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PRODUCT LIABILITY UPDATE

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Where plaintiff failed to heed product warnings, and failed to use safety devices that came with product, a non-suit was proper because plaintiff failed to prove that product was unsafe even if warnings had been followed and safety devices had been used.

Gigus v. Giles & Ransome, Inc., 868 A.2d 459 (Pa. Super. 2005)

During the course of her employment, plaintiff, Darlene Gigus, was operating an excavator which was equipped with a hydraulic hammer and tool point. Gigus was using the machinery to chop rocks when a piece of the hammer tool point broke off and flew into the cab of the excavator and struck her in the shoulder. The excavator was supplied with a safety glass windshield. At the time of the accident, however, Gigus did not have the glass windshield in place. 868 A.2d at 461.

Gigus sued Giles & Ransome, Inc., the company which rented the excavator to Gigus' employer, Caterpillar, Inc., the manufacturer of the excavator, NPK Construction Equipment, Inc., the manufacturer and distributor of the hammer, and Nippon Pneumatic Manufacturing, the manufacturer of the tool point. Her primary theory of liability was that the excavator was unsafe because it failed to include a Lexan shield and was not equipped with certain specific warnings. *Id.*

The trial court granted a nonsuit in favor of all defendants, holding that Gigus failed to offer proof that the excavator was defective. Specifically, the trial court found that Gigus did not present any evidence that the windshield of the excavator, which was made of one-quarter-inch thick laminated safety glass, would have failed to protect her had it been in place. The trial court also found that a warning sticker on the windshield of the excavator warned of the danger of flying debris and stated that the operator must be "protected by a suitable shield." The label also included a depiction of improper use of the machinery by showing a drawing of the windshield in an open position with a large red "X" over the diagram. *Id.* at 62.

On appeal, the Superior Court affirmed. The excavator came with a protective windshield and a warning notice to use the shield before operation, and Gigus conceded that she knew that the excavator should be used with the windshield in the closed position, yet she failed to heed that warning. Thus, the court held that for Gigus to prevail, she would have to prove that the product would not have been safe even if the warnings were followed and the windshield was in place. *Id.*

The court agreed with the trial court's conclusion that it was Gigus' responsibility to establish that had the windshield been in place, as required by the warnings, it would have been insufficient to protect her from the injury she ultimately sustained. However, the court found that no such evidence had been presented. The question of whether a Lexan shield would have offered greater protection, or would have been necessary for proper protection, did not need to be addressed where plaintiff failed to establish that the safety feature offered, but not used, was insufficient. *Id.* at 463.

Citing Comment j to the Restatement (Second) of Torts 402A, the court noted that the seller of a product may assume that a warning will be read and heeded. "Where a product is safe for use when its warnings are followed, it is not defective, nor unreasonably dangerous." *Id.* (citing *Fletcher v. Raymond Corp.*, 623 A.2d 845, 848 (Pa. Super. 1993)). Here, however, the plaintiff simply failed to offer any evidence that the excavator was unsafe even if its warnings had been followed and its safety features had been employed.

The court also rejected plaintiff's claims that additional warnings were necessary regarding the use of the tool point on the hard rock, hammering in excess of a certain length of time, or the use of a Lexan shield.

> Where Appellants failed to offer evidence that the warnings given and the safety feature offered, which was not used, would have failed to protect Appellant from the injury she sustained, it cannot be found that additional warnings were necessary. A manufacturer is not required to warn against dangers that may arise if the stated warnings are not heeded.

Id. (citing *Davis v. Berwind Corp.*, 690 A.2d 186, 190 (Pa. Super. 1997)).

New trial granted where expert reports summarizing heavy truck accidents were improperly admitted to show truck manufacturer's "state of mind" because plaintiff failed to establish a "substantial similarity of conditions" between the other accidents and the accident that injured the plaintiff.

Hutchinson v. Penske Truck Leasing Co., 2005 WL 1154832 (Pa. Super. 2005)

Ryan Hutchinson was seriously injured when the 18-wheel tractor trailer he was driving left the roadway, hit a guardrail, and rolled down an embankment near a ramp connecting US 130 and I-295 in New Jersey. After the accident, Hutchinson was trapped in the cab, the roof of which was crushed, for two hours. He was ultimately extricated and flown to a trauma center, where his left arm, which had protruded from the cab, was amputated. 2005 WL 1154832, * 1.

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The ramp from US 130 to I-295 had a posted speed limit of 35 m.p.h. Prior to the accident, Hutchinson had set his cruise control for 62 m.p.h. in a 55 m.p.h. zone. Hutchinson claimed that the accident occurred because of the failure of the truck's cruise control mechanism to disengage for several seconds after braking, causing the truck to travel onto the entry ramp for I-295 at too great a speed. *Id.*

Hutchinson filed suit against Freightliner L.L.C., the manufacturer and seller of the truck, Penske Truck Leasing Company, which had purchased the truck, Keystone Foods, Hutchinson's employer, which had leased the truck from Penske, and McDonald's Corporation, which had hired Keystone foods to deliver supplies.

By the time of trial, only Freightliner and Penske remained as defendants, and the only remaining claim was that of strict liability. Hutchinson set forth two theories of strict liability. First, he alleged that the cruise control mechanism was defective in two ways: It remained stuck in the on position for several seconds after application of the brakes, and there was no failsafe mechanism in place to ensure effective disengagement should the primary mechanism fail. Second, Hutchinson alleged that the structural design of the cab was defective in that it lacked sufficient crashworthiness to allow the driver to escape serious injury after a roll-over accident. *Id.*

The jury returned a verdict against both Freightliner and Penske in the amount of $5,500,000 in compensatory damages and $10,000,000 against Freightliner in punitive damages. On post-trial motions, the trial court vacated the punitive damages award, holding that it was not supported by the evidence. The trial court molded the verdict to include delay damages, yielding a total compensatory damages award of $5,974,237. *Id.*

The parties filed cross-appeals. Freightliner and Penske sought judgment n.o.v. or a new trial based on he improper admission of evidence at trial. Hutchinson appealed the trial court's order vacating the award of punitive damages.

Freightliner's primary issue on appeal was that the court improperly admitted three expert reports on heavy truck safety that provided detailed analyses and conclusions from studies of hundreds of truck accidents. Freightliner contended that these studies were improperly admitted because they did not meet the "substantial similarity" test required to admit "other accident" evidence. *Id.* at * 4.

A plaintiff in a strict liability case may rely on evidence of other, similar accidents involving the product to prove defectiveness. However, "for 'other accident' evidence to be admissible, the plaintiff must first establish that there is a 'substantial similarity of conditions' between the other accidents and the accident that injured the plaintiff." *Id.* at *2 (citing *Spino v. John S. Tilley Ladder Co.*, 671 A.2d 726, 735 (Pa. Super. 1996), *aff'd* 696 A.2d 1169 (Pa. 1997)).

The trial court agreed with Freightliner that the expert reports did not pass the substantial similarity test, and were therefore not admissible to prove a product defect. However, the court ruled that the reports were admissible to prove Freightliner's "state of mind," which was a relevant consideration with respect to the issue of punitive damages, even though the reports were not based on facts substantially similar to the facts of the present case. *Id.* at * 4.

On appeal, the Superior Court reversed, noting that the "state of mind" that Hutchinson sought to prove was nothing more or less than Freightliner's knowledge or notice of the alleged lack of crashworthiness of its cabs. *Id.* Because Hutchinson failed to present evidence as to the substantial similarity of the reports to the truck, the accident, or the circumstances of the case, the information in the reports was not directly relevant to the truck or accident at issue. The burden to prove substantial similarity rests with the plaintiff, and Hutchinson failed to carry that burden. *Id.* at * 5.

> We hold that the reports of heavy truck accident studies constitute evidence of other accidents, and therefore the substantial similarity test must be satisfied prior to their admission as evidence. We further hold that the reports did not satisfy the substantial similarity test and were therefore improperly admitted to establish defect of the product, causation, or notice or knowledge of state of mind of the defendant.

Id.

For the admission of the reports to constitute reversible error, they must have been harmful to Freightliner. *Id.* (citing *Aldridge v. Edmunds*, 750 A.2d 292, 298 (Pa. 2000)). Because plaintiff's counsel relied heavily on the reports to cross-examine two Freightliner employees, showed a figure from the report to the jury (which represented a different cab from the one involved in the accident), and referred to and quoted the reports in his closing argument, the court concluded the reports "very likely affected the jury's verdict." *Id.* at * 6. Accordingly, the court reversed and remanded for a new trial.

One interesting question was not addressed by the Superior Court: If the trial court found the expert reports to be admissible only for Freightliner's "state of mind" on punitive damages, yet subsequently vacated the award of punitive damages as being unsupported by the evidence, wasn't that an acknowledgement by the trial court that the expert reports were improperly admitted since they failed to support the sole purpose (punitive damages) for which they were purportedly admitted in the first place?

Where plaintiff's expert report relied upon OSHA and ANSI regulations, and these standards were inapplicable because defendant did not exercise "direct control" over rigging operations, expert testimony had no adequate basis in fact, was properly precluded, and summary judgment was properly granted in favor of defendant.

Kelly v. Thackray Crane Rental, Inc., 2005 WL 1039275 (Pa. Super. 2005)

Plaintiff, Joseph Kelly was an ironworker who was employed by Dy-Core of Pennsylvania, Inc. to connect pre-cast concrete planks on a hotel construction project in Philadelphia. L.F. Driscoll was the construction manager for the project. Dy-Core was the subcontractor who manufactured, delivered and installed the pre-cast concrete planks. Dy-Core rented a crane and crane operator, Arthur Andrassy, from Thackray Crane Rental, Inc. Dy-Core supplied its own patented metal clamps and rigging devices. On the ground, the clamps were attached to each end of the plank by gripping grooves on each side of the plank, and the clamps were also attached to spreader cables that were attached to the crane. 2005 WL 1039275, * 1.

Kelly was injured while attempting to guide a concrete plank into place on the

seventh floor. He noticed that a metal rod was interfering with the setting of the plank. A Driscoll employee signaled for Andrassy to move the plank away from Kelly. As Andrassy did so, Kelly bent over to reposition the rod. When he did so, the plank broke free of a clamp on the opposite side while the plank remained attached to the clamp closest to Kelly. That end dropped down and struck Kelly on the back, neck, and head at least twice before Kelly jumped down to the sixth floor to avoid being struck again by the plank. Kelly sustained injuries as result of both being struck by the plank and by his fall. *Id.*

Kelly filed suit against Thackray, Dy-Core, and Driscoll, along with other defendants. The claims against Dy-Core and Driscoll were dismissed based on the workers' compensation bar. Prior to trial, Thackray filed a Motion *in Limine* to preclude defendant's expert, Stephen Estrin, from testifying that Thackray breached its standard of care. The trial court denied this motion. After plaintiff's testimony, however, the trial court revisited the issue and preliminarily concluded that Estrin's report "was incompetent as a matter of law to establish a duty and breach thereof." After hearing arguments from the parties, the trial court vacated its prior order and granted Thackray's motion to preclude Estrin's testimony. Thackray then made an oral motion for summary judgment, which was granted by the trial court. Plaintiff appealed.

Estrin relied upon OSHA and ANSI standards to conclude that Thackray breached its standard of care. Pursuant to the OSHA standard at 29 C.F.R. § 1926.550(b)(2), all crawler, truck, or locomotive cranes "shall meet the applicable requirements for design, inspection, construction, testing, maintenance and operation as prescribed in ANSI B30.5-1968, Safety Code for Crawler, Locomotive and Truck Cranes." The ANSI standard states:

> The operator shall be responsible for those operations under his direct control. Whenever there is any doubt as to safety, the operator shall have the authority to stop and refuse to handle loads until safety has been assured.

ANSI B.30.5-3.1.2(d)-1968. *Id.* at * 3.

At issue was the term "direct control" in the ANSI regulation. The trial court concluded that Thackray and the crane operator, Andrassy, did not have direct control over the rigging operation. Dy-Core chose the rigging mechanism and supplied it. Driscoll approved the rigging mechanism. Dy-Core employees attached the clamps to the planks, removed the clamps, and acted as signalmen to Andrassy. Because Thackray and Andrassy did not exercise "direct control" of the rigging and hoisting operation, the OSHA and ANSI regulations were not applicable. Having relied on those standards in reaching his opinions, Estrin's expert testimony was not based on adequate factual testimony and was therefore inadmissible. *Id.*

In affirming, the Superior Court relied found the reasoning of a 5th Circuit case to be persuasive. In *Melerine v. Avondale Shipyards, Inc.*, 659 F.2d 706, 713 n. 21 (5th Cir. 1981), the only case that discussed the ANSI standard, the Fifth Circuit found that a violation of the standard would not establish negligence because it applied only "to crane operations 'under direct control' of the crane operator" and that the trial judge determined that the operation was under the supervision of another subcontractor. *Id.*

The court also rejected Kelly's argument that the question of whether Andrassy exercised direct control of the rigging operation should have been decided by a jury. The trial court must decide whether expert testimony relies upon an adequate basis in fact. *Id.* at * 4 (citing *Kravinsky v. Glover*, 396 A.2d 1349 (Pa. Super. 1979)). Here, the dispute centered around the interpretation of the ANSI regulation, not a particular fact. Thus, the issue was whether Thackray and Andrassy owed a duty to Kelly under the ANSI regulation. The existence of a duty is a question of law for the court to decide, a point that plaintiffs themselves argued. *Id.* (citing *Sharpe v. St. Luke's Hospital*, 821 A.2d 1215 (Pa. 2003)). Thus, in order for the court to determine the relevance of Estrin's testimony, the trial court had to decide whether Thackray and Andrassy owed a duty to Kelly under the ANSI standard. Only if the trial court found that such a duty existed would Estrin's testimony be relevant for a jury to determine whether that duty had been breached. Thus, the court conlcluded that the trial court was well within its province in determing whether Estrin's use of the OSHA and ANSI standards were an adequate basis of fact upon which to base his expert testimony. *Id.*

Because the Kelly's relied solely on Estrin's testimony to establish Thackray's standard of care and causation, there was no genuine triable issue of fact once that testimony was precluded. Thus, the trial court properly granted Thackray's motion for summary judgment.

Summary judgment granted in favor of diet drug manufacturer on plaintiff's failure to warn claim due to lack of causation where plaintiff's treating physician testified that he still would have prescribed drug to plaintiff even had a warning for valvular heart disease been given.

Lineberger v. Wyeth, 2005 WL 1274458 (Phila. 2005)

Patricia Lineberger filed a Phen-Fen mass tort action alleging that she developed aortic and mitral valve regurgitation from her ingestion of two diet drugs, Pondimin and Redux, which were manufactured by the defendant, Wyeth. Lineberger alleged that her injuries were caused by Wyeth's failure to warn of the association between these diet drugs and heart valve damage. 2005 WL 1274458, * 1.

Wyeth moved for summary judgment, arguing that Lineberger was unable to prove that a different warning regarding the association between the ingestion of the diet drugs and valvular heart disease would have prevented her physician from prescribing those drugs for her. Wyeth further argued that without such evidence that an additional warning would have caused her physician to alter his prescribing practices, Lineberger was unable to establish that Wyeth's failure to warn was the proximate cause of her alleged injuries. The Honorable Norman Ackerman of the Philadelphia Court of Common Pleas agreed with Wyeth's position and granted summary judgment in their favor. *Id.*

In beginning his analysis, Judge Ackerman noted that while the manufacturers of potentially dangerous drugs are held to a high degree of care, Pennsylvania courts have repeatedly refused to impose strict liability on manufacturers of prescription drugs. "Where the adequacy of warnings associated with prescription drugs is an issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Id.* at * 2 (citing *Hahn v. Richter*, 673 A.2d

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888, 891 (Pa. 1996)). Thus, a "manufacturer [of prescription drugs] is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Id*. (quoting *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984)).

The duty to warn however runs not to the patient or the general public, but to the prescribing physician. "Since the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." *Id.* (quoting *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971)). Under the so-called "learned intermediary doctrine," the prescribing physician must balance the risks of a particular drug against the utility of its use. "The warnings are directed to the prescribing physician who must make that balancing judgment in light of his personal knowledge of the patient's medical history." *Id*. (quoting *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 458 (Pa. Super. 1973)).

To prevail on a failure to warn claim, a plaintiff must not only establish a duty and a failure to warn, but must further establish proximate causation "by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Id*. (Quoting *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996)).

Applying the foregoing standards, Judge Ackerman concluded that Lineberger was unable to establish proximate causation between Wyeth's failure to warn and her alleged injuries. He cited the testimony of Lineberger's physician, Dr. John Lafferty. Dr. Lafferty admitted that, even if the words "valvular heart disease" had been listed among the possible side effects of the diet drugs, he still would have prescribed it to Lineberger. Dr. Lafferty further testified that he specifically chose Lineberger to be included among a group of patients that he personally felt were good candidates for the diet drug therapy. Dr. Lafferty's deposition testimony was also supported by his affidavit, wherein he unequivocally stated "even if the words 'valvular heart disease' had been added to the 'Warnings' section of the label of the Physician's Desk Reference while Pondimin and/or Redux were still on the market, I probably would have prescribed both drugs depending on the level of risk."

Judge Ackerman also rejected Lineberger's argument that she was entitled to a rebuttable presumption that either she or Dr. Lafferty would have followed an adequate warning had Wyeth provided one. Judge Ackerman reiterated that a drug manufacturer's duty to warn runs to the physician not the patient. He also stated that the so-called "heeding presumption" was not applicable in this case since it had been applied exclusively to strict liability claims. As Judge Ackerman noted earlier in his opinion, negligence is the only recognized basis of liability for failure to warn for manufacturers of prescription drugs.

This case is currently on appeal to the Pennsylvania Superior Court.

Summary judgment granted in favor of diet drug manufacturer on plaintiff's failure to warn claim due to lack of causation where plaintiff's treating physician died during the pendency of the case, without having given any testimony that he would not have prescribed drug to plaintiff had a warning for valvular heart disease been given.

Anderson v. Wyeth, 2005 WL 1383174 (Phila. 2005)

Mary Anderson filed a Phen-Fen Mass Tort Action against Wyeth alleging that she developed mitral and aortic valve regurgitation, aortic insufficiency and pulmonary hypertension resulting in mitral and aortic valve replacement surgery and stroke, all from her ingestion of diet drugs, Pondimin, Redux, and Adipex/Phentermine, which were manufactured by Wyeth. The basis of her action was that Wyeth failed to warn of the association between diet drugs and heart valve damage was the cause of her injuries. 2005 WL 1383174, * 1.

Anderson's treating physician was Dr. A.B. Husky, who died 10 months after the litigation began, without ever being deposed. Plaintiff testified that Dr. Husky told her at some point that "he was cut off" and that he could no longer prescribe the diet drugs for her. There was, however, no other testimony or evidence regarding Dr. Husky's prescription of the diet drugs, or his decision to discontinue doing so. Accordingly, Wyeth moved for summary judgment, arguing that without evidence that a warning of valvular heart disease would have caused her physician to alter his prescribing practices, Anderson was unable to establish that Wyeth's failure to warn was the proximate cause of her injuries. This motion was granted by the Honorable Norman Ackerman of the Philadelphia Court of Common Pleas. *Id.*

Under the "learned intermediary doctrine," Anderson needed to show that had her physician, Dr. Husky, received a different warning regarding the association between diet drugs and valvular heart disease, he would have altered his prescribing habits, and the alleged injury would have been avoided. *Id.* at * 3.[1]

Anderson submitted an affidavit of William H. Pentz, M.D., who testified that:

> a reasonable physician who was properly warned of the significant risk of valvular heart disease would look to other treatment options for the management of obesity. Further, a reasonable physician would engage in a thorough cardiac evaluation of the patient prior to prescribing this drug, and warn the patient of the dire consequences of taking the drug.

Id. at * 2. Judge Ackerman rejected this argument, holding that an affidavit as to what a "reasonable physician" would have done with appropriate knowledge was inadmissible, irrelevant, and contrary to proper legal standard in Pennsylvania. *Id.* at * 6.

> The evidence of *sufficient weight to establish a reasonable likelihood* is evidence that the learned intermediary, Dr. Husky, and *only* Dr. Husky, would provide to the effect that *he, Dr. Husky*, would have altered *his* behavior. That is the *express* language of *Demmler.*

Id. at * 5 (citing *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996)) (emphasis in original).

As he did in *Lineberger*, Judge Ackerman also rejected plaintiff's argument that she would have followed an adequate warning from Wyeth had one been provided. The heeding presumption only applies in strict liability cases, and negligence is the only recognized basis of liability for failure to

warn for manufacturers of prescription drugs. *Id.* at * 6 (citing *Incollingo v. Ewing*, 282 A.2d, 206, 219 (Pa. 1971)).

Finally, Judge Ackerman rejected plaintiffs' argument that because Wyeth "completely" failed to provide "adequate warnings to the medical community," no prescribing physician would have had accurate or sufficient information about the connection between Pondimin and valvular heart disease. Thus, there could be no "learned intermediary." Judge Ackerman noted that a "learned intermidiary" is "learned" because of his own training and experience, not because of information from obtained from a pharmaceutical manufacturer. Thus, the learned intermediary doctrine remained in force. *Id.* at * 7.

This case is currently on appeal to the Pennsylvania Superior Court.

New trial on liability granted to diet drug manufacturer where plaintiff's expert did not explain on direct examination the factual grounds upon which his opinions were based, thereby failing to comply with Pa. R.E. 705.

Hansen v. Wyeth, Inc., 2005 WL 1114512 (Phila. 2005)

In consolidated cases, Lucy Hansen, Mildred Hill, and Joyce Jensen alleged that defendant Wyeth failed to "respond to a signal" that the diet drug Pondimin causes valvular regurgitation. The plaintiffs each claimed that as a result of this failure, Wyeth failed to warn their prescribing physician of the risks of using that drug. A Philadelphia jury awarded Hansen $400,000, Hill $395,000, and Jensen $560,000. On post-trial motions, the Honorable Mark I. Bernstein granted Wyeth a new trial on liability only. 2005 WL 1114512, * 1.

At issue was the testimony of plaintiff's expert, Dr. Harris Busch, who asserted throughout his testimony that Wyeth missed a "signal" that the diet drug Fen Phen (of which Pondimin or fenfluramine is a part) caused valvular heart disease. Judge Bernstein concluded, however, that Dr. Busch's testimony failed to comply with Pa. R.E. 705, which requires an expert to testify as to the facts or data on which his testimony is based. Although Dr. Busch offered "a number of purportedly scientific bases for his opinion," Judge Bernstein held that many of these bases upon which he supposedly relied were "illogical, inapplicable, or employed circular reasoning." In addition, plaintiffs had failed to supply him with information that he specifically requested. *Id.* at * 10.

The first half of Judge Bernstein's opinion is a lengthy and scholarly dissertation on the meaning of Pa. R.E. 705. Pursuant to Rule 705:

> The expert may testify in terms of opinion or inference and give reasons therefore; however, the expert must testify as to the facts or data on which the opinion or inference is based.

The Federal counterpart to Rule 705 reads to the contrary:

> The expert may testify in terms of opinion or inference and give reasons therefore without first testifying to the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Pennsylvania has rejected the Federal approach by requiring the proponent of expert testimony to introduce on *direct* examination the underlying facts that support the opinion. By contrast, the Federal approach places the burden on the cross-examiner to probe the basis of the expert's opinion.

> "[R]elying on cross-examination to illuminate the underlying assumptions may further confuse jurors already struggling to follow complex testimony. Additionally, total reliance on cross-examination permits the party propounding the expert evidence to introduce it generally in a conclusory manner without relation to the record and cast the whole burden of disqualifying it on the opponent. This is contrary to the usual practice of allocating to the proponent of evidence, as the party with the laboring [oar] the duty of laying a logically understandable foundation."

Id. at * 2 (quoting *Kozak v. Struth*, 531 A.2d, 420, 423 (Pa. 1987))

Thus, Rule 705 contains three distinct requirements: (1) The factual basis must be explained by the expert in direct examination; (2) the factual basis must be independently "of record;" and (3) the expert cannot bootstrap an opinion by "adding" facts to the record by way of assumptions about which the expert has no independent knowledge. *Id.* at * 9.

Although Judge Bernstein determined that Dr. Busch was well-qualified to render an opinion, he held that the expert testimony failed to comply with Rule 705 in several signficant respects. First, Dr. Busch received only limited material that had been prescreened by plaintiffs' attorneys. Dr. Busch also requested, but did not receive, specific material that was available through discovery. *Id.* at * 10-11.

Second, Dr. Busch's testimony was improperly based on "the entire record." Although he claimed to have reviewed 20 depositions, internal documents, adverse drug events reports, and undertaken a complete medical literature search, these factual bases were presented to the jury in summary form, without citation to any specific facts. *Id.* at * 11.

Third, Dr. Busch testified without any factual basis that the Wyeth Surveillance Department was inadequate. Although Dr. Busch estified that the entire surveillance department was not adequately staffed, trained, or qualified to their task, he conceded that he had no factual basis for this conclusion "beyond the circular logic that they were unqualified because the missed the 'signal' which only Dr. Busch could discern." *Id.*

Fourth, Dr. Busch testified in a conclusory manner that the medical literature describing the connection between valvular heart disease and serotonin should have put Wyeth on notice of Fen-Phen's dangerous propensities. However, Dr. Busch conceded on cross-examination that everyone has serotonin in their bodies and that the medical literature confirmed that fenfluramine drugs caused very little change in the serotonin levels. *Id.* at * 14

Fifth, although Dr. Busch testified about adverse drug event reports received by Wyeth which were "reports of patients ingesting Fenfluramine and developing heart disease," the direct examination focused on all reports which contained any notation of Fenfluramine and valvular heart disease without regard to whether there was a causal link between the two. Dr. Busch was never asked on direct examination whether any adverse drug events report actually demonstrated that valvular heart disease was caused by Fenfluramine. *Id.* at * 15.

Finally, Dr. Busch testified on direct examination that he had performed an

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extensive literature search which formed the basis of his opinions on Pondimin. On cross-examination, however, he acknowledge that this literature search was limited. *Id.* at * 18.

Judge Bernstein concluded that Dr. Busch may have had a scientific, medical, and factual basis for his opinions, but it was never explained to the jury. If he did have such a basis, plaintiffs should not be precluded from proving their case. Thus, the clear violation of Rule 705 did not warrant judgment n.o.v., but did warrant a new trial on liability. *Id.* at * 19.

ENDNOTES

1 Judge Ackerman's subsequent legal analysis of the learned intermediary doctrine and the duty owed by drug manufacturers was virtually identical to that set forth in his opinion in *Lineberger v. Wyeth*, which was decided 15 days earlier.