IN THE DISTRICT COURT OF APPEAL OF THE STATE OF FLORIDA
FIFTH DISTRICT JULY TERM 2010

JANSSEN PHARMACEUTICAL PRODUCTS, L.P., et al.,

Appellants/Cross-Appellees,

v. Case No. 5D09-30

SCOTT DAVID HODGEMIRE, PERSONAL, etc.,

Appellee/Cross-Appellant.
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Opinion filed August 13, 2010

Appeal from the Circuit Court
for Seminole County,
Clayton D. Simmons, Judge.

William E. Lawton and Lamar D. Oxford of Dean, Ringers, Morgan & Lawton, P.A., Orlando, Barry Richard of Greenberg Traurig, Tallahassee, Charles C. Lifland of O'Melveny & Myers LLP, Los Angeles, and Ernest W. Auciello of Tucker Ellis & West LLP, Cleveland, OH, for Appellants/Cross-Appellees, Janssen Pharmaceutical Products, L.P., and ALZA Corporation.

Bard D. Rockenbach and Philip M. Burlington of Burlington & Rockenbach, P.A., West Palm Beach, Joseph M. Taraska and Harry Jacobs of Jacobs & Goodman, P.A., Altamonte Springs, and E. Clay Parker of E. Clay Parker, P.A., Orlando, for Appellee/Cross-Appellant.

PER CURIAM.

Appellants, Janssen Pharmaceutical Products, L.P., and ALZA Corporation, appeal from a jury verdict in favor of Appellee, Scott Hodgemire, as Personal

Representative of the Estate of Susan Hodgemire, his deceased wife. Appellants challenge a number of pre-trial, trial, and post-trial rulings. With the exception of the trial court's ruling on a setoff, we affirm in all respects.[1]

One of the products Appellants advertise, manufacture, and distribute is Duragesic. Duragesic is a prescription transdermal patch that delivers a time-released dose of fentanyl, an exceptionally potent synthetic opiate. Mrs. Hodgemire was initially prescribed one 75 µg[2] Duragesic patch following spinal fusion surgery performed by Jewett Orthopaedic Clinic (hereinafter "Jewett"). Her prescribing doctor, Dr. Villalobos, subsequently doubled her dose after she continued to experience pain.

Several nights after her dosage was increased, Mrs. Hodgemire awoke Appellee complaining of nausea and vomiting over several hours. At her request, Appellee called the hospital and he was advised to call Jewett. Doing so, Mrs. Hodgemire spoke to Kurt Wood, an on-call physician's assistant at Jewett. Wood instructed Mrs. Hodgemire to take anti-nausea medication and call her family doctor the following Monday. Complying with these instructions, Mrs. Hodgemire returned to bed and fell asleep. Although he repeatedly checked on Mrs. Hodgemire the following morning, Appellee discovered his wife dead in the early afternoon. Following an autopsy, the medical

[1] Because we are affirming, it is unnecessary to address the issue raised in Appellee's cross-appeal.

[2] µg stands for microgram.

examiner concluded Mrs. Hodgemire died from fentanyl toxicity, based in part on her postmortem blood fentanyl level of 22 ng/ml.[3]

Three claims were presented to the jury for its consideration: medical negligence against Wood; strict liability against Appellants for defectively manufacturing, designing, and failing to warn of the dangers associated with Duragesic; and a claim against Appellants for negligently manufacturing and failing to warn of the dangers associated with Duragesic.[4]

The primary issue at trial was whether Mrs. Hodgemire's postmortem fentanyl blood level could have been caused by properly working Duragesic patches. Appellee asserted that there was a defect in the design and manufacture of the patch, such that Mrs. Hodgemire received too much of the drug too quickly. In support, Appellee presented expert testimony, complaints of defective Duragesic patches, testimony of manufacturing defects, as well as evidence of a recall. The jury heard sharply conflicting testimony about whether a properly working patch could explain Mrs. Hodgemire's postmortem fentanyl blood level.

Appellee's experts testified that the maximum amount of fentanyl Mrs. Hodgemire would have received from two or three[5] properly working patches ranged from 3.4 to 9.3 ng, accounting for the mean plus two standard deviations higher. This testimony was predicated on Appellants' published data in the package insert that was included with

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[3] Complicating this case was the fact that the Duragesic patches removed from Mrs. Hodgemire by the medical examiner's office were not retained.

[4] Dr. Villalobos and Jewett settled with Appellee pre-trial.

[5] The parties disputed whether Mrs. Hodgemire was wearing two or three patches at the time of her death.

the Duragesic patches. The package insert stated the mean "Maximal Concentration" for a person using one 75 µg patch to be 1.7 ng with a standard deviation of .7. Because Mrs. Hodgemire's blood fentanyl level was measured after death, the experts also accounted for postmortem redistribution.

Postmortem redistribution is the process by which drugs stored in the body's tissues are released back into the bloodstream upon death. It is calculated by measuring the amount of a drug in central (heart) blood and femoral blood. Under the theory that femoral blood more accurately represents the antemortem level of a drug in a person's body, the central blood level is compared to the femoral blood level to develop a ratio.[6] This ratio represents the amount a drug redistributes after death.[7]

In rendering their opinion on postmortem redistribution, Appellee's experts relied on two sources. The first source was a published journal article. The second source was an affidavit; it was prepared by the author of the journal article for another case and updated the research from the article with additional case studies. The research looked at deaths from the Los Angeles County, CA coroner's office where the decedent's blood tested positive for fentanyl. Taking those cases that reported central and femoral blood fentanyl concentrations, the affidavit concluded that the ratio of postmortem redistribution between central and femoral blood averaged 1:1.2.

[6] Conversely, it is assumed that more of a drug leeches back into the heart than the femoral artery.

[7] Because fentanyl-related deaths are not predictable, and obviously cannot be induced for research purposes, studies on postmortem redistribution are limited to an analysis of postmortem fentanyl blood.

Adopting the 1:1.2 postmortem redistribution fentanyl ratio from the affidavit, Appellee's experts multiplied the ratio with the maximum level of fentanyl they testified properly working patches would produce. Accounting for postmortem redistribution, the experts testified that the maximum amount of fentanyl they would have expected properly working patches to produce in Mrs. Hodgemire was 7.44 ng/ml for two patches or 11.16 ng/ml for three patches. Comparing this number to her postmortem level of 22 ng/ml, the experts concluded that Mrs. Hodgemire died from a lethal dose of fentanyl due to a failure in the Duragesic patch.

In stark contrast, Appellants' expert opined that a person using 150 µg of Duragesic would have a blood fentanyl level between 1.5 to 13.5 ng/ml.[8] Placing emphasis on the fact that blood was not drawn from Mrs. Hodgemire until three days after her death, Appellants' expert testified that postmortem redistribution would increase the level of fentanyl in her blood by two to seven-fold. He also testified that the postmortem level of fentanyl only indicated that Mrs. Hodgemire used fentanyl and could not be used to predict or reach conclusions about her fentanyl level before she died. After hearing this and a wealth of other testimony, the jury returned a verdict in favor of Appellee, apportioning liability eighty percent against Appellants and twenty percent against Wood.

The first issue in their brief and primary focus at oral argument was the trial court's denial of Appellants' motion to exclude expert testimony that calculated Mrs. Hodgemire's antemortem fentanyl blood level from her postmortem blood level.

[8] Compared to the information contained in Appellants' package insert and Appellee's experts' testimony, this range was on the far extreme of what would have been expected.

Appellants challenged the testimony on the basis that it did not meet the Frye[9] standard of admissibility. We review this issue de novo. Hildwin v. State, 951 So. 2d 784, 791 (Fla. 2006).

Before addressing the merits of Appellants' Frye challenge, this court requested supplemental briefing on whether this issue was preserved for review. Appellants contend they preserved the issue by raising it in a pre-trial motion in limine and receiving an adverse ruling. Appellee argues the issue was not preserved because Appellants did not expressly request a Frye hearing.

A party may preserve a Frye challenge by making a specific objection at trial. Thus, generally objecting to the expert under section 90.702, Florida Statutes, is insufficient. See United States Sugar Corp. v. Henson, 787 So. 2d 3, 12 (Fla. 1st DCA 2000). Objecting that the expert's opinion goes to the ultimate issue in the case or that the expert is not competent to testify is also insufficient. See Hadden v. State, 690 So. 2d 573, 580 (Fla. 1997). Rather, the objection must challenge the expert's testimony on the basis that the "novel scientific evidence is unreliable." Id.

A party may also raise a Frye challenge pre-trial. The supreme court has recognized this as the better procedure because it minimizes any inconvenience to the jury. Ramirez v. State, 651 So. 2d 1164, 1168 n.4 (Fla. 1995). If raised pre-trial, courts have recognized that, normally, an evidentiary hearing should be held. See United States Sugar Corp., 787 So. 2d at 21; Holy Cross Hosp., Inc. v. Marrone, 816 So. 2d 1113, 1121 (Fla. 4th DCA 2001) (opinion on denial of rehearing). However, an evidentiary hearing is not always required. See United States Sugar Corp., 787 So. 2d

[9] Frye v. U.S., 293 F. 1013 (D.C. Cir. 1923).

at 21. This is particularly true when the face of the motion indicates that the expert's testimony is not subject to a Frye analysis.

In this case, Appellants' motion in limine sought to exclude any expert who would calculate Mrs. Hodgemire's antemortem blood fentanyl level from her postmortem blood level because it did not "pass muster under Frye." At the hearing scheduled to resolve the parties' motions in limine, approximately twenty-four in total, Appellants introduced their Frye motion by stating: "We have moved in limine to exclude reference to the decedent's postmortem fentanyl blood level. And the reason for that is the postmortem blood level of a person is scientifically unreliable . . . ." The trial court subsequently denied the motion, concluding the testimony was not subject to Frye.

Both Appellants' motion and argument at the hearing put opposing counsel and the trial court on notice that Appellee's experts were being challenged based on Frye. Although Appellants did not specifically request a Frye hearing, we believe they sufficiently preserved it for this court's review. However, we conclude that Appellee's experts' testimony was not subject to Frye.

A Frye inquiry ensures that the scientific principles and methodologies underlying an expert's testimony are generally accepted in the scientific community. See United States Sugar Corp. v. Henson, 823 So. 2d 104, 110 (Fla. 2002). Frye is only implicated when an "expert attempts to render an opinion that is based upon new or novel scientific techniques." Id. at 109. As long as the expert's opinion is based on "generally accepted scientific principles and methodology, it is not necessary that the expert's deductions based thereon and opinion also be generally accepted as well." Id. at 109-10; see also Berry v. CSX Transp., Inc., 709 So. 2d 552, 567 (Fla. 1st DCA 1998).

Appellants advance two arguments why Appellee's experts' testimony was not scientifically valid or reliable in violation of Frye. First, Appellants assert that these experts took Mrs. Hodgemire's postmortem fentanyl blood level of 22 ng/ml and, accounting for postmortem redistribution, extrapolated backwards to draw inferences about her antemortem fentanyl blood level. Stated differently, Appellants contend that Appellee's experts took Mrs. Hodgemire's measured postmortem fentanyl blood level and subtracted the effect of postmortem redistribution to calculate her antemortem fentanyl blood level. This argument is unpersuasive because Appellee's experts did not employ this methodology to calculate Mrs. Hodgemire's antemortem fentanyl blood level.

Rather than back-extrapolating, Appellee's experts simply compared Mrs. Hodgemire's measured postmortem fentanyl level with the antemortem fentanyl level they assumed properly working Duragesic patches would produce after accounting for postmortem redistribution. In rendering their opinion, the experts first used the information in the Duragesic package insert that was published by Appellants to calculate the maximum level of fentanyl they expected properly working patches would deliver. Second, the experts testified regarding how much they expected postmortem redistribution would increase the amount of fentanyl in the blood after death. Third, the experts multiplied these numbers together to obtain the maximum range of fentanyl they would have expected Mrs. Hodgemire to have at the time of her death if the patches functioned properly. Comparing this number range, 7.44 or 11.16 ng/ml, to the level measured after Mrs. Hodgemire died, 22 ng/ml, the experts concluded the patches were defective. Contrary to Appellants' assertion, Appellee's experts did not calculate Mrs.

Hodgemire's antemortem fentanyl blood level by extrapolating backwards from her postmortem fentanyl blood level.

Appellants' second argument is that there was no scientific basis for Appellee's experts to testify that the average postmortem redistribution ratio for fentanyl was 1:1.2. According to Appellants, the medical literature does not support a 1:1.2 average. Appellants also claim the literature reflects wide individual variability and there is no evidence "remotely" suggesting that calculating an average ratio for postmortem redistribution is valid for predicting its effect in any individual. This argument does not raise a Frye issue.

As long as Frye concerns are met that the underlying theory, methodology, and principles are generally accepted, Frye does not require an expert's opinion to be generally accepted. See United States Sugar Corp., 823 So. 2d at 109. In this case, the parties concede that the theory underlying postmortem redistribution is generally accepted. The parties concede that postmortem redistribution with fentanyl is generally accepted. There is also no dispute that the methodology for determining how the postmortem redistribution ratio is calculated is generally accepted. Because none of the science underlying postmortem redistribution is being challenged, Appellee's experts' opinions concerning the amount of redistribution did not have to be generally accepted as well. See id. at 110; contra Battle v. Gold Kist, Inc., 2008 WL 4097717 (M.D. Fla. 2008)[10] (excluding expert opinion on marijuana impairment, in part, because no evidence was presented that postmortem redistribution occurred with marijuana).

[10] In contrast to the pre-trial hearing in this case, the trial court in Battle v. Gold Kist, 2008 WL 4097717 (M.D. Fla. 2008), was presented with numerous studies

The only other issue we briefly address is Appellants' argument that they are entitled to a setoff from Jewett's settlement with Appellee, "calculated in accordance with the ratio of economic damages to total damages established by the jury." Under this calculation, Appellants assert they are entitled to a setoff of $55,775. At oral argument, Appellee conceded error on this point. Consequently, we remand for a corrected judgment. We summarily reject Appellants' remaining arguments on appeal.

AFFIRMED IN PART, REVERSED IN PART, and REMANDED.

TORPY and EVANDER, JJ., concur.
COHEN, J., concurring and concurring specially, with opinion.

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addressing the reliability of blood measurements in assessing the validity of postmortem redistribution and whether it occurred with cannabis. The trial court in this case only had the benefit of counsels' argument.

COHEN, J., concurring specially.

Under the current case law, I am compelled to agree with the majority's finding that the Frye issue was preserved for appeal. The objection, albeit contained in a lengthy motion in limine, placed opposing counsel and the trial court on notice of the Frye challenge.

The trial court in this case was placed in a difficult position. This case had been pending for over four years and the three week trial was scheduled for October 6, 2008. Less than thirty days before trial, the parties filed a total of twenty-four motions in limine, one of which was the Frye motion now being challenged on appeal. These motions were heard twelve days before trial and the argument on the Frye motion made up all of eleven pages of a 149 page transcript. Given the importance Appellants placed on this issue in their brief and at oral argument, it is not only surprising that so little argument was devoted to it, but that it was not even the first motion argued. In any event, I believe this was not the proper way to raise a Frye challenge in this case.

Although the motions in limine were heard in advance of trial, it is not uncommon, given a lack of resources and increasing case loads, that motions in limine are heard while the parties wait for potential jurors to be brought to the courtroom. In most cases, while not ideal, this process is adequate. What, then, if the trial court determines a need for an evidentiary hearing? We know the proponent of the testimony being challenged is required to present independent experts to establish that the principles involved are not new or novel. See Ramirez v. State, 810 So. 2d 836, 851 (Fla. 2001). Assuming the proponent of the testimony has independent experts retained and

available, an expensive proposition, delay is inherent. It is difficult enough to schedule experts to testify at trial, much less having to secure and coordinate additional independent experts. To believe this can be accomplished immediately before, or even in the middle of trial, presents an unworkable model. Either the judge's trial schedule will be impacted and/or the jury's time will be extended while such a hearing is conducted. Neither procedure results in an efficient administration of justice.

If counsel believes there is a good faith basis for excluding testimony based upon Frye, a separate motion filed sufficiently in advance of trial, and clearly identifying the issue, should be required. The better practice would then be to set a hearing so the trial court could determine Frye's applicability or whether a further evidentiary hearing is needed.