Larrazet experiment, and Dr. Waller's observations in the Ayers case. These all are recognized and accepted scientific methodologies, used for assessing the possible side-effects and hazards associated with particular drugs and the causes of disease. The fact that Mrs. Globetti's AMI was caused by her ingestion of Parlodel can be reliably inferred from the facts known about the vasoconstrictive effect of bromocriptine.

Id. at 1179; see also Kuhn v. Sandoz Pharm. Corp., 14 P.3d 1170 (Kan. 2000) (expert testimony that Parlodel caused woman's postpartum seizure, cerebral edema and death ruled admissible). Likewise, the court in Brasher v. Sandoz Pharmaceuticals Corporation, 160 F. Supp. 2d 1291,1296 (N.D. Ala. 2001) (even without epidemiological

study establishing causation and with other possible explanations for strokes, experts' opinions that Parlodel caused postpartum strokes found to be sufficiently reliable), ruled that this type of evidence was reliable and rejected a requirement of scientific certainty relative to causation evidence:

> Daubert does not require proof to a scientific certainty, or even proof convincing to the trial judge. The trial judge is not required to find that the proffered opinion is scientifically correct, but only that it is trustworthy because it is tied to good scientific grounds. What Daubert does require is that the expert's opinion be based on sound methodologies of the type used by experts in the field in which the opinion is offered. There can be little question that scientists routinely use animal studies, case reports, and pharmacological comparisons of similar classes of drugs to infer conclusions, which are expressed in peer-reviewed journals and textbooks. Unquestionably, epidemiological studies provide the best proof of the general association of a particular substance with particular effects, but it is not the only scientific basis on which those effects can be predicted. In science, as in life, where there is smoke, fire can be inferred, subject to debate and further testing.

We believe the scientific evidence on which the Gundersons' causation experts based their testimony was sufficiently reliable in the present case and that there was substantial evidence supporting the court's ruling of reliability in this case. While Dr. Petro admitted that epidemiological evidence is the gold standard for determining causation, the Gundersons' causation experts, including Dr. Petro, testified that they also relied on other scientific evidence to assess causation. Each of the disputed pieces of evidence considered by the Gundersons' experts (case reports, animal studies, and general chemical properties of ergot drugs) had scientific underpinnings, was derived from recognized scientific methodologies, and was shown to have general acceptance within the scientific community as a factor tending to show that Parlodel causes postpartum seizures.

As for the relevancy of the causation evidence at issue, relevance is determined by evaluating "whether [that] reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93, 113 S. Ct. at 2796. "The consideration of relevance has been described as one of 'fit.'" Thompson, 11 S.W.3d at 578 (quoting Daubert, 509 U.S. at 591, 113 S. Ct. at 2796, 125 L. Ed. 2d at 481-82). We deem the case reports, animal studies, and general chemical properties of ergot drugs to be relevant scientific evidence that would assist the jury in making the determination of general causation in this case – whether Parlodel was capable of causing a postpartum seizure. Both Dr. Kulig and Dr. Petro testified that they considered this type of evidence (among other evidence as shall be discussed below) because it tended to show how the ingestion of Parlodel would have affected a postpartum woman and that it was capable of causing a fatal seizure. Accordingly, the trial court did not abuse its discretion in its relevancy ruling.

SUFFICIENCY OF CAUSATION EVIDENCE

Dr. Armstrong argues that Appellants were entitled to a directed verdict because Appellees did not present sufficient reliable evidence that Parlodel caused Mary Gunderson's alleged seizure. In ruling on a directed verdict motion, the trial court should draw all inferences in favor of the nonmoving party, and a verdict should not be directed unless the evidence is insufficient to sustain the verdict. Kroger Co. v. Willgruber, 920 S.W.2d 61, 64 (Ky. 1996) (citing Spivey v. Sheeler, 514 S.W.2d 667, 673 (Ky. 1974)). Questions as to the weight and credibility to be given to the evidence are reserved for the jury. Commonwealth v. Benham, 816 S.W.2d 186, 187 (Ky. 1991).

Medical causation must be proved to a reasonable medical probability. Brown-Forman Corp. v. Upchurch, 127 S.W.3d 615, 621 (Ky. 2004); Turner v. Commonwealth,

5 S.W.3d 119, 122 (Ky. 1999). As to general causation, Dr. Kulig and Dr. Petro testifed that Parlodel causes late postpartum seizures, based on their review of case reports, ADRs, animal studies, the ERI study, toxicology knowledge about ergot drugs, clinical trial results and observations. Dr. Kulig testified that he also considered other factors - medical textbooks and publications, Sandoz's reports and causation analyses on Parlodel, FDA evaluations of Parlodel, his knowledge of pharmacokinetics, and his observations of and experience with patients taking Parlodel. We agree with the trial court's assessment that although the individual pieces of evidence may not conclusively prove general causation, together they tend to show that Parlodel can cause postpartum seizures in women taking the drug for PPLS. As the court stated in Brasher, 160 F. Supp. 2d at 1296, "Although it is true that none of these bits of evidence establish conclusively that Parlodel can cause vasoconstriction and vasospasm, taken together they present a compelling picture, one which can support a reasonable scientific inference." Additionally, as noted earlier, Dr. Kulig and Dr. Petro both testified that the ERI study actually supported their opinion because, contrary to Rothman's analysis of the data, they viewed the data as showing that women taking Parlodel for PPLS had a 2.86% greater risk of having a seizure than postpartum women not taking Parlodel. Even the internal Sandoz memos from 1982 acknowledged a connection between Parlodel and postpartum hypertension and seizures.

The next question is whether the Gundersons presented sufficient evidence of specific causation – that Mary Gunderson's death was actually caused by a seizure due to her ingestion of Parlodel. All of the Gundersons' causation experts employed a methodology called differential diagnosis in determining Mrs. Gunderson's cause of death to be a Parlodel-induced seizure. Differential diagnosis is a well-recognized and

widely-used technique in the medical community to identify and isolate causes of disease and death. Globetti, 111 F. Supp. 2d at 1177. "The differential diagnosis calls for the physician to list the known possible causes of a disease or condition, usually from most likely to least likely. Then, utilizing diagnostic tests, the physician attempts to eliminate causes from the list until he is left with the most likely cause." Id. Differential diagnosis has been accepted by many courts as a reliable method of ascertaining medical causation. Kennedy v. Collagen Corp., 161 F.3d 1226 (9th Cir. 1998); Glaser v. Thompson Med. Co., Inc., 32 F.3d 969 (6th Cir. 1994); Perkins v. Origin Medsystems, Inc., 299 F. Supp. 2d 45 (D. Conn. 2004). Even in Dr. Armstrong's appellate brief, he acknowledges that "differential diagnosis is an accepted methodology in choosing among known causes of a disease in an individual."

Dr. George Nichols, a physician, board-certified in forensic pathology with twenty years' experience as Chief of the Kentucky Medical Examiner's Office, looked at the following in reaching his conclusion that Mrs. Gunderson died as a result of a seizure caused by taking Parlodel: thorough examination of the body during the autopsy, including microscopic studies of the lung, heart, and brain tissues; the police report and photos of how the body was found; Mrs. Gunderson's medical history; medical records from her pregnancy; the toxicology report; dozens of depositions taken in the case; and reports by the family about Gunderson's behavior and condition the night of her death. Dr. Nichols also relied on much of the same evidence that Drs. Petro and Kulig did regarding general causation – the ERI study, 73 case reports of women taking Parlodel for PPLS having seizures, animal studies, and the vast amount of scientific literature on Parlodel. Dr. Nichols estimated that he had conducted more than 10,000 autopsies in

his career as a pathologist and stated that he had spent more time investigating the death of Mary Gunderson than any other case in his career.

Upon examination of Mrs. Gunderson's body, Dr. Nichols and Dr. McCloud, another pathologist from the Medical Examiner's Office who conducted the first examination of the body, could not find any anatomic cause of death. Dr. Nichols testified that from the autopsy, he was able to eliminate all possible causes of death (e.g., pulmonary embolism, stroke, heart attack) except some form of sudden death syndrome. The toxicology report revealed a normal therapeutic amount of acetaminophen in the body, which was consistent with the prescription for the pain medication Percocet (a combination of acetaminophen and oxycodone) that Mrs. Gunderson was given upon her release from the hospital. Dr. Nichols rejected an overdose of Percocet as a possible cause of death because she was not acting intoxicated prior to going to bed, the therapeutic levels of acetaminophen in her system, and the number of pills left in her prescription suggested she was taking the medication according to the prescription.

In reviewing the photos of Mrs. Gunderson's body and the way her arms were flexed up around her head and her hands were clenched, Dr. Nichols testified that it was apparent that her muscles had contracted for a long enough amount of time to develop rigor mortis. Dr. Nichols posited that only three things could account for such a position at death – electrocution, military combat, or a seizure. After eliminating electrocution and military combat as possible causes of death, Dr. Nichols concluded that Mrs. Gunderson died from a seizure. According to Dr. Nichols, the fact that Mrs. Gunderson had voided from her bladder was also consistent with a seizure.

Mrs. Gunderson's medical history indicated that she was generally healthy, although she smoked and was somewhat overweight. She had no history of seizures. Dr. Nichols rejected Sandoz's assertions that she had an enlarged heart at the time of death, explaining that Mrs. Gunderson's heart was at the upper limit of normal, which is normal for a postpartum woman and not significant. Dr. Jay Patrick Lavery testified that in his opinion, Mrs. Gunderson had gestational hypertension during her delivery in 1993 and immediately after the birth. However, Dr. Lavery opined that the gestational hypertension was not the cause of Mrs. Gunderson's death because her blood pressure was steadily improving after the delivery. The medical records from Mrs. Gunderson's pregnancy four years earlier indicated that she took Parlodel for PPLS and suffered no ill effects. However, Dr. Nichols testified that it is not uncommon for a patient to not have an adverse reaction to a drug the first time they take it, and then suffer an adverse or paradoxical reaction upon the second or subsequent administration of the drug. Dr. Nichols also testified that the evidence that Mrs. Gunderson had a severe headache prior to her death was indicative of an adverse reaction to Parlodel. Both Dr. Nichols and Dr. Petro noted that in many of the case reports for women taking Parlodel for PPLS who suffered a stroke or seizure, the women reported a severe "crescendo" headache prior to the adverse event. Dr. Nichols and Dr. Petro further stated that the pain that Mrs. Gunderson was experiencing between her shoulder blades on the day she died was consistent with an adverse brain event.

The Gundersons also presented the testimony of Dr. Michael Balco, a forensic neuropathologist, who viewed the slides of Mary Gunderson's autopsy. Dr. Balco testified that the slides of Mary Gunderson's brain showed evidence of damage to her brain consistent with a seizure.

Dr. Petro and Dr. Kulig relied on much of the same facts and information as Dr. Nichols in forming their opinions that Mrs. Gunderson died from a seizure caused by taking Parlodel. Dr. Petro agreed that the symmetric, flexed, gravity-defying position of Mrs. Gunderson's arms was proof that she died of a seizure. Dr. Petro also noted that seizures are more common at night.

The Gundersons' causation experts all agreed that the fact the Mrs. Gunderson's death occurred seven days after the birth was a significant factor in attributing the seizure to Parlodel because the data from the ERI study and the case reports revealed that the postpartum seizures suffered after the ingestion of Parlodel for PPLS were more likely to occur late in the postpartum period – more than 72 hours after delivery. Dr. Kulig and Dr. Petro acknowledged the studies showing that the postpartum period itself is associated with seizures, strokes and heart attacks. However, they opined that the seizure suffered by Mrs. Gunderson was Parlodel-induced because postpartum seizures attributable to the postpartum status alone rarely occur late in the postpartum period and are much more likely to occur soon after delivery.

In reviewing the record, we believe there was sufficient reliable and relevant evidence that Mrs. Gunderson died as a result of a Parlodel-induced seizure to submit the issue before the jury in this case. Hence, the trial court properly denied Appellants' motions for directed verdict.

LIMITATION OF CROSS-EXAMINATION OF EXPERTS

Appellants argue they were denied due process when the trial court unfairly limited their cross-examination of Appellees' causation experts. Appellants sought to cross-examine the experts with certain scientific studies showing no association between Parlodel and adverse health effects. The trial court adjudged that the

witnesses could not be cross-examined as to those studies unless the Appellants established their reliability or the witness agreed the studies were reliable. Appellants thereafter failed to put the desired cross-examination on the studies in the record by avowal. Hence, the issue is not subject to our review. Noel v. Commonwealth, 76 S.W.3d 923 (Ky. 2002); KRE 103(a)(2).

FAILURE TO GIVE LEARNED INTERMEDIARY INSTRUCTION

On the products liability claim, Sandoz tendered the following instruction with its proposed jury instructions:

> Sandoz has no duty to provide warnings directly to Mrs. Gunderson, but only to Dr. Armstrong. Therefore, in order for plaintiffs to prevail, you must be satisfied from the evidence that Sandoz provided an inadequate warning to Dr. Armstrong regarding the risk of seizure purportedly associated with Parlodel. Otherwise, you will find for Sandoz.

The trial court declined to give the above instruction to the jury. The court instructed the jury as follows relative to Sandoz's duty to Mrs. Gunderson as a consumer of Parlodel:

> 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. . . .

Approximately three months after the trial in the case at bar, this Court rendered its decision in Larkin v. Pfizer, Inc., 153 S.W.3d 758, 762 (Ky. 2004), wherein we adopted the learned intermediary doctrine from the Restatement (Third) of Torts: Prods.

Liab. § 6(d)(1) (1998). This doctrine, which is an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer, relieves the prescription drug manufacturer from liability to the ultimate consumer if it provides an adequate warning about the drug to the prescribing physician. Id. at 764. As to what constitutes an adequate warning, the Larkin Court stated:

> An adequate warning has been defined as one 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.

Id. at 764-65 (citations and internal quotations omitted).

Sandoz argues that the information in the package insert for Parlodel and in the Physician's Desk Reference, as well as "Dear Doctor" letters it sent directly to doctors, constituted an adequate warning to Dr. Armstrong of the dangers of Parlodel, thus entitling it to the tendered jury instruction on the learned intermediary doctrine. In affirming the trial court's refusal to give the learned intermediary rule instruction, the Court of Appeals ruled that a specific instruction on the doctrine's application in the case was not required under Ford Motor Company v. Fulkerson, 812 S.W.2d 119, 123 (Ky. 1991) (rejecting a fact-specific instruction in products liability case in favor of general instruction stating liability in terms of Restatement (Second) of Torts § 402A). In our view, whether an instruction on the learned intermediary doctrine was required in the present case was not a question of whether a general or fact-specific instruction was warranted, as in Fulkerson. Rather, it was an issue of adequately and accurately instructing the jury on the law of the case. See Shewmaker v. Richeson, 344 S.W.2d

802, 806 (Ky. 1961). If the evidence supported application of the learned intermediary doctrine in the instant case, it was error for the trial court to not submit a learned intermediary instruction because the instructions, as given, did not give the jury an opportunity to find whether Sandoz provided an adequate warning to Dr. Armstrong of the risks associated with Parlodel, which would have precluded a judgment against Sandoz under the law.

The package insert for Parlodel and the Physician's Desk Reference (PDR) information on Parlodel at the time of Mrs. Gunderson's prescription 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 during therapy with Parlodel . . . were also preceded by visual disturbances (blurred vision and transient cortical 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.

The above warning was approved by the FDA in 1987. In conjunction with the new warning, the FDA required Sandoz to send a "Dear Doctor" letter to obstetricians

noting the changes in the package insert and specifically calling attention to the adverse reactions. At trial, the Gundersons presented evidence that Sandoz failed 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 the FDA's 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 reconsider Parlodel's indication for use as a lactation suppressant at a 1988 FDA advisory committee meeting. Upon reviewing the available data on Parlodel's use for PPLS during that meeting, including the results of the ERI study and ADRs, the advisory committee recommended that Parlodel's indication for PPLS should be withdrawn. The committee concluded that risks of potentially serious side effects from Parlodel use outweighed the relatively minor discomfort of postpartum lactation. The committee recommended that the condition be treated conservatively as it had traditionally been, with breast binding and analgesics. The FDA adopted the committee's recommendation in 1989 and asked manufacturers of bromocriptine to voluntarily withdraw their drug's lactation suppression indications. With the exception of Sandoz, all manufacturers complied with the FDA's request. Sandoz, however, continued to market Parlodel for PPLS. In fact, in the second "Dear Doctor" letter sent by Sandoz dated May 3, 1990, Sandoz wrote:

> The results of the epidemiologic study, conducted by Epidemiology Resources, Incorporated, were presented [to the FDA Fertility and Maternal Health Advisory Committee] showing no causal relationship between reported seizures and the use of Parlodel.
>
> . . .
>
> Subsequently, the FDA requested Sandoz to voluntarily withdraw this [PPLS] indication for Parlodel. Sandoz considers this request 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.

Prior to the above-mentioned change in the package insert, Sandoz had placed an ad for Parlodel in the March 1984 issue of Obstetrics and Gynecology (commonly referred to in the obstetric community as "the green journal") claiming that Parlodel had a "low order side effects, " was "natural," and left patients "completely free" of engorgement. The Gundersons offered into evidence a letter to Sandoz from the FDA maintaining that said ad was misleading as to those three claims, and further that the ad failed to inform doctors of the high rate of rebound with Parlodel therapy. There was also evidence that Sandoz instructed its sales force not to mention the risks or the FDA's concerns about Parlodel unless questioned by the doctor. Instead, the sales representatives were to continue to encourage doctors to include Parlodel on standing orders as a routine therapy for PPLS. Further, the Gundersons presented evidence that before Mrs. Gunderson's death in 1993, Sandoz knew of additional adverse reactions to Parlodel and misrepresented them or failed to report them to the FDA as required by law. In particular, there was evidence that prior to 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 made no effort to provide doctors with these

updated figures after the 1987 package insert. It was not until 1994, after the FDA had initiated procedures to withdraw its approval for the PPLS indication for Parlodel, that Sandoz voluntarily withdrew that indication.

In his deposition read at trial,[2] Dr. Armstrong admitted that he had not read the 1987 updated package insert for Parlodel. Dr. Armstrong testified that he did not receive either "Dear Doctor" letter sent by Sandoz regarding Parlodel, and that if he had, he would not have prescribed Parlodel for Mrs. Gunderson.

From our review of the record, we conclude that Sandoz failed to present sufficient evidence of an adequate warning to Dr. Armstrong of the risks of Parlodel, thus it was not error for the trial court to fail to give the jury instruction on the learned intermediary doctrine. While the package insert and PDR entry for Parlodel contained warnings of the risks of seizure and hypertension for postpartum patients, other evidence undermined the effectiveness of these warnings

The evidence that Sandoz did not send the "Dear Doctor" letters to Dr. Armstrong, the language in the second letter maintaining that Parlodel was a reasonable and effective treatment for PPLS, the evidence that Sandoz misrepresented or failed to report known additional ADRs (for seizures, strokes and hypertension), the misleading ad in the journal of Obstetrics and Gynecology, and Sandoz's instructions to its sales representatives to encourage the continued use of standing orders for Parlodel for PPLS and not to mention the risks of the drug, was strong evidence of its efforts to minimize or conceal the risks of Parlodel (much of which was undisputed). This evidence showed that Sandoz repeatedly attempted to downplay or conceal the risks of Parlodel and intentionally undermined any existing warnings. This systematic approach

[2] Dr. Armstrong's deposition was taken in July of 1996, some six months before his death.

to minimizing the risk posed by Parlodel rendered the various warnings that were available inadequate under the learned-intermediary doctrine. Thus, we conclude that the trial court did not err in failing to instruct the jury as to the learned-intermediary defense.

FAILURE TO GIVE AN "UNAVOIDABLY UNSAFE" INSTRUCTION

Dr. Armstrong argues that the trial court erred in failing to instruct the jury that the inherent risk of prescription drugs such as Parlodel makes them "unavoidably unsafe" but not unreasonably dangerous pursuant to Restatement (Second) of Torts § 402A cmt. k. In viewing Dr. Armstrong's brief before the Court of Appeals, we note that Dr. Armstrong failed to argue this issue before the Court of Appeals. Hence, the argument is precluded from our review. Marksberry v. Chandler, 126 S.W.3d 747, 753-54 (Ky.App. 2003).

FAILURE TO DIRECT A VERDICT ON MEDICAL MALPRACTICE CLAIM

Dr. Armstrong argues that he was entitled to a directed verdict because the Gundersons failed to show that his treatment of Mary Gunderson violated the applicable standard of care. It is Dr. Armstrong's position that there was insufficient evidence that he violated the standard of care owed to Mrs. Gunderson because the evidence established that: Parlodel was approved by the FDA for PPLS in 1993; the prescription for Parlodel for Mrs. Gunderson was not in violation of the contraindications in the package insert; Parlodel's use for PPLS was per a standing order of Suburban Hospital in 1993; Dr. Armstrong's partner had prescribed Parlodel to Mrs. Gunderson for PPLS after her previous pregnancy in 1989 with no adverse reaction; and Dr. Armstrong had prescribed Parlodel for PPLS for years in his practice with no adverse results. Citing Prewitt v. Higgins, 231 Ky. 678, 22 S.W.2d 115, 117 (1929), Dr. Armstrong asserts that,

even assuming that the decedent died as a result of a Parlodel-induced seizure, it does not necessarily follow that he was negligent in prescribing the drug because "[i]njury may result from the use of the drug even when the doctor has proceeded with the utmost care and skill."

We agree that "[i]t is necessary . . . in order to make out a case [for medical negligence], that something more be shown than mere injury by the drug." Id. In a medical malpractice case, 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 the injury or death. Reams v. Stutler, 642 S.W.2d 586 (Ky. 1982). A physician has the duty to use the degree of care and skill expected of a competent practitioner of the same class and under similar circumstances. Grubbs ex rel. Grubbs v. Barbourville Family Health Ctr., P.S.C., 120 S.W.3d 682 (Ky. 2003); Mitchell v. Hadl, 816 S.W.2d 183, 185 (Ky. 1991); Cordle v. Merck & Co., Inc., 405 F. Supp. 2d 800 (E.D. Ky. 2005).

Appellees presented the testimony of Dr. Jay Patrick Lavery, a board-certified obstetrician/gynecologist who practiced in Louisville from 1975-1987. During that time, he had a private practice in Louisville and, from 1980-1987, was Director of Obstetrics at University Hospital. From 1987 to the present, he has operated an obstetrics practice in Michigan specializing in high risk pregnancies. Dr. Lavery stated that in his opinion, it was not a breach of the applicable standard of care in 1989 to prescribe Mrs. Gunderson Parlodel for PPLS after the birth of her first child. In Dr. Lavery's opinion it was, however, a deviation of the standard of care for Dr. Armstrong to prescribe Mrs. Gunderson Parlodel for PPLS in 1993. Dr. Lavery explained that by 1993, there was information available in the medical literature indicating that Parlodel had adverse

vascular properties and was ineffective for PPLS because of its rebound propensity. Dr. Lavery specifically noted two articles, one in the "green journal" and one in the American Journal of Obstetrics and Gynecology, questioning the safety of Parlodel's use for PPLS because of an association between Parlodel and postpartum hypertension, strokes, seizures, and heart attacks. Dr. Lavery testified that given Mrs. Gunderson's gestational hypertension in 1993, he would not have prescribed Parlodel for PPLS because of the high risk of an adverse vascular event and low potential benefit of the drug. Dr. Lavery testified that he ceased prescribing Parlodel for PPLS in 1984 or 1985, when he was still practicing in Louisville, and since that time, he has successfully treated postpartum breast pain and engorgement with traditional therapies such as breast binding and analgesics.

When confronted on cross-examination with the fact that prescribing Parlodel to Mrs. Gunderson in 1993 was not contraindicated by the information in the FDA-approved package insert, Dr. Lavery testified that it was nevertheless a breach of the standard of care to prescribe the drug to Mrs. Gunderson at that time. Dr. Lavery testified that even though a drug is approved by the FDA for a certain use and may not be contraindicated by the package insert, a reasonably prudent doctor still has to weigh the risks and benefits of the drug relative to a particular patient. This testimony is consistent with the majority view that while the information about the drug in the package insert and the PDR is relevant and useful information regarding the prescribing physician's standard of care, it is not the sole determinant of the standard of care. Richardson v. Miller, 44 S.W.3d 1, 16-17 (Tenn. Ct. App. 2000); Spensieri v. Lasky, 723 N.E.2d 544, 548 (N.Y. 1999); Morlino v. Med. Ctr. of Ocean County, 706 A.2d 721, 728-

30 (N.J. 1998); Craft v. Peebles, 893 P.2d 138, 150-52 (Haw. 1995).[3] The information in the package insert and PDR can only be analyzed in the context of the medical condition of the individual patient. Spensieri, 723 N.E.2d at 548; Morlino, 706 A.2d at 730.

> As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Larkin, 153 S.W.3d at 763 (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974)).

Relative to the claim that Dr. Armstrong could not have violated the standard of care when he prescribed Parlodel to Mrs. Gunderson in 1993 because she had taken the drug with her first pregnancy in 1989 with no adverse reaction, Dr. Nichols testified that it is not uncommon for a patient to not have an adverse reaction to a drug the first time they take it, and then suffer an adverse or paradoxical reaction upon the second or subsequent administration of the drug. Moreover, as emphasized by Dr. Lavery, Mrs. Gunderson did not have gestational hypertension with her first pregnancy. Thus, the vascular risks of the drug were more significant for Mrs. Gunderson in 1993.

As stated earlier, Dr. Armstrong admitted in his deposition that he had not read the 1987 updated package insert for Parlodel. Although he maintained that he regularly read the green journal and the PDR addendums, Dr. Armstrong denied having knowledge of the potential vascular risks of Parlodel and testified that the only side

[3] But see the minority view that the FDA-approved information in the drug's label and the PDR are prima facie evidence of the standard of care for prescribing the drug. Haught v. Maceluch, 681 F.2d 291, 303 (5th Cir. 1982); Ohligschlager v. Proctor Cmty. Hosp., 303 N.E.2d 392, 396 (Ill. 1973); Mulder v. Parke Davis & Co., 181 N.W.2d 882, 887 (Minn. 1970); Mueller v. Mueller, 221 N.W.2d 39, 42-43 (S.D. 1974).

effects he was aware of were headaches and nausea. Dr. Armstrong testified that had he known about the information in the "Dear Doctor" letters sent by Sandoz, he would not have prescribed Parlodel for Mrs. Gunderson in 1993. Incorporated in a physician's duty of reasonable care to his patient is the duty of requisite knowledge. Jones v. Furnell, 406 S.W.2d 154, 156 (Ky. 1966), overruled on other grounds, 459 S.W.2d 166 (Ky. 1970). Drawing all reasonable inferences in favor of Appellees, we believe the Appellees presented sufficient evidence that Dr. Armstrong breached his standard of care, by failing to have knowledge of the vascular risks of Parlodel in 1993 and prescribing the drug to Mrs. Gunderson for PPLS, to withstand the motion for directed verdict. See Thomas v. Greenview Hosp., Inc., 127 S.W.3d 663, 673 (Ky.App. 2004), overruled on other grounds, 171 S.W.3d 14 (Ky. 2005). Dr. Lavery's expert testimony was evidence that the standard of care for an obstetrician in Louisville in 1993 was such that a reasonably prudent doctor would have known not to prescribe Parlodel to a woman with gestational hypertension. Accordingly, Dr. Armstrong's motion for directed verdict was properly denied.

MITIGATION EVIDENCE ON LOSS OF PARENTAL CONSORTIUM CLAIM

At trial, Sandoz and Dr. Armstrong attempted to present evidence of Wesley and Nicholas Gunderson's close relationship with Janice Hays, Ronald Gunderson's girlfriend of the last four years, for the purpose of mitigating damages on their loss of parental consortium claim. They offered avowal testimony that Ms. Hays often stayed overnight at the Gunderson residence, fixed the children breakfast, packed their lunch, helped with their schooling and generally helped care for them when Ronald was working. The Appellants also sought to admit a letter in which Nicholas spoke favorably about Ms. Hays. Sandoz and Dr. Armstrong argued that Ms. Hays' relationship with

Wesley and Nicholas was relevant to their loss of parental consortium claim because she provided consortium-giving benefits to the boys which mitigated the loss of consortium with their mother. The Gundersons objected to the admission of such evidence, arguing that the boys' relationship with Ms. Hays could never replace the loss of their mother.

The trial court recognized that, while the evidence of the relationship with Hays was arguably relevant to the loss of parental consortium claim, it was not admissible as to Mr. Gunderson's wrongful death claim pursuant to Adams v. Davis, 578 S.W.2d 899, 902 (Ky.App. 1979) (holding that evidence of surviving spouse's remarriage is inadmissible in wrongful death action). Reasoning that an admonition limiting the evidence to the parental consortium claim would not be effective, the trial court refused to allow specific evidence of the relationship with Ms. Hays to be admitted. The court did allow, however, general hypothetical questions about how any potential subsequent relationships of Mr. Gunderson's might affect the boys. The Court of Appeals held that evidence of other consortium-giving relationships can be relevant to a child's lost consortium claim if the relationship is sufficiently close and intimate to compare to a parental relationship. The court then concluded that Mr. Gunderson's relationship with Ms. Hays was not of sufficient duration and stability to be admissible in the instant case. The court noted that Mr. Gunderson had only known Ms. Hays for four years and that Ms. Hays did not reside at the Gunderson household exclusively.

This issue of whether evidence of other consortium-giving relationships is relevant in a loss of parental consortium claim is one of first impression in Kentucky. This Court first recognized a minor child's independent claim for loss of parental consortium in Kentucky in Giuliani v. Guiler, 951 S.W.2d 318 (Ky. 1997). The Giuliani

decision, however, provided little guidance as to how such claim was to be proved and the type of evidence that was considered relevant to the claim:

> The proof of such loss and the necessary proof of monetary loss resulting therefrom are factors to be considered by the trier of fact separate from any wrongful death statute.

Id. at 323. Appellants urge this Court to allow the consideration of whether other consortium-giving relationships are available to the child as one factor in determining the amount of damages for loss of parental consortium, as some other jurisdictions have allowed. See Reagan v. Vaughn, 804 S.W.2d 463, 467 (Tex. 1990); Belcher v. Goins, 400 S.E.2d 830, 842 (W.Va. 1990); Villareal v. Ariz. Dep't. of Transp., 774 P.2d 213, 220-21 (Ariz. 1980). Appellants also point to Miller ex. rel. Monticello Baking Co. v. Marymount Medical Center, 125 S.W.3d 274, 285 (Ky. 2004), wherein this Court stated that evidence of a spouse's live-in relationship with his girlfriend was relevant to his claim for loss of spousal consortium.

While this Court does not seek to minimize the loss of a spouse's consortium, it cannot be denied that a child's loss of a parental consortium is different than an adult's loss of spousal consortium. The Giuliani Court recognized the necessity for protection by the law of a child's unique right "to a parent's love, care and protection so as to provide for the complete development of that child." 951 S.W.2d at 320. As acknowledged in Giuliani, "[t]he loss suffered by each child in this case is separate and distinct . . . from the loss suffered by their father[,]" and "in any disruption of the parent-child relationship, it is probably the child who suffers most." Id. at 320-21. "Furthermore, while an adult is capable of seeking out new relationships in an attempt to fill in the void of his or her loss, a child may be virtually helpless in seeking out a new adult companion." Smith v. Vilvarajah, 57 S.W.3d 839, 843 (Ky.App. 2000) (citing

Theama v. City of Kenosha, 344 N.W.2d 513, 516 (Wis. 1984)). Accordingly, the fact that evidence of the spouse's new relationship may be relevant in a loss of spousal consortium case does not persuade this Court that the evidence of the parent's new relationship should be admissible in the child's loss of parental consortium action.

The basis of this Court's ruling in Giuliani was that "[t]he claim of loss of parental consortium is a reciprocal of the claim of the parents for loss of a child's consortium which was recognized in KRS 411.135." Id. at 321. We agree with the views expressed in Simmons v. University of Chicago Hospitals and Clinics, 642 N.E.2d 107, 114 (Ill. 1994), wherein the court held that evidence that parents subsequently had two more children was irrelevant in parents' loss of child's consortium claim:

> [T]he relationship between parent and child is different from that of husband and wife. The parent-child relationship is not replaceable and is not limited to the society of only one child. Every child is unique, and the loss of society a parent suffers upon a child's death cannot be replaced with the society of a child subsequently born.

And so it is with a child's loss of a parent, who likewise cannot be replaced. Accordingly, the trial court properly excluded the evidence of Janice Hays' relationship with Nicholas and Wesley Gunderson.

TESTIMONY OF DR. BOWER

The Gundersons sought to present the expert testimony of Dr. Barbara Bower to testify as to how the loss of their mother affected Nicholas and Wesley relative to their loss of parental consortium claim. Dr. Bower established that she has a doctorate in counseling psychology and is a certified/licensed mental health counselor in Indiana, Ohio, and Kentucky. Dr. Bower testified that she had taught at two universities, had twenty years of experience as a private children's counselor and fifteen years as a school guidance counselor. The Gundersons asked Dr. Bower to perform a

psychological assessment of Nicholas and Wesley for purposes of this lawsuit. She met with the boys eight times during 2000 and 2001 and attempted, through observation, conversations, drawings, and writing assignments, to elicit their feelings about themselves and the loss of their mother. Dr. Bower did not use any standard psychological tests to evaluate the boys and did not attempt to diagnose or treat the boys.

It was Dr. Bower's opinion that both boys had been deeply affected by the loss of their mother. Relative to Nicholas, Dr. Bower testified that he expressed a sense of abandonment and sadness, which she attributed to the fact that he was four years old and had already bonded with his mother when she was abruptly taken away from him. Dr. Bower explained that losing a mother at age four affects a child's sense of appropriate behavior and their overall trust in the world. As to Wesley, Dr. Bower testified that he had attachment and trust issues stemming from the fact that he was never able to know or bond with his mother, and that his family was thrown into chaos after her death. She stated that both boys would be at an increased risk for developmental problems, risk-taking behavior, and depression as a result of losing their mother at such a young age. Dr. Bower displayed to the jury pictures drawn by the boys and, with some pictures, described the significance of the pictures relative to the loss of their mother. She also read letters that she had asked the boys to write to their mother.

Prior to trial, Appellants filed a motion in limine to exclude the testimony of Dr. Bower on grounds that it was too subjective, speculative, and inflammatory, and the subject matter was not outside the common knowledge of the jurors. Appellants

maintained that Dr. Bower's testimony was not in keeping with Daubert because it was not based on good science or methodology such as an objective testing method.

We view Dr. Bower's testimony as properly within the scope of KRE 702 in this case. Dr. Bower had specialized knowledge in child psychology by virtue of her experience and education to assist the jury in understanding how the Gunderson children were affected by their mother's death and the extent of the emotional injury from that loss, which was clearly relevant in assessing damages on the loss of parental consortium claim. KRE 402. Although laypersons are generally aware that children are negatively affected by the loss of a parent, Dr. Bower was able, through her observations of and conservations with the boys, to specifically describe and explain certain emotional issues Nicholas and Wesley were contending with as a result of losing their mother at such a young age. And while it is true that Nicholas and Wesley testified at trial, the boys were only fifteen and eleven years old, respectively, at the time, and Dr. Bower had specialized knowledge and skills in getting children to express emotions they may not have otherwise been able to articulate at such a young age.

As to Appellants' claim that her testimony was too subjective and speculative, we note that Dr. Bower was not making a definitive scientific diagnosis of the boys. See Jenson v. Eveleth Taconite Co., 130 F.3d 1287, 1297-99 (8th Cir. 1997). Rather, she was assessing the emotional impact of the death of their mother. When asked why she did not administer any objective psychological tests on the boys, Dr. Bower explained that she felt that may have impeded their trust in her and hindered their willingness to open up to her about their mother. Given Dr. Bower's extensive education and experience in counseling children, and the limited purpose of her testimony, we adjudge that it was sufficiently reliable under Daubert to be offered relative to the loss of parental

consortium claim. See Rogers v. Detroit Edison Co., 328 F. Supp. 2d 687, 690-92 (E.D. Mich. 2004) (psychologist's testimony about psychological problems caused by appellant's accident deemed reliable given psychologist's education and professional experience and the fact that the opinion was based on multiple therapy sessions with appellant.) Accordingly, the trial court did not abuse its discretion in allowing it to be admitted.

Appellants' argument as to the pictures drawn by Nicholas and Wesley and Dr. Bower's testimony about the pictures was not properly preserved. KRE 103. Nowhere in the record do we see that Appellants raise the issue of "art therapy" before the trial court. See Payne v. Hall, 423 S.W.2d 530 (Ky. 1968). The argument was not part of Appellants' motion in limine regarding Dr. Bower's testimony, and the only objection made when the pictures were displayed at trial was Dr. Armstrong's objection that he was not permitted to introduce a picture drawn about Ms. Hays.

EVIDENCE OF DR. ARMSTRONG'S CROSS-CLAIM

In September 1998, Dr. Armstrong's estate filed a cross-claim against Sandoz alleging fraudulent misrepresentation and gross negligence in Sandoz's marketing of Parlodel and seeking damages for injury to Dr. Armstrong's reputation as well as indemnification in the event Dr. Armstrong was found liable for Mrs. Gunderson's death. The cross-claim specifically alleged that Sandoz engaged in a deliberate marketing effort to misrepresent to prescribing doctors that Parlodel was safe and effective for PPLS when, in fact, it was not, and that had Sandoz fully disclosed the risks of the drug, Dr. Armstrong would not have prescribed it to Mrs. Gunderson. Prior to trial, Sandoz entered into an indemnification agreement with Dr. Armstrong whereby his claims were settled and Sandoz took over defense of the claims against Dr. Armstrong. Accordingly,

the cross-claim was dismissed, and at trial, Dr. Armstrong offered no evidence against Sandoz. In response to Sandoz's motion in limine to exclude evidence of the cross-claim, the trial court ruled that the Gundersons could introduce the cross-claim as evidence of the Defendants' non-adverse relationship with each other pursuant to KRE 408 and as relevant to the credibility of Dr. Armstrong's evidence. The Gundersons quoted and discussed the cross-claim during their opening and closing statements. The cross-claim was also mentioned during voir dire (by Sandoz, apparently preemptively, after the motion in limine had already been denied) and introduced into evidence by the Gundersons.

The Gundersons claimed at trial that the purpose of introducing the cross-claim was to show that prior to the settlement agreement, Dr. Armstrong claimed that Sandoz had failed to adequately inform him of the risks of Parlodel and deceptively marketed the drug. After the settlement agreement, Dr. Armstrong decided not to introduce any evidence critical of Sandoz's warnings about Parlodel or its marketing of Parlodel. The Gundersons argued that they were entitled to present the cross-claim pursuant to KRE 408 to expose to the jury how Dr. Armstrong's position changed after the settlement agreement and the collusive nature of their relationship at trial, i.e., bias. Sandoz argues that the cross-claim was blatant inadmissible hearsay introduced as substantive evidence against Sandoz. KRE 801. The Gundersons assert on appeal that the cross-claim was non-hearsay as an admission of a party-opponent (KRE 801A(b)) because in the cross-claim, Dr. Armstrong averred that Parlodel was unsafe and caused Mrs. Gunderson's death, which directly contradicted Dr. Armstrong's position at trial that Parlodel was safe and did not cause postpartum hypertension or seizures.

The Court of Appeals ruled that, although the cross-claim may not have been admissible under KRE 801A, the trial court did not abuse its discretion in admitting the cross-claim under KRE 408 as evidence of the Defendants' potential motive to downplay each other's wrongdoing at trial. The Court of Appeals went on to state that even if it was an abuse of discretion to admit the cross-claim, it was harmless error in this case.

Under KRE 408, evidence of a settlement agreement is not admissible to prove liability or invalidity of the claim, but is admissible to show the potential bias of parties who were previously adversaries in the litigation and who may now be motivated to downplay each other's fault. Miller ex. rel. Monticello Baking Co., 125 S.W.3d 274. Neither Defendant in the instant case questioned the admissibility of the settlement agreement. Sandoz simply argues that the cross-claim is wholly independent of the settlement agreement and, thus, does not fall within the ambit of KRE 408. The Gundersons maintain that the admission of the cross-claim was necessary to give meaning to the settlement agreement. While this argument may be tenable in theory, the cross-claim in this case was clearly used by the Gundersons to try to prove Sandoz's liability, as we shall explain below, which is not permitted by KRE 408.

KRE 801A(b)1 allows the introduction as non-hearsay of an adverse party's admissions, including admissions contained in superceded or abandoned pleadings, but only against the declaring party. See Dalton v. Mullins, 293 S.W.2d 470 (Ky. 1956) (pre-Rules holding that Appellant's abandoned pleading was admissible as competent evidence against Appellant). As this Court made clear in Fisher v. Duckworth, 738 S.W.2d 810, 813 (Ky. 1987) (quoting Lawson, The Kentucky Evidence Law Handbook § 8.10 (2d ed. 1984)), "Admissions are not admissible against a declarant's coparty." See

also James v. Wilson, 95 S.W.3d 875, 898 (Ky.App. 2002). The Gundersons contend on appeal that the cross-claim was admissible pursuant KRE 801A(b) because it was used against Dr. Armstrong to contradict his position at trial that Parlodel was safe and could not have caused Mrs. Gunderson's fatal seizure. However, a review of the record belies this contention. In arguing the admissibility of the cross-claim at trial, the Gundersons' counsel stated, "this cross-claim only goes against the conduct of Sandoz" and "would tend to . . . exculpate Dr. Armstrong." He further stated, "this cross-claim is very prejudicial against, as far as the evidence, against Sandoz, not against Dr. Armstrong." In fact, all of the references to the cross-claim during the Gundersons' opening and closing statements were made in the context of arguing the liability of Sandoz (Dr. Armstrong's co-party), which is not permitted by either KRE 408 or KRE 801A(b). The Gundersons primarily quoted and displayed pleadings alleging Sandoz's deliberate marketing scheme misrepresenting the safety of Parlodel and its failure to warn Dr. Armstrong of the dangers of the drug. The Gundersons did not qualify these references with any statement to the effect that these pleadings tended to show the bias of Dr. Armstrong's estate or how its position changed at trial after the settlement agreement had been executed. Accordingly, it was error to allow the cross-claim to be admitted for the purpose of proving Sandoz's liability.

We must now determine if the error was reversible. KRE 103(a). It must be noted that Sandoz never asked for an admonition limiting the scope of the cross-claim to show only the bias of Dr. Armstrong, pursuant to KRE 105(a), which provides:

> When evidence which is admissible for one (1) purpose . . . but not admissible . . . for another purpose is admitted, the court, upon request, shall restrict the evidence to its proper scope and admonish the jury accordingly. In the absence of such a request, the admission of the evidence by the trial

> judge without limitation shall not be a ground for complaint on appeal, except under the palpable error rule.

As the Court of Appeals recognized in its analysis of whether the error was harmless:

> The cross-claim was merely one exhibit out of 172; it was introduced not through a witness but simply through a housekeeping 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.

We would add that the evidence that was cumulative of the cross-claim was voluminous and quite damning. In addition to evidence that we have discussed previously (Sandoz's failure to send the "Dear Doctor" letters, the language in the second letter maintaining that Parlodel was a reasonable and effective treatment for PPLS, the evidence that Sandoz misrepresented or failed to report known additional ADRs, the misleading ad in the journal of Obstetrics and Gynecology, the attempt to manipulate and downplay the risks of seizure in the ERI report, and Sandoz's instructions to their sales representatives to encourage the continued use of Parlodel for PPLS and not to mention the risks of the drug), there was considerable evidence of Sandoz's sales strategy to push Parlodel for PPLS and that Sandoz referred to Parlodel as their "cash cow", despite the known problems with, and the FDA's position on, the drug. Dr. Armstrong's deposition testimony was also cumulative in that he testified that he had not received any information about the risks of Parlodel for PPLS from Sandoz, and that if he had, he would not have prescribed the drug to Mrs. Gunderson. While we recognize the bolstering nature of the allegations in the cross-claim in coming from a co-

defendant in the case, in light of the vast amount of persuasive evidence that was cumulative of the allegations therein, we cannot say the error was palpable, i.e., no manifest injustice resulted. KRE 103(e); CR 61.02.

PUNITIVE DAMAGES

In 2003, the United States Supreme Court rendered its decision in State Farm Mutual Automobile Insurance Company v. Campbell, 538 U.S. 408, 422-23, 123 S. Ct. 1513, 155 L. Ed. 2d 585 (2003), wherein it held that under the due process clause, out-of-state conduct of a defendant regarding a non-party cannot be used to award punitive damages. While the Court allowed consideration of out-of-state conduct in assessing the reprehensibility of the defendant's conduct, the Court stated that the out-of-state conduct "must have a nexus to the specific harm suffered by the plaintiff." Id. at 422.

At trial in the instant case, Sandoz tendered a punitive damage instruction pursuant to Campbell which provided that the jury could "not use punitive damages to punish Sandoz for any conduct outside the state of Kentucky." The trial court declined to submit the tendered instruction and instead submitted the standard punitive damage instruction in Kentucky at the time.

Some six months after the trial in this case, this Court rendered its decision in Sand Hill Energy, Inc., v. Smith, 142 S.W.3d 153 (Ky. 2004), which had been remanded by the United States Supreme Court for reconsideration in light of Campbell. In Sand Hill, the jury heard abundant evidence regarding the out-of-state conduct of Ford Motor Company in manufacturing and selling vehicles with the defect in question. Id. at 157. Following the dictates of Campbell, we vacated the punitive damages award and remanded for a new determination of punitive damages using a jury instruction with a limitation regarding extraterritorial punishment. Id. at 166.

On appeal, Sandoz argued that the trial court erred in failing to submit its tendered punitive damage instruction. Citing Sand Hill, the Court of Appeals agreed that given all of the evidence of the extraterritorial conduct of Sandoz, Sandoz was entitled to an instruction limiting punitive damages to its conduct in Kentucky. The Court of Appeals thus vacated the punitive damages award and remanded "for a new determination of the amount of punitive damages."

Sandoz argues before us that the remand by the Court of Appeals for a new determination only on the amount of punitive damages violated Sandoz's right to a fair trial because it improperly assumed that the Gundersons were entitled to punitive damages in the first place. In particular, Sandoz contends that there was no evidence of a nexus between Sandoz's out-of-state conduct relative to Parlodel and the harm suffered by Mary Gunderson. Sandoz is essentially arguing that the trial court erred in failing to grant its motion for a directed verdict on the issue of punitive damages. We agree with the Court of Appeals that the Gundersons presented sufficient evidence that Sandoz acted with wanton or reckless disregard for Mary Gunderson to be outrageous and implicitly malicious and, thus, a punitive damage instruction was warranted. See Phelps v. Louisville Water Co., 103 S.W.3d 46, 52 (Ky. 2003).

The Gundersons presented evidence that by 1985 Sandoz knew of a causal link between Parlodel and hypertension and seizures, and by 1988 Sandoz was on notice that the FDA had advised that Parlodel should not be prescribed routinely for PPLS. Despite the fact that all other drug companies had taken bromocriptine mesylate off the market for PPLS, Sandoz continued to aggressively market Parlodel for routine use for PPLS. During this time, Sandoz also engaged in conduct that sought to keep concerns about the drug from coming to the attention of doctors. As we have already discussed,

the Gundersons presented evidence that Sandoz: misrepresented or underreported known ADRs associated with Parlodel; published a misleading ad regarding the safety and effectiveness of Parlodel; failed to send "Dear Doctor" letters calling attention to the revised package insert to all members of the college of obstetrics and gynecology as required by the FDA; sent out a "Dear Doctor" letter in 1990 flouting the FDA and maintaining the safety and effectiveness of Parlodel for PPLS; instructed its sales force not to mention the risks of the drug unless specifically asked by a doctor; and attempted to manipulate and downplay the risks of seizure in the ERI report. This conduct evinced a deliberate and systematic campaign to downplay or conceal the risks of Parlodel from prescribing doctors for the purpose of continuing to sell the drug. Further, this evidence of out-of-state conduct by Sandoz had a sufficient nexus with Mary Gunderson's death in that Dr. Armstrong testified that had he known of information in the "Dear Doctor" letter or the FDA's position on Parlodel at the time, he would not have prescribed Parlodel to Mary in 1993. Accordingly, the court properly denied Sandoz's motion for directed verdict on punitive damages.

Sandoz next asserts that remanding for a new trial solely on punitive damages presupposes a finding by the jury that Sandoz's conduct was reprehensible. As the suggested jury instruction in Sand Hill provides, the jury on remand should be explicitly instructed that it can only consider Sandoz's out-of-state conduct "in determining whether [Sandoz's] conduct occurring in Kentucky was reprehensible, and if so, the degree of reprehensibility." Sand Hill, 142 S.W.3d at 167 (emphasis added). We would also clarify that while the present case was remanded by the Court of Appeals "for a new determination of the amount of punitive damages," as in Sand Hill, the instruction and verdict form on remand should allow for a possible finding of no punitive damages.

Id. As this Court's proposed instruction properly stated in Sand Hill, "Whether you make an award of punitive damages, in addition to the compensatory damages previously awarded, is a matter exclusively within your discretion." Id.

Finally, Sandoz argues that the issues of compensatory liability and punitive liability were so inextricably interwoven that a retrial solely on the issue of punitive damages would be in error. We do not agree. Retrial on a distinct and severable issue is permitted unless retrial would result in injustice. Deutsch v. Shein, 597 S.W.2d 141, 146 (Ky. 1980). We cannot say that a retrial solely on the issue of punitive damages would result in an injustice to Sandoz in this case.

CONCLUSION

While we deem it was error to fail to allow the cross-claim to be admitted in this case, we adjudge it to be harmless error. Finding no other error, the opinion of the Court of Appeals is affirmed.

Minton, C.J.; Cunningham, Noble, Schroder, Scott and Venters, JJ., concur. Abramson, J., not sitting.

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Supreme Court of Kentucky

2006-SC-000175-DG

HYMAN & ARMSTRONG, P.S.C., ET AL. — APPELLANTS

ON REVIEW FROM COURT OF APPEALS
V. CASE NOS. 2004-CA-001536 & 2004-CA-001537
JEFFERSON CIRCUIT COURT NO. 94-CI-004680

RONALD GUNDERSON
(ADMINISTRATOR OF THE ESTATE OF MARY
MARGARET GUNDERSON), ET AL. — APPELLEES

AND 2006-SC-000179-DG

SANDOZ PHARMACEUTICALS CORPORATION
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CORPORATION) — APPELLANT

ON REVIEW FROM COURT OF APPEALS
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ORDER GRANTING PETITION FOR REHEARING

On motion of the Appellant, Sandoz Pharmaceuticals Corporation (n/k/a Novartis Pharmaceuticals Corporation), rehearing shall be granted, and the Opinion of the Court

by Justice Schroder rendered April 24, 2008 shall be modified. Due to pagination, the entire Opinion shall be substituted, as attached hereto, in lieu of the Opinion as originally rendered.

Minton, C.J.; Cunningham, Noble, Schroder, Scott and Venters, JJ., concur. Abramson, J., not sitting.

Entered: November 26, 2008.