

NON-PRECEDENTIAL DECISION - SEE SUPERIOR COURT I.O.P. 65.

GEORGE PAULEY AND SUSAN PAULEY,	:	IN THE SUPERIOR COURT OF
H/W,	:	PENNSYLVANIA
Appellants	:	
vs.	:	
BAYER CORPORATION AND BAYER AG	:	
GLAXOSMITHKLINE,	:	
Appellees	:	No. 2681 EDA 2005

Appeal from the Judgment entered September 14, 2005
In the Court of Common Pleas of Philadelphia County
Civil, March Term, 2002, No. 002729

BEFORE: KLEIN, GANTMAN, JJ., AND MCEWEN, P.J.E.

MEMORANDUM: **FILED JUNE 12, 2009**

Appellants, George Pauley and Susan Pauley, h/w, (collectively "Appellant") appeal from the judgment entered in the Philadelphia County Court of Common Pleas, following a jury trial and verdict in favor of Appellees, Bayer Corporation¹ and Bayer AG (collectively "Bayer"), and Glaxosmithkline ("GSK"). We affirm.

The relevant facts and procedural history of this case are as follows. Appellant has a medical history of hypertriglyceridemia.² In 1999,

¹ Bayer Corporation is a division of Bayer AG, a foreign corporation.

² Elevated blood levels of triglycerides.

Appellant's cardiologist, Dr. Peter Caples, prescribed certain drugs known as statins³ to lower Appellant's cholesterol. Ultimately, Dr. Caples prescribed the statin, Zocor. Dr. Caples also prescribed Gemfibrozil, a lipid reducer. Appellant tolerated this drug combination without any problems.

Bayer manufactured a statin called Baycol; Bayer and GSK co-marketed Baycol. In December 1999, Bayer notified the U.S. Food and Drug Administration ("FDA") that Bayer was changing the Baycol warning label to include a contraindication to prescribing physicians. The contraindication warning stated:

CONTRAINDICATIONS:

Concurrent treatment with gemfibrozil due to a risk for rhabdomyolysis^[4] (see **WARNINGS: Skeletal Muscle**).

WARNINGS

Skeletal Muscle: The combined use of cerivastatin [Baycol] and gemfibrozil is contraindicated due to a risk for rhabdomyolysis (see **Contraindications**).

PRECAUTIONS

GEMFIBROZIL: The potential for clinically relevant interaction between gemfibrozil and cerivastatin has not been assessed in clinical trials. However, during postmarketing surveillance, patients on cerivastatin who

³ Statins are cholesterol-reducing drugs that block a liver enzyme involved in the synthesis of cholesterol.

⁴ Rhabdomyolysis is the breakdown of skeletal muscle. The process can lead to acute renal failure due to accumulation of muscle breakdown products in the bloodstream, which injure the kidney.

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experienced rhabdomyolysis and associated renal failure,

were in most cases also taking gemfibrozil. (see **CONTRAINDICATIONS** and **WARNINGS: Skeletal Muscle**).

ADVERSE EVENTS

Concomitant Therapy: Concurrent treatment with gemfibrozil is contraindicated (see **CONTRAINDICATIONS** and **WARNINGS: Skeletal Muscle**).

(U.S. Label Changes, 12/99; R.R. at R.63a) (emphasis in original). In addition to the change in Baycol's warning label, on December 15, 1999, Bayer sent a letter to all healthcare providers advising against concurrent treatment with Baycol and Gemfibrozil.

In November 2000, Appellant informed Dr. Caples that Zocor was not a preferred drug under Appellant's health insurance, and Appellant did not tolerate Lipitor. Dr. Caples tailored Appellant's therapy and prescribed Baycol and Gemfibrozil, despite the contraindications. Appellant took Baycol and Gemfibrozil from December 2000 until June 12, 2001. On Friday, June 8, 2001, Appellant called Dr. Caples' office and reported muscle cramps. Dr. Caples' office assured Appellant the cramps were "a normal reaction." Appellant then contacted the office of his family physician, Dr. Jeffrey Armitage. Dr. Armitage was away for the weekend, but his office gave Appellant the first available appointment. On Tuesday, June 12, 2001, Appellant saw Dr. Armitage, who advised Appellant immediately to cease taking Baycol and Gemfibrozil. Appellant fully recovered from his muscle

spasms by Friday, June 15, 2001. Subsequently, on August 8, 2001, Bayer independently decided to withdraw Baycol from the market.

Appellant, who is a resident of Ohio, filed suit on March 19, 2002, against Bayer and GSK in the Philadelphia County Court of Common Pleas. The short form complaint asserted claims for negligence, fraud, breach of warranty and loss of consortium. On November 12, 2004 and November 15, 2004, the court heard oral arguments on several defense pre-trial motions *in limine*. The court made three rulings relevant to this appeal. The court granted in part Bayer's and GSK's Motion *in Limine* No. 8 to exclude Certain Evidence and Argument Regarding Adverse Event Reports ("AERs"). The court's order provided:

1. No evidence or argument shall be presented to the jury that spontaneous ["AERs"] may be considered as evidence that Baycol caused any patient condition reported in AERs.
2. No evidence or argument shall be presented to the jury that AERs should have been given to physicians.

* * *

4. No evidence or argument shall be presented to the jury, based on either AER data or comparative AER data that adverse events occurred more frequently with Baycol than with other drugs.

(Trial Court Order, dated 11/16/04; R.R. at R.161a). The court also granted the defense Motion to Exclude Testimony by Appellant's expert, Dr. Sorrell L. Schwartz, Ph.D. In pertinent part, the court's order stated:

Prof. Schwartz may not testify to the following:

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- a. the diagnosis of any patient
- b. that "Patient 1301" [in the Baycol clinical trials] had rhabdomyolysis....

(Trial Court Order, dated 11/16/04; R.R. at R.594a).

Finally, the court granted in part the defense Motion *in Limine* No. 12 to exclude Evidence and Argument Regarding Animal-Based Toxicological Evidence. The order stated:

1. No evidence or argument shall be presented to the jury regarding the results of animal toxicological studies, reports or other references.
2. However, [Appellant] may submit an offer of proof to attempt to demonstrate the admissibility of such evidence.

(Trial Court Order, dated 11/16/04; R.R. at R.424a).

On November 15, 2004, the jury trial commenced. On November 23, 2004, the jury found in favor of Bayer and GSK, resulting in a defense verdict. On December 3, 2004, Appellant timely filed a motion for a new trial, challenging several of the court's evidentiary rulings. By order dated September 13, 2005, and filed September 14, 2005, the court denied Appellant's post-trial motion and entered judgment on the jury's verdict. On September 22, 2005, Appellant timely filed a notice of appeal. On September 28, 2005, the court ordered Appellant to file a concise statement of matters complained of on appeal pursuant to Pa.R.A.P 1925(b). Appellant timely complied on October 12, 2005.

On appeal, Appellant raises the following issues for our review:

WHERE DEFENDANTS COLLECTED BUT FAILED TO TIMELY DISCLOSE [AERS] THAT REVEALED RATES OF DEATH AND SEVERE MUSCLE INJURY OCCURRING WITH BAYCOL AS MUCH AS 80 TIMES GREATER THAN OTHER COMPARABLE DRUGS, WHERE SUCH COMPARATIVE [AERS] WERE RELIED UPON BY THE MANUFACTURER TO VOLUNTARILY WITHDRAW ITS DRUG FROM MARKETING, WHERE THE PRESCRIBING DOCTOR WAS PREPARED TO TESTIFY THAT HAD HE BEEN WARNED OF THIS DATA HE WOULD NOT HAVE PRESCRIBED THE MEDICATION, AND WHERE FDA REGULATIONS ENCOURAGE MANUFACTURERS TO PUBLISH SUCH EMERGING SAFETY DATA AS SOON AS POSSIBLE EVEN THOUGH NO CAUSAL ASSOCIATION NEED BE PROVEN, SHOULD [APPELLANT] BE PRECLUDED FROM INTRODUCING THIS RELEVANT EVIDENCE TO ESTABLISH A FAILURE TO WARN CLAIM?

WHETHER THE DECISION TO PRECLUDE [APPELLANT'S] PHARMACOLOGY EXPERT FROM TESTIFYING WITHIN HIS DISCIPLINE TO A CONCLUSION THAT DEFENDANTS' DRUG CAUSED SEVERE MUSCLE INJURY DURING A CLINICAL TRIAL THAT WAS NOT DISCLOSED IN THE DRUG'S LABEL WAS PLAIN ERROR AND PREJUDICIAL TO [APPELLANT'S] ASSERTIONS THAT THE LABEL FAILED TO WARN OF THE DRUG'S DANGEROUS PROPENSITIES?

WHETHER [APPELLANT WAS] PREJUDICED BY PRECLUDING INTRODUCTION OF PRECLINICAL TOXICOLOGY STUDIES OF A DRUG THAT REVEALED IT TO POSSESS A DANGEROUSLY STEEP DOSE/RESPONSE CURVE THAT WOULD LEAD ANY REASONABLE MANUFACTURER NOT TO MARKET THE DRUG?

(Appellant's Brief at 3).

As a preliminary matter, we observe:

In conflict of law cases involving procedural matters, Pennsylvania will apply its own procedural laws when it is serving as the forum state. In cases where the substantive laws of Pennsylvania conflict with those of a sister state in the civil context, Pennsylvania courts are to take a flexible approach which permits analysis of the policies and interests underlying the particular issue before

the court. This approach gives the state having the most interest in the question paramount control over the legal issues arising from a particular factual context, thereby allowing the forum to apply the policy of the jurisdiction most intimately concerned with the outcome.

* * *

A substantive right is defined as a right to equal enjoyment of fundamental rights, privileges and immunities. By contrast, a procedural right is the method of enforcing rights or obtaining redress for their invasion.

Larrison v. Larrison, 750 A.2d 895, 898 (Pa.Super. 2000). Here, the parties stipulated that Ohio substantive law governed the negligence/failure to warn claims.⁵ Because Pennsylvania served as the forum state, Pennsylvania procedural law applied. *Id.*

In his first issue, Appellant argues Bayer failed to warn of the significant number of AERs attributed to Baycol, as compared to other statins available on the market. Appellant asserts Dr. Caples would not have prescribed Baycol to Appellant, had Dr. Caples been aware of the comparative AERs. Appellant claims Ohio law requires a manufacturer to disclose all known risks of a drug. Appellant insists that FDA regulations permitted Appellees to disseminate additional safety information without prior FDA approval, such as a change to the warning label on Baycol or a

⁵ In *Wyeth v. Levine*, ___ U.S. ___, 129 S.Ct. 1187, ___ L.Ed.2d ___ (2009), the United States Supreme Court recently held that federal regulations do not preempt state law negligence/failure to warn claims in drug manufacturing cases.

public advertisement about Baycol's risks. Appellant concludes the court erred when it precluded evidence at trial of the comparative AERs; and Appellant is entitled to a new trial on the ground. We disagree.

The following principles guide our evaluation of an order denying a motion for a new trial:

When presented with an appeal from the denial of a motion for a new trial, "absent a clear abuse of discretion by the trial court, appellate courts must not interfere with the trial court's authority to grant or deny a new trial." *Harman ex rel. Harman v. Borah*, 562 Pa. 455, 466, 756 A.2d 1116, 1121-22 (2000).

In *Harman*, the Court noted that the trial court must follow a two-step process in responding to a request for a new trial. The trial court must determine whether a factual, legal or discretionary mistake was made at trial. If the trial court determines that one or more mistakes were made, it must then evaluate whether the mistake provided a sufficient basis for granting a new trial. Moreover, the Court noted[:] "A new trial is not warranted merely because some irregularity occurred during the trial or another trial judge would have ruled differently; the moving party must demonstrate to the trial court that he or she has suffered prejudice from the mistake."

The Court then set forth an additional two-step analysis for appellate review of a trial court's determination to grant or deny⁶ a new trial. First, the appellate court must examine the decision of the trial court to determine whether it agrees that a mistake was, or was not, made. In so doing, the Court noted that the appellate court must apply the appropriate standard of review. If the alleged mistake involved an error of law, the appellate court must scrutinize for legal error. If the alleged mistake at trial involved a discretionary act, the appellate court must review for an abuse of discretion. The Court reiterated that a trial court

abuses its discretion by rendering a judgment that is manifestly unreasonable, arbitrary or capricious, or has failed to apply the law, or was motivated by partiality, prejudice, bias or ill will.

⁶The Court specifically held that a review of a denial of a new trial requires the same analysis as a review of a grant of a new trial.

If the appellate court agrees with the trial court's determination that there were no prejudicial mistakes at trial, then a decision by the trial court to deny a new trial must stand and we need not reach the second prong of the analysis. If the appellate court discerns that a mistake was made at trial, however, it must analyze whether the trial court abused its discretion in ruling on the motion for a new trial.

Ettinger v. Triangle-Pacific Corp., 799 A.2d 95, 106 (Pa.Super. 2002), *appeal denied*, 572 Pa. 742, 815 A.2d 1042 (2003) (internal citations omitted). We will overturn the decision only where the trial court abused its discretion or committed an error of law that controlled the outcome of the case. ***Colville v. Crown Equipment Corp.***, 809 A.2d 916, 926 (Pa.Super. 2002). We view the evidence in the light most favorable to the verdict winner to determine "whether a new trial would produce a different verdict." ***Gunn v. Grossman***, 748 A.2d 1235, 1239 (Pa.Super. 2000), *appeal denied*, 564 Pa. 711, 764 A.2d 1070 (2000). "Consequently, if there is any support in the record for the trial court's decision to deny a new trial, that decision must be affirmed." *Id.* Further, a new trial is granted only where the verdict is so contrary to the evidence as to shock one's sense of justice, not where the evidence is conflicting or where the court might have reached a different conclusion on the same facts. ***Andrews v. Jackson***, 800 A.2d 959, 962 (Pa.Super. 2002), *appeal denied*, 572 Pa. 694, 813 A.2d 835 (2002).

MacNutt v. Temple University Hosp., Inc., 932 A.2d 980, 984-85 (Pa.Super. 2007) (*en banc*), *appeal denied*, 596 Pa. 708, 940 A.2d 365

(2007). This Court must decide, “whether the trial court committed an error of law which controlled the outcome of the case or committed an abuse of discretion.” ***Christian v. Yanoviak***, 945 A.2d 220, 225 (Pa.Super. 2008).

An abuse of discretion is not merely an error of judgment, but if in reaching a conclusion the law is overridden or misapplied, the judgment exercised is manifestly unreasonable, or the result of partiality, prejudice, bias or ill will, as shown by the evidence or the record, discretion is abused. ***Sutherland v. Monongahela Valley Hosp.***, 856 A.2d 55 (Pa.Super. 2004). A new trial is granted only where the verdict is so contrary to the evidence as to shock one’s sense of justice, not where the evidence is conflicting or where the trial judge would have reached a different conclusion on the same facts. ***Lombardo v. DeLeon***, 828 A.2d 372 (Pa.Super. 2003), *appeal denied*, 579 Pa. 704, 857 A.2d 679 (2004).

We also observe:

The admission or exclusion of evidence is within the sound discretion of the trial court, and in reviewing a challenge to the admissibility of evidence, we will only reverse a ruling by the trial court upon a showing that it abused its discretion or committed an error of law. Thus, our standard of review is very narrow.... To constitute reversible error, an evidentiary ruling must not only be erroneous, but also harmful or prejudicial to the complaining party.

McManamon v. Washko, 906 A.2d 1259, 1268 (Pa.Super. 2006), *appeal denied*, 591 Pa. 736, 921 A.2d 497 (2007) (internal citations omitted).

Pennsylvania trial judges enjoy broad discretion regarding the admissibility of potentially misleading and confusing

evidence. Relevance is a threshold consideration in determining the admissibility of evidence. A trial court may, however, properly exclude evidence if its probative value is substantially outweighed by the danger of unfair prejudice. Generally for the purposes of this evidentiary rule, "prejudice" means an undue tendency to suggest a decision on an improper basis. The erroneous admission of harmful or prejudicial evidence constitutes reversible error.

Whyte v. Robinson, 617 A.2d 380, 383 (Pa.Super. 1992) (internal citations omitted).

A motion *in limine* is a procedure for obtaining a ruling on the admissibility of evidence prior to or during trial, but before the evidence has been offered. When reviewing rulings on motions *in limine*, we apply the scope of review appropriate to the particular evidentiary matter.

Delpopolo v. Nemetz, 710 A.2d 92, 94 (Pa.Super. 1998).

The question of whether evidence is admissible is a determination that rests within the sound discretion of the trial court and will not be reversed on appeal absent a showing that the court clearly abused its discretion.

Moroney v. General Motors Corp., 850 A.2d 629, 632 (Pa.Super. 2004), *appeal denied*, 580 Pa. 714, 862 A.2d 1256 (2004). To constitute reversible error, an evidentiary ruling must not only be erroneous, it must also be harmful or prejudicial to the complaining party. ***Ettinger, supra*** at 110.

Ohio state law applies the "learned intermediary doctrine" to claims for failure to warn involving pharmaceutical drugs. ***Tracy v. Merrell Dow Pharmaceuticals, Inc.***, 58 Ohio St.3d 147, 569 N.E.2d 875 (1991). Under the learned intermediary doctrine, a pharmaceutical manufacturer discharges its duty to warn the consumer if the manufacturer has provided

reasonable and proper warnings to a learned intermediary, the consumer's physician. *Howland v. Purdue Pharma L.P.*, 104 Ohio St.3d 584, 821 N.E.2d 141 (2004).

The rationale behind [the learned intermediary doctrine] is that the physician stands between the manufacturer and the patient as a learned intermediary. The physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use. The physician is in the best position, therefore, to balance the needs of patients against the risks and benefits of a particular drug or therapy, and then to supervise its use.

Tracy, supra at 149, 569 N.E.2d at 878.

"If the product is properly labeled with the appropriate warnings and instructions to fully inform the physician (a learned intermediary) of the risks involved and the procedures for use, the manufacturer may reasonably assume that the physician will exercise [an] informed judgment in the patient's best interests." *Id.* at 150, 569 N.E.2d at 878.

The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. The adequacy of such warnings is measured not only by what is stated, but also by the manner in which it is stated. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency. A jury may find that a warning is inadequate and unreasonable even where the existence of a "risk," i.e., a causal relationship between use of the product and resulting injury, has not been definitely established. Thus, where scientific or medical

evidence exists tending to show that a certain danger is associated with use of the drug, the manufacturer may not ignore or discount that information in drafting its warning solely because it finds it to be unconvincing.

Seley v. G. D. Searle & Co., 67 Ohio St.2d 192, 198, 423 N.E.2d 831, 837 (1981). ***See also Daniel v. Fisons Corp.***, 740 N.E.2d 681 (Ohio App. 2000) (holding pharmaceutical manufacturer was not liable for failure to warn, where doctor ignored warning on pharmaceutical drug label and additional warning would not have influenced doctor's decision to prescribe drug).

Likewise, Pennsylvania applies the learned intermediary doctrine to claims for failure to warn involving pharmaceutical drugs. ***Lineburger v. Wyeth***, 894 A.2d 141 (Pa.Super. 2006).

[T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and

weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Taurino v. Ellen, 579 A.2d 925, 927 (Pa.Super. 1990), *appeal denied*, 527 Pa. 603, 589 A.2d 693 (1991) (quoting *Makripodis by Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374, 378 (Pa.Super. 1987)). A manufacturer is liable only if the manufacturer fails to exercise reasonable care to inform the prescribing doctor of the facts that are likely to make a drug dangerous. *Brecher v. Cutler*, 578 A.2d 481 (Pa.Super. 1990) (granting summary judgment to manufacturer where drug insert warned physician of possible injury actually sustained by plaintiff).

With respect to AERs, the FDA provides the following description:

The [AERs] database is a computerized system for storing adverse events reported by health professionals and others. The system contains adverse events detected and reported after marketing of the drug.

[AERs] relies on health professional[s] to detect new clinical events, to attribute the appearance of the clinical event to the administration of a drug, and to report that clinical event.

The health professional may choose to report the adverse reaction to the FDA or from a drug firm, who must, by law, report to the FDA. Ninety percent of the FDA's reports are received from drug manufacturers. [The Office of Postmarketing Drug Risk Assessment] receives the remaining ten percent directly from other reporters. (i.e. Health Professionals and consumers).

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Adverse Event Reporting System—Brief Description with Caveats of System, dated 10/18/99; R.R. at R.22-R.23a). The FDA cautions against reliance on AERs:

The information contained in the reports has not been scientifically or otherwise verified.

For any given report, there is no certainty that the suspected drug caused the reaction. This is because physicians are encouraged to report suspected reactions. The event may have been related to the underlying disease for which the drug was given, to concurrent drugs being taken, or may have occurred by chance at the same time the suspected drug was taken.

Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.

Numbers from these data must be carefully interpreted as reporting rates and not occurrence rates. True incidence rates cannot be determined from this database. Comparisons of drugs cannot be made from these data.

(*Id.*; R.R. at R.23a).

Instantly, the court addressed Appellant's AERs claim as follows:

The FDA's [AERs] System collects information on adverse events reported by health professions and other[s] concerning previously-approved drugs. The system relies upon health professionals to detect new clinical events, to attribute those events to the administration of a drug, and to report the event to [the AERs System].

[AERs System] data has not been scientifically or otherwise verified; it is not the product of laboratory research or any type of controlled study. It is merely the compilation of experiential reports submitted by those in the field[.]

* * *

Case reports and AERs are compilations of occurrences, not scientific evidence; they are not proof of the data they contain, and do not directly bear upon the adequacy of label warnings.¹

¹ To be sure, receipt of a number of similar AERs reports may raise a red flag to a drug-maker to go back and re-examine clinical data, but the reports are not a substitute for the [clinical] data itself.

Judge Kafrisen permitted [Appellant] to question [his] expert **about** the AERs data, but [the court] declined—and properly so—to permit [Appellant] to show the actual data to the jury or to argue that the data directly supported [his] case-in-chief.²

² Again, Judge Kafrisen allowed [Appellant] to elicit testimony about the conclusion that a physician might draw as to the risk presented by Baycol (as compared to other satin drugs) based upon the information contained in the [AERs]...; the contents of the AERs themselves, were properly excluded.

Accordingly, Judge Kafrisen's decision to limit [Appellant's] use of the [AERs] data was correct.

(Trial Court Opinion, dated January 26, 2006 at 3-4) (emphasis in original).

We agree with the court's reasoning. Appellees had no duty to inform the medical community of the comparative AERs, because AERs are generally unreliable and not scientifically verified. **See** Adverse Event Reporting System—Brief Description with Caveats of System, *supra*. For example, Dr. Caples testified that he does not utilize AERs when making prescription decisions:

[Bayer's Counsel]: As we discussed earlier, the FDA receives spontaneous adverse event reports from lawyers, people, doctors, all across the country, right?

[Dr. Caples]: Correct.

[Bayer's Counsel]: Do you generally receive those reports from, or copies of those reports, from the FDA or from lawyers, and the patients, and the doctors?

[Dr. Caples]: Not that I recollect.

[Bayer's Counsel]: All right. You generally [do not] rely upon spontaneous adverse event reports in deciding which medications [you are] going to prescribe; is that fair to say?

[Dr. Caples]: Fair to say.

(N.T. Trial, 11/18/04, Videotape Transcript at 29; R.R. at R.1230a-R.1231a).

The record demonstrates the warning label on Baycol contained a specific contraindication for concurrent use of Baycol and Gemfibrozil, due to risk of rhabdomyolysis. Bayer also sent a letter to all health care providers warning against concurrent treatment with Baycol and Gemfibrozil. Despite these obvious and clear warnings, almost one year after the warnings were issued, Dr. Caples prescribed Baycol and Gemfibrozil concurrently for Appellant. Dr. Caples also testified:

[Appellees' Counsel]: [The] Baycol labels and package insert also warned of the potential for myalgias or muscle symptoms; is that right?

[Dr. Caples]: To the best of my knowledge.

* * *

[Bayer's Counsel]: And are you aware that Gemfibrozil used in combination with a statin increases the risk of muscles aches or myopathies?

[Dr. Caples]: Absolutely.

[Bayer's Counsel]: And [that is] true for all of the statin medications?

[Dr. Caples]: To the best of my knowledge.

[Bayer's Counsel]: And at the time that you were treating [Appellant], you certainly knew that there was an increased risk of myopathy or muscle problems when Gemfibrozil and statins were used together, right?

[Dr. Caples]: Correct.

(*Id.* at 42, 49-50; R.R. at R.1235a, R.1237a). Dr. Caples admittedly was aware of the risks in prescribing these medications concurrently. **See Daniels, supra.** Further, Dr. Caples admitted he received the letter from Bayer alerting physicians to the contraindication for Baycol and Gemfibrozil. The evidence presented at trial makes clear that, under Ohio law, Bayer's warning on Baycol's drug labels was reasonable in factual content, in expression of the facts, and in the method or form in which the warning was conveyed. **See Seley, supra.** Given the explicit contraindication on Baycol's label, we conclude the court's limitation on the use of the AERs data at trial was appropriate, because it was anecdotal, not scientific. Further, Dr. Caples admitted he did not consult AERs when making his decisions to prescribe medications. Thus, under Ohio law, the properly limited evidence would not have proved Appellant's inadequate warning claim. **See Tracy, supra.** Thus, we see no reason to disturb the court's decision to deny a new trial on this ground.

In his second issue, Appellant argues his expert, Dr. Schwartz, routinely assesses and interprets adverse drug-related events and is qualified to diagnose rhabdomyolysis in a patient in the Baycol clinical trials. Dr. Schwartz's schedule required Appellant to present his live testimony at the beginning of trial. Although, Bayer's safety officer, Dr. Felix Monteagudo, M.D., later testified to one confirmed case of rhabdomyolysis in the Baycol clinical trials, Dr. Schwartz was unable to comment on that diagnosis. In what Appellant calls a "forced juxtaposition," he insists his expert was denied an opportunity to testify regarding a fact admitted later at trial in the case for the defense. Appellant submits he was deprived of the opportunity to have Dr. Schwartz follow-up on that admission for the purpose of demonstrating "the habitual behavior of Bayer to understate the toxicity of Baycol." (Appellant's Brief at 35). Appellant concludes the proposed commentary was not cumulative; the court erred in preventing Dr. Schwartz from stating the diagnosis of any patient or that "Patient 1301" in the Baycol clinical trials had rhabdomyolysis; and Appellant is entitled to a new trial on this ground. We disagree.

Initially, we observe that the mode of a trial "is a form of procedural law; not law, in our sense of substantive law"; thus, the administration of a trial is procedural in nature and represents the method of how substantive rights are enforced. *See generally Bethea v. Philadelphia AFL-CIO Hosp. Ass'n*, 871 A.2d 223 (Pa.Super. 2005), *appeal denied*, 594 Pa. 684,

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934 A.2d 71 (2007); *Ferraro v. McCarthy-Pascuzzo*, 777 A.2d 1128 (Pa.Super. 2001). *See also Commonwealth v. Wharton*, 495 Pa. 581, 435 A.2d 158 (1981) (opinion in support of affirmance). For our purposes, the court's decision to admit or limit testimony is procedural in nature and governed by Pennsylvania law.⁶ *Id.*

An expert witness is "a witness who possesses knowledge not within ordinary reach of understanding, and who, because of this knowledge, is specially qualified to address a particular subject." *Bergman v. United Services Auto. Ass'n*, 742 A.2d 1101, 1105 (Pa.Super. 1999). The topic of the expert's testimony must be "so distinctly related to some science, profession, business or occupation" that it is beyond the understanding of the average layperson." *Id.* at 1105 (quoting *McDaniel v. Merck, Sharp & Dohme*, 533 A.2d 436, 440 (Pa.Super. 1987), *appeal denied*, 520 Pa. 589, 551 A.2d 215-16 (1988)). Pennsylvania applies a liberal standard for the qualification of experts. *Miller v. Brass Rail Tavern, Inc.*, 541 Pa. 474, 664 A.2d 525 (1995).

Determining whether a witness may testify as an expert is a matter within the sound discretion of the trial court, whose decision will only be reversed for a clear abuse of discretion. In order to qualify as an expert in a given field, a witness must possess more expertise than is within the ordinary range of training, knowledge, intelligence, or experience. The test to be applied when qualifying a witness to testify as an expert witness is whether the

⁶ For issues two and three regarding the conduct of the trial, Appellant relies solely on Pennsylvania law.

witness has any reasonable pretension to specialized knowledge on the subject under investigation. If a witness possesses neither experience nor education in the subject matter under investigation, the witness should be found not to qualify as an expert.

Yacoub v. Lehigh Valley Medical Associates, P.C., 805 A.2d 579, 591 (Pa.Super. 2002) (*en banc*), *appeal denied*, 573 Pa. 692, 825 A.2d 639 (2003) (internal citations and quotation marks omitted).

“An expert may express his opinion only on matters which are within his...scientific training and experience.” ***Commonwealth v. Crawford***, 468 Pa. 565, 572, 364 A.2d 660, 664 (1976). “[I]t may appear that the scope of the witness’s experience and education may embrace the subject in question in a general way, but the subject may be so specialized that even so, the witness will not be qualified to testify.” ***Wexler v. Hecht***, 847 A.2d 95, 99 (Pa.Super. 2004), *affirmed*, 593 Pa. 118, 928 A.2d 973 (2007). A witness who admits that he lacks experience or education in the subject matter under investigation is incompetent as an expert. ***Dierolf v. Slade***, 581 A.2d 649 (Pa.Super. 1990). The court has broad discretion regarding the admission of cumulative evidence. ***Sprague v. Walter***, 656 A.2d 890 (Pa.Super. 1995), *appeal denied*, 543 Pa. 695, 730, 670 A.2d 142, 673 A.2d 336 (1996).

Instantly, Dr. Schwartz admitted at trial that he was not qualified to make medical diagnoses:

[Bayer’s Counsel]:
correct, sir?

Now, [you are] not a physician,

[Dr. Schwartz]: [That is] correct.

[Bayer's Counsel]: You [do not] prescribe medications?

[Dr. Schwartz]: No.

[Bayer's Counsel]: And [you have] never treated a patient?

[Dr. Schwartz]: Not directly, no.

(N.T., 11/16/04, at 33; R.R. at R.942a).

With regard to the limitations placed on Dr. Schwartz's testimony, the trial court reasoned as follows:

Judge Kafriksen prevented [Appellants'] expert, Dr. Schwartz—a pharmacologist holding a Ph.D., neither an M.D. nor a D.O.—from giving [a] diagnosis of one patient (Patient 1301) in an early clinical trial of Baycol, because Dr. Schwartz himself admitted that he was not qualified to make medical diagnoses, that he had never treated a patient and that he was not allowed to prescribe medications. (N.T., 11/16/04; [R.R. at 942a]).

Further, Bayer's safety officer, Felix Monteagudo, M.D., admitted that Patient 1301 indeed suffered rhabdomyolysis during that clinical trial; the evidence that Judge Kafriksen excluded was therefore—at best—merely cumulative.⁴

⁴ There would appear to be little reason to allow cumulative testimony to confirm an admitted fact.

This decision...was entirely proper.

(Trial Court Opinion at 5-6). We accept this analysis on the exercise of the court's discretion. *See Yacoub, supra*. Dr. Schwartz admitted he had no experience or special knowledge in medical diagnosis. *See Dierolf, supra*.

Therefore, Dr. Schwartz was not competent to testify on the medical diagnosis of the patient in the Baycol clinical trials. *See id.* We see no abuse of discretion in the trial court's decision to limit Dr. Schwartz's testimony in this regard. Moreover, Dr. Schwartz's schedule directed the order of his trial testimony. Finally, Dr. Schwartz's proposed commentary on the single diagnosis of rhabdomyolysis in clinical trial cannot be said to demonstrate "habitual behavior of Bayer to understate the toxicity of Baycol." Therefore, Appellant's claim warrants no relief.

In his third issue, Appellant argues he intended to introduce at trial Bayer's knowledge of animal toxicology studies, not to show Baycol caused any injury in humans, but to establish Bayer had notice that Baycol was so toxic it should not have been sold. (Appellant's Brief at 36). Appellant complains the trial court blanketly precluded him from employing these studies in his case in chief for notice purposes. Appellant maintains it was plain error to restrict Appellant's case in this fashion, where Appellant wanted to establish notice of the drug's toxicity. Appellant concludes he is entitled to a new trial on this allegation of error. We disagree.

As a prefatory matter, in Appellant's response to the defense Motion *in Limine* No. 12 to exclude Evidence and Argument Regarding Animal-Based Toxicological Evidence, Appellant announced his intent to use the studies under a theory of "notice," but made no specific offer of proof on the probative value of the data, which was not apparent from the context of

Appellant's responsive motion. In ruling on the motion, the trial court precluded Appellant's use at trial of the results of animal toxicological studies, reports or other references. The court, however, explicitly gave Appellant an opportunity to submit at trial an offer of proof to demonstrate the admissibility of the animal toxicology studies data to prove notice. On November 15, 2004, Appellant's counsel sought to reference in his opening statement a letter discussing the animal toxicology studies. Faced with specific defense objections, Appellant's counsel did not make an offer of proof. (**See** N.T. Trial, 11/14/04, at 25-26; R.R. at R896a-R897a.) Arguably, Appellant waived the issue by failing to make an offer of proof at any time. **See** Pa.R.E. 103(a)(2) (stating: "(2) *Offer of Proof*. In case the ruling is one excluding evidence, the substance of the evidence was made known to the court by offer or by motion *in limine* or was apparent from the context within which the evidence was offered").

As to the preclusion of the animal toxicology data, the trial court reasoned as follows:

The results of drug studies conducted on animals are not conclusive evidence that the same results will obtain on human subjects.

The methodology used to assess the teratogenicity of drugs is more complex than simply collecting certain types of data, *i.e.*, from chemical structure analysis, *in vitro* and *in vivo* studies, and re-analysis of epidemiological studies. Replicated epidemiological studies consistently finding a strong association are necessary to establish causation; chemical structure analysis and *in vitro* testing can confirm the

biological plausibility of a causal relationship suggested by epidemiology, but without an epidemiologically demonstrated association, they contribute nothing to the demonstration of causation. Animal studies can also provide evidence suggestive of causation. However, animal studies without epidemiological studies cannot prove causation in humans because drugs do not have the same effect on humans as they do on animals; the doses given to animals in animal studies are very different from those given to humans.

[*Blum v. Merrell Dow Pharmaceuticals, Inc.*, 705 A.2d 1314, 1323 (Pa.Super. 1997), *affirmed*, 564 Pa. 3, 764 A.2d 1 (internal citations omitted)].

Judge Kafrissen therefore permitted [Appellant] to utilize the animal study data for the purpose of demonstrating that one **might expect** Baycol to be myotoxic in humans even at therapeutic doses, because studies performed on animals showed such an effect;³ Judge Kafrissen properly excluded the animal study data itself, because—taken alone, without epidemiological studies—that data is simply not probative of the drug’s **actual** effect on humans.

³ This evidence was intended to demonstrate that the warnings on the Baycol label were inadequate, and not to show an actual cause-and-effect relationship.

Judge Kafrissen’s decision to limit use of the animal studies was thus correct.

(Trial Court Opinion at 4-5) (emphasis in original). The record belies Appellant’s claim. The trial court did allow Appellant to use the existence and results of the animal studies to try to establish notice of Baycol’s alleged toxicity. The specific data from the studies, however, was precluded because the data was not probative of the drug’s actual effect on humans. As the court stated: “In the face of the plain language of the Baycol label,

[Appellant] shifted the focus of [his] presentation, attempting instead to show that Baycol was riskier than other drugs of its class, that [Bayer] knew of the additional risk presented by Baycol well before the fall of 2000, and that—given such knowledge—label warnings quoted above were insufficient under the circumstances.” (*Id.* at 2). The adverse effects noted in the animal studies did not necessarily or definitively demonstrate the drug would be highly toxic to humans, because Appellant could not support his theory with evidence that tests in humans reached the same results. Moreover, the data from the animal studies were highly prejudicial in light of the strong tendency to evoke the jury’s natural sympathy for animals. Absent an offer of proof as to the probative value of the data from the animal studies, combined with the unduly prejudicial nature of the proposed evidence, we conclude Appellant’s final claim fails. Accordingly, we confirm the court’s decision to deny Appellant a new trial on the grounds stated and affirm the judgment entered on the jury verdict in favor of Bayer.

Judgment affirmed.

*JUDGE KLEIN FILES A DISSENTING MEMORANDUM.

J. A21009/06

Judgment Entered.


Prothonotary

Date: _____