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ALLEN TRACH, Appellant v. J. FELLIN AND THRIFT DRUG/ECKERD STORE, THRIFT DRUG, INC. AND ECKERD DRUG CO.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1921 Eastern District Appeal 2000

Appeal from the Order Entered May 18, 2000,
in the Court of Common Pleas of Lehigh County
Civil Division, No. 97-C-1535

ALLEN TRACH v. THRIFT DRUG, INC. (J. FELLIN, THRIFT DRUG/ECKERD DRUG STORE, AND ECKERD DRUG CO.), Appellants	:	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 1949 Eastern District Appeal 2000

Appeal from the Order Entered May 18, 2000,
in the Court of Common Pleas of Lehigh County
Civil Division, No. 97-C-1535

BEFORE: DEL SOLE, P.J., FORD ELLIOTT, JOYCE, STEVENS, MUSMANNO, ORIE MELVIN, LALLY-GREEN, KLEIN, AND BENDER, JJ.

OPINION BY FORD ELLIOTT, J.: Filed: February 11, 2003

¶ 1 We granted ***en banc*** review in this case in order to reevaluate the circumstances under which a party seeking to exclude expert scientific

evidence may test the admissibility of that evidence pursuant to ***Frye v. United States***, 293 F. 1013 (D.C. Cir. 1923). In the process, we are required to revisit several recent panel decisions of this court to determine whether we have extended ***Frye*** beyond the parameters our supreme court has established, keeping in mind that ***Frye*** is an exclusionary rule of evidence. As such, it must be construed narrowly so as not to impede admissibility of evidence that will aid the trier of fact in the search for truth. ***See*** Pa.R.E. 702, 42 Pa.C.S.A. ("If scientific, technical or other specialized knowledge beyond that possessed by a layperson will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise[]"). ***See also id.*** at Comment--1998 (noting that Rule 702 does not alter Pennsylvania's adoption of the ***Frye*** standard; also noting that the Rule does not change the rule for qualifying a witness as an expert enunciated in ***Miller v. Brass Rail Tavern, Inc.***, 541 Pa. 474, 480-481, 664 A.2d 525, 528 (1995) (holding, "The test to be applied . . . is whether the witness has any reasonable pretension to specialized knowledge on the subject under investigation. If he does, he may testify and the weight to be given to such testimony is for the trier of fact to determine.")).

¶ 2 In this case, the trial court vacated the jury's verdict of $5 million and granted Thrift Drug, Inc. a new trial as to damages, having determined that

it erred when it allowed Allen Trach's scientific expert to testify. Thrift Drug challenged the expert's methodologies and conclusions, claiming neither had been generally accepted in the scientific community. After a thorough analysis of the circumstances under which a party may invoke ***Frye*** to exclude expert testimony, however, we are constrained to conclude that the trial court erred when it vacated the jury's verdict because Trach allegedly failed to establish a causal connection between Trach's long-term medical problems and Thrift Drug's negligence.

¶ 3 The facts of this case are not in dispute. Allen Trach ("Trach"), a healthy, 47-year-old man, went to his dentist on July 11, 1995, complaining of pain in his jaw. The dentist, suspecting an infection, gave Trach a prescription for forty 250-mg. capsules of Amoxil, an antibiotic, which Trach then took to a Thrift Drug Store pharmacy to fill. A pharmacy assistant mistakenly gave Trach 29 capsules of the antidepressant Doxepin, and told him to return for the remaining 11 capsules in a few days, as the pharmacy did not have 40 capsules in stock.

¶ 4 Doxepin has the potential to cause serious adverse reactions in individuals who take it in the recommended dosage. Trach, however, took the Doxepin according to the dosage his dentist prescribed for Amoxil, for

which the dosage was appropriate.[1] According to Trach's expert's report, Trach took 1,800 milligrams ("mg.") of Doxepin on the first day. (Expert report of John J. Shane, M.D. ("Shane's expert report"), citing Physician's Desk Reference ("PDR") for Doxepin, R. at 31 Exhibit A.) The recommended optimal dose range for Doxepin is between 75 mg. and 150 per day, while the maximum recommended dose is 300 mg. per day. Physicians' Desk Reference ("PDR") at 2408 (53rd ed. 1999).[2]

¶ 5 When Trach immediately experienced side effects, including visual symptoms, he consulted his physician, who diagnosed the problem as trigeminal neuralgia, but did not believe it was a side effect of the antibiotic. (Plaintiff's complaint at 3 ¶ 12, R. at 7.) Trach subsequently developed a sore throat, and, believing the sinus infection caused it, took an additional ten capsules of Doxepin over the next 24 hours. (***Id.***) Despite suffering hallucinations, heartburn, confusion, and extreme difficulty concentrating, Trach continued to take the medication until, according to Dr. Shane, he had consumed 4,800 mg. of Doxepin over a five-day period. (Shane's expert report at 1.)

[1] The prescription called for Trach to take two 250 mg. capsules of the antibiotic four times per day, or 2,000 mg. per day. Testimony presented at trial indicated that the Doxepin capsules the pharmacy assistant gave Trach were 150 mg. capsules. (Notes of testimony, 6/16/99 at 184.)

[2] While slight discrepancies existed between Dr. Shane's report and his testimony at trial as to the exact amount of Doxepin Trach took, no one disputed that it was a massive overdose.

¶ 6 On July 18, Trach returned to Thrift Drug to pick up the remainder of the prescription, and his wife noticed that the 11 new pills were different from the original 29. She called the pharmacy, and upon investigation, the pharmacist stated that Trach had been given the wrong medication initially, an antidepressant called Doxepin. Trach then went to the hospital for testing. (Trial court opinion, 5/18/00 at 5.) While most of Trach's reactions to the Doxepin subsided within a month, he continues to experience cognitive difficulties, cluster headaches, and vision problems.

¶ 7 In March of 1996, eight months after the Doxepin overdose and following repeated efforts to determine the nature of Trach's problems with his vision, Trach was diagnosed with glaucoma. (Notes of testimony, 6/17/99 at 138.) Mark E. Moran, D.O., the ophthalmologist who treated Trach's glaucoma, described it as "chronic open-angle glaucoma or even more specifically pigmentary glaucoma." (***Id.*** at 116.) Additionally, Trach has a crescent-shaped blind spot, known as an arcuate scotoma, in his right eye as a result of optic nerve damage from the glaucoma. The damage to his eyesight is permanent and affects his ability to read and to engage in the hobbies of photography and hunting that he previously enjoyed. He is also concerned that he may not be able to retain his job because of his vision and cognitive problems.

¶ 8 According to the PDR, adverse reactions to Doxepin when taken in the ***recommended*** dosage may include blurred vision, confusion, disorientation,

and hallucinations. The PDR also indicates that death or coma may result from an overdose of Doxepin, as well as confusion, disturbed concentration, transient visual hallucination, dilated pupils, and other serious consequences. Additionally, one of Thrift Drug's medical experts, Michael Naidoff, M.D., an ophthalmologist, acknowledged that Doxepin can cause narrow or closed-angle glaucoma in susceptible individuals. (Deposition of Michael A. Naidoff, M.D. ("Naidoff deposition"), 6/8/99 at 25, Defendant's Exhibit 4.) For obvious reasons, however, no one has conducted studies to determine the effects of a massive overdose of Doxepin such as the dose Trach took; therefore, no studies exist indicating that a massive overdose can cause open angle or pigmentary glaucoma, the form of glaucoma from which Trach continues to suffer. Similarly, no studies exist indicating that the usually transient side-effects of Doxepin, such as unsteadiness, confusion, poor memory, cluster headaches, and inability to concentrate, of which Trach still complains, can become permanent when an individual takes a massive overdose of Doxepin.

¶ 9 To support his claim that the Doxepin overdose caused the cognitive and vision problems he continues to experience, Trach proffered expert testimony from a board-certified pathologist and toxicologist, Dr. John Shane. Prior to trial, Thrift Drug filed a motion ***in limine*** to preclude Dr. Shane's testimony, claiming it did not meet the requirements for scientific expert evidence set forth in ***Frye***, ***supra***, and its progeny in

Pennsylvania (the ***Frye*** test). ***See***, ***e.g.***, ***Commonwealth v. Blasioli***, 552 Pa. 149, 713 A.2d 1117 (1998); ***Commonwealth v. Crews***, 536 Pa. 508, 640 A.2d 395 (1994); and ***Commonwealth v. Topa***, 471 Pa. 223, 369 A.2d 1277 (1977), the case in which our supreme court adopted the ***Frye*** test. ***See also Blum v. Merrell Dow Pharmaceuticals, Inc.***, 705 A.2d 1314 (Pa.Super. 1997), ***affirmed***, 564 Pa. 3, 764 A.2d 1 (2000). The trial court denied Thrift Drug's motion.

¶ 10 Dr. Shane was Trach's only expert witness on the issue of causation. The trial court in its opinion summarized Dr. Shane's expert testimony as follows:

> Doxepin is a tricyclic antidepressant. . . Doxepin works by blocking the amine pump that transmits nerve impulses across synapses, the junction points at which nerve cells hook up with each other. The transmission of nerve impulses across synapses depends on an intact chemical environment. Doxepin interferes with this environment by blocking the transmission of the chemical acetylcholine. This blocking action is known as an anticholinergic effect. There may be adverse reactions or side effects from even a therapeutic dose of Doxepin. There are also contraindications for Doxepin, i.e., symptoms or conditions that may be exacerbated by the drug. The known side effects and contraindications have been determined through clinical trials prior to approval of the drug by the Federal Food and Drug Administration (the 'FDA') and also from clinical experience since the drug has been on the market. The side effects and contraindications for a therapeutic dose of Doxepin are identified in the manufacturer's insert and in the Physician's Desk Reference (the 'PDR'). The manufacturer's insert is included with each package of a drug that has been approved for marketing by the FDA. The PDR is a

> compilation of drugs that are available for the treatment of patients. It is considered authoritative and is relied on regularly by physicians in prescribing drugs to patients. . . The symptoms experienced by Trach after ingesting Doxepin are consistent with the adverse reactions identified in the manufacturer's package insert and in the PDR. These adverse reactions or side effects included ataxia (unsteadiness on his feet), dizziness, blurred vision and disorientation. . . Glaucoma is a condition of increased ocular pressure in the eye that causes pathologic change to the eye. It may result in damage to the optic nerve that is irreversible, and in some cases, loss of vision. Both the manufacturer's insert and the PDR state that Doxepin is contraindicated for glaucoma. This is for two reasons. First, the anticholinergic effect of Doxepin causes the pupils of the eye to dilate unequally, a condition known as mydriasis. Second, the anticholinergic effect also causes the ciliary muscle of the eye to become inactive, a condition referred to as cycloplegia. . . The combination of mydriasis and cycloplegia leads to blurred vision. It also leads to changes in the eye, specifically a blockage of the Canal of Schlemm, a circulatory channel between the front chamber and back chamber of the eye. The result is increased pressure in the eye. In addition, the dilation of the iris, the colored part of the eye, causes pigmentary loss. The pigment is deposited in the filter system at the Canal of Schlemm, further clogging up the filter and also causing increased pressure in the eye. The combination of mydriasis and cycloplegia is a mechanism that leads to narrow-angle glaucoma, sometimes referred to as closed-angle glaucoma. However, the distinctions between narrow or closed-angle glaucoma and open-angle glaucoma are often confused in the medical profession. Consequently, some authorities have recommended that the nomenclature be changed to eliminate the distinction. . .

Trial court opinion, 5/18/00 at 7-9, citing notes of testimony, 6/16/99 at 168-251.

¶ 11 Further, Dr. Shane testified to a reasonable degree of toxicological certainty that all the symptoms Trach suffered immediately after ingesting the Doxepin, and his continuing symptoms, including the glaucoma and scotoma and various cognitive problems, are the direct result of the overdose of Doxepin. (Notes of testimony, 6/16/99 at 208-215.) At the close of all the evidence, Thrift Drug moved to strike Dr. Shane's testimony in its entirety; however, the trial court denied the motion.[3] As noted ***supra***, Trach also called Dr. Moran, the ophthalmologist who has been treating Trach for his eye problems and who referred Trach to various specialists, one of whom finally diagnosed glaucoma. Dr. Moran did not testify as to causation, however. (Notes of testimony, 6/17/99 at 114-148.)

¶ 12 In response to Trach's expert testimony, Thrift Drug offered the testimony of two experts; Dr. Naidoff, the ophthalmologist mentioned

[3] Trach argues that Thrift Drug waived its ***Frye*** challenge when it failed to object to Shane's testimony during trial, instead waiting until the close of all the evidence to move for a nonsuit, a directed verdict, or to strike Dr. Shane's testimony in its entirety. We note, however, that Pa.R.E. 103(a)(1) provides that when a litigant challenges the admission of evidence, the issue is preserved if there is "a timely objection, motion to strike or motion in limine stating the specific ground of objection." The Comment to the Rule further states: "A ruling on a motion in limine on the record is sufficient to preserve the issue for appeal, without renewal of the objection or offer at trial."

Nevertheless, we agree with Trach that it is questionable whether Thrift Drug's ***Frye*** challenge in this case comports with established procedure because Thrift Drug's limited challenge to Dr. Shane's expert report in its motion ***in limine*** did not support a motion to strike Dr. Shane's testimony in its entirety, especially at the close of ***all*** the evidence. We therefore do not condone the ***manner*** in which Thrift Drug raised and preserved its ***Frye*** challenge, and caution counsel against using such a procedure in the future. We will, however, address the issue in this case.

earlier, who regularly treats glaucoma patients and who had examined Trach's medical records but had never examined Trach; and Richard I. Katz, M.D., a board-certified neurologist who, like Dr. Naidoff, had only examined Trach's medical records. Dr. Naidoff, through his videotaped deposition, testified that while Doxepin can cause closed-angle glaucoma, there is nothing in the medical literature indicating it can cause the type of glaucoma from which Trach suffers, of which the cause is unknown. (Naidoff deposition, 6/8/99 at 14-24.) Dr. Katz testified that Trach's neurological symptoms would have subsided within a month, and that Trach's medical records indicated no objective signs of neurological damage, instead indicating that he was neurologically normal. (Notes of testimony, 6/16/99 at 252-315.)

¶ 13 As noted ***supra***, at the close of the evidence, Thrift Drug moved for a compulsory nonsuit, a directed verdict, or a motion to strike Dr. Shane's testimony. Instead, the trial court directed a verdict in Trach's favor as to negligence and sent to the jury the issue of damages. The jury returned a verdict in favor of Trach in the amount of $5 million. Thrift Drug then filed a post-trial motion requesting judgment n.o.v. or, in the alternative, a new trial, arguing that the trial court should not have admitted Dr. Shane's testimony. The trial court denied Thrift Drug's motion for j.n.o.v. but granted a new trial as to damages only, agreeing that Dr. Shane's causation testimony as to the long-term effects of Doxepin did not meet the standard

required by ***Frye***. (Trial court opinion, 5/18/00 at 33.) Both parties filed appeals, Trach claiming trial court error in ordering a new trial as to damages on the basis that Dr. Shane's testimony as to the long-term effects of Doxepin did not pass the ***Frye*** test; and Thrift Drug claiming trial court error in not granting a j.n.o.v. as to Trach's long-term injuries, and/or a new trial as to both causation and damages because Dr. Shane's allegedly inadmissible testimony prejudiced Thrift Drug. (Trach's brief at 4; Thrift Drug's brief at 1.)

¶ 14 We first note our standard of review in this appeal from the grant of a new trial. Where, as here, the trial court set forth the specific basis for its grant of a new trial, we consider whether the court abused its discretion or committed an error of law in its decision on that stated basis only. ***Coker v. S.M. Flickinger Co***., 533 Pa. 441, 449-450, 625 A.2d 1181, 1185-1186 (1993). Therefore, we consider only whether the trial judge erred in ordering a new trial as to damages on the basis that a portion of Trach's ***causation*** evidence did not meet the ***Frye*** test and was improperly admitted at trial.[4]

[4] We recognize that Thrift Drug challenged both Dr. Shane's conclusions and his methodology, and the trial court addressed both in its May 18, 2000 opinion. Nevertheless, the trial court granted a new trial solely on the basis of Dr. Shane's causation testimony. (***See*** trial court opinion, 5/18/00 at 33; trial court opinion, 8/18/00 at 1-2.) Because we find that Dr. Shane's conclusions and his methodology are inextricably intertwined, however, we will address both.

¶ 15 We first consider the circumstances under which our supreme court has analyzed the admissibility of evidence pursuant to ***Frye***. We begin with the observation that ***Frye***, by definition, only applies where expert testimony is required. ***Frye***, 293 F. at 1014 ("'When the question involved does not lie within the range of common experience or common knowledge, but requires special experience or special knowledge, then the opinions of witnesses skilled in that particular science . . . are admissible in evidence'"), quoting brief for the United States.

¶ 16 A review of our supreme court's application of ***Frye*** over the past twenty-five years also supports the proposition that ***Frye*** only applies when a party seeks to introduce ***novel*** scientific evidence. ***See Blasioli***, ***supra*** at 153, 713 A.2d at 1119 ("In determining whether ***novel*** scientific evidence is admissible . . . , Pennsylvania courts apply the test set forth in ***Frye*** . . . .") (emphasis added). ***See also Topa***, ***supra***, a case involving novel scientific methodology. Thus, ***Frye*** does not apply every time science enters the courtroom.

¶ 17 The supreme court reaffirmed the proper application of ***Frye*** when it adopted Pa.R.Civ.P. 207.1, "Motion to Exclude Expert Testimony Which Relies upon Novel Scientific Evidence." Pa.R.Civ.P. 207.1, 42 Pa.C.S.A., adopted 2001, January 22, 2001, effective July 1, 2001. As the explanatory comment to that Rule states, "The purpose of new Rule 207.1 is to provide the procedure for pre-trial motions concerning the admissibility of expert

testimony which relies upon novel scientific evidence." ***Id.***, Explanatory Comment—2001.[5]

¶ 18 We are therefore concerned with this court's pronouncement in ***Blum***, ***supra***, in which a panel of this court opined that ***Frye*** applies "***whenever science enters the courtroom***, because 'there is the danger that the trial judge or jury will ascribe a degree of certainty to the testimony of the expert . . . which may not be deserved.'" ***Blum***, 705 A.2d at 1317 (emphasis added), quoting ***Topa***, ***supra*** at 230, 369 A.2d at 1281. ***See also Commonwealth v. Rodgers***, 605 A.2d 1228, 1234 (Pa.Super. 1992) (stating, "Before scientifically adduced evidence may be considered admissible, it must first be shown that it meets the standard established in ***Frye*** . . .").[6]

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[5] Rule 207.1 did not take effect until after the trial in this case; however, it clearly indicates the state of the law in Pennsylvania.

[6] We note additionally that the Supreme Court in ***Daubert v. Merrell Dow Pharmaceuticals, Inc.***, 509 U.S. 579 (1993), although abandoning the ***Frye*** test as having been superseded by the Federal Rules of Evidence, nevertheless observed:

> Although the ***Frye*** decision itself ***focused exclusively on*** '***novel*' *scientific techniques***, we do not read the requirements of Rule 702 to apply specially or exclusively to unconventional evidence. Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended. Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Federal Rules of Evidence 201[]").

Id. at 592 n.11 (emphasis added). Thus, even though the ***Daubert*** court abandoned ***Frye***, it recognized that ***Frye*** was limited to novel scientific evidence.

¶ 19 In both ***Topa***, ***supra***, and ***Rodgers***, ***supra***, however, the cases upon which a panel of our court relied in ***Blum***, ***supra***, the statements regarding the necessity for applying the ***Frye*** standard every time science enters the courtroom involved novel scientific methodology; in ***Topa***, the methodology was spectrography, or voice print analysis; in ***Frye***, the novel methodology was a systolic blood pressure deception test, which was alleged to determine whether an individual was telling the truth. Likewise, ***Rodgers*** involved DNA/RFLP[7] analyses performed on bloodstains found on the victim's and Rodgers' clothing. Thus, in the context of those cases, the court stated that ***Frye*** applied because the scientific methodology was novel. Clearly, however, our supreme court did not intend that trial courts be required to apply the ***Frye*** standard every time scientific experts are called to render an opinion at trial, a result that is nothing short of Kafkaesque to contemplate.

¶ 20 We, like the dissent, are aware that ebb and flow are at the heart of the scientific method: the theory of relativity is only valid until someone

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Our supreme court, which so far has not abandoned the ***Frye*** test in favor of the ***Daubert*** analysis, granted allocatur in ***Grady v. Frito-Lay, Inc***., 789 A.2d 735 (Pa.Super. 2001) (***en banc***), to address the issue whether the ***en banc*** panel of this court correctly applied the law when it reversed the decision of the trial court to preclude [plaintiff's] expert testimony. ***Grady v. Frito-Lay, Inc.***, 569 Pa. 46, 800 A.2d 294 (2002) (***per curiam***). The supreme court also directed the parties to address the effect of both ***Frye***, ***supra***, and ***Daubert***, ***supra***, on the analysis of this issue. ***Id.*** We suspect that our decision here today will ultimately travel the same route.

[7] DNA/RFLP signifies "deoxyribonucleic acid restriction fragment length polymorphism." ***Rodgers***, 605 A.2d at 1234-1235.

disproves it. As the ***Frye*** court so elegantly stated, however, "While courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." ***Frye***, 293 F. at 1019. In this single, simple sentence, the ***Frye*** court recognized that the essence of admissibility is general acceptance: that a principle or discovery can fall by the wayside as science advances is just another way of saying it is not generally accepted. We therefore conclude that we are merely stating the law in Pennsylvania when we state that ***Frye*** applies only to novel science.

¶ 21 Having delineated two prerequisites for applying ***Frye***, that expert scientific evidence is being offered and that the scientific evidence is, in some sense, novel, we must next ask what it is that must be novel about the science. We note recent cases from this court and from our sister court holding that the ***Frye*** standard applies when either the methodology the scientist uses ***or*** the conclusion the scientist reaches is novel. ***See Blum***, 705 A.2d at 1322 (opining, "A close reading of the relevant cases yields two ways to analyze the question of whether the causation testimony proffered in this case meets the ***Frye***/***Topa*** standard. One focuses on whether the causal relationship is generally accepted by the scientific community, and the other on whether the methodology is generally accepted by the scientific community[]").

¶ 22 The panel of this court deciding ***Blum***, ***supra***, relied on ***McKenzie v. Westinghouse Elec. Corp.***, 674 A.2d 1167 (Pa.Commw. 1996), ***appeal denied***, 547 Pa. 733, 689 A.2d 237 (1997), to reach the conclusion that both the causal relationship and the methodology must be generally accepted in the relevant scientific community. According to ***Blum***, ***supra***, the ***McKenzie*** court interpreted ***Frye*** and ***Topa*** to hold that "'there must be a showing, not that the studies establishing the causal relationship follow generally accepted methodologies, but that ***the existence of the causal relationship is generally accepted by the relevant medical community***.'" ***Blum***, 705 A.2d at 1322, quoting ***McKenzie***, 674 A.2d at 1172 (emphasis in ***Blum***).

¶ 23 While our supreme court affirmed this court's decision in ***Blum***, ***supra***, it based its affirmance on the fact that "the primary evidence at trial supporting the conclusion that Bend[e]ctin [the drug at issue in that case] caused appellant's birth defect . . . was so flawed as to render [the expert's] conclusions unreliable and therefore inadmissible under either ***Frye*** or ***Daubert***." ***Blum***, ***supra*** at 8, 764 A.2d at 4. The majority did not state that the scientific community must have generally accepted the causal relationship about which the expert is to testify. Rather, in a footnote quoting an opinion from the Ninth Circuit Court of Appeals, the majority stated, "'When a scientist ***claims to rely on a method*** practiced by most scientists, yet presents conclusions that are shared by no other scientist, ***the***

[trial] court should be wary that the method has not been faithfully applied.'" ***Id.*** at 7 n.5, 764 A.2d at 4 n.5, quoting ***Lust v. Merrell Dow Pharmaceuticals, Inc.***, 89 F.3d 594, 598 (9th Cir. 1996) (emphasis added).[8]

¶ 24 Additionally, we note that two justices in ***Blum*** wrote strong dissents, both specifically rejecting ***McKenzie***, ***supra***, and its "two bases" analysis. Justice, now Chief Justice, Cappy, for example, observing that the majority had not addressed this court's reasoning in its affirmance of ***Blum***, stated, "I believe that in this matter it is important to discuss the Superior Court's recitation of the ***Frye*** test as it has the potential to mislead the lower courts and the practicing bar." ***Blum***, ***supra*** at 9, 764 A.2d at 5 (Cappy, C.J., dissenting). As Chief Justice Cappy continued:

> Specifically, I refer to the Superior Court's statement that there are 'two ways to analyze the question of

[8] In ***Blum***, Dr. Done, one of the Blums' experts, recalculated the data that appeared in a published study, one of the studies Justice Castille so vigorously criticized in his dissent, discussed ***infra***, because Merrell Dow's lead expert witness was the editor of the journal in which it appeared, and because the attorneys representing Merrell Dow allegedly edited the studies. ***Blum***, ***supra*** at 14-15 and 15 n.3, 764 A.2d at 8 and 8 n.3 (Castille, J. dissenting), citing trial court slip op. at 67-68, 70-71.

Nevertheless, Dr. Done based his re-calculation on a ***methodology*** that was not generally accepted. ***Blum***, 705 A.2d at 1320. As Judge Beck explained in ***Blum***, "Epidemiology deals with population samples and seeks to generalize those results; it goes from the specific, i.e., a sample, to the general, i.e., a population." ***Id.*** at 1323-1324. According to Judge Beck, "While epidemiologists choose their data and engage in statistical analysis in order to ensure that their experimental populations are not biased, Dr. Done did not." ***Id.*** at 1324. Instead, Dr. Done eliminated all the standardization and used simple arithmetic. ***Id.*** As Judge Beck observed, "Epidemiological analyses that are not standardized are not generally accepted." ***Id.***

> whether the causation testimony proffered . . . meets the ***Frye*** . . . standard. One focuses on whether the causal relationship is generally accepted by the scientific community, and the other on whether the methodology is generally accepted by the scientific community.'

Id. Noting that the supreme court has "not stated that the ***conclusion*** reached by the scientist regarding causation must also be generally accepted," ***id.***, Chief Justice Cappy opined:

> The ***Frye*** standard is limited to an inquiry into whether the ***methodologies*** by which the scientist has reached her conclusions have been generally accepted in the scientific community. . . . It restricts the scientific evidence which may be admitted as it ensures that the proffered evidence results from scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creations [sic] of a renegade researcher. Yet, such a standard is not senselessly restrictive for it allows a scientist to testify as to new conclusions which have emerged during the course of properly conducted research.

Id. at 9-10, 764 A.2d at 5 (Cappy, C.J., dissenting) (emphasis in original). Hence, Chief Justice Cappy concluded that he would "squarely reject that portion of the Superior Court's holding which would require that a scientist's conclusions, as well as the methodologies utilized in reaching those conclusions, are generally accepted in the medical community." ***Id.*** at 10, 764 A.2d at 5 (Cappy, C.J., dissenting).

¶ 25 Similarly, Justice Castille, in a lengthy and provocative dissent, rejected Commonwealth court's "rather novel opinion" that "the expert's opinion as to the causal relationship at issue, and not just the expert's

methodology, must find general acceptance in the relevant scientific community before it may even be heard." ***Id.*** at 13, 764 A.2d at 7 (Castille, J., dissenting).[9]

¶ 26 Finally, we note that the Supreme Court in ***Daubert***, ***supra***, discussing F.R.E. 702, explicitly stated that "the focus . . . must be solely on principles and methodology, not on the conclusions that they generate." ***Daubert***, 509 U.S. at 595. Thus, having reviewed the case law and history behind the "two bases" analysis, we conclude that our supreme court has never adopted it, and therefore hold that ***Frye*** only applies to determine if the relevant scientific community has generally accepted the principles and methodology the scientist employs, ***not*** the conclusions the scientist reaches, before the court may allow the expert to testify. ***See Blasioli***, ***supra*** at 153, 713 A.2d at 1119. To the extent the decisions of this court in

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[9] In his dissent, Justice Castille vigorously objected to the manner in which Merrell Dow allegedly obtained "general acceptance" for its methodology and conclusions in the relevant scientific community. As Justice Castille observed:

> The trial court disagreed [with Merrell Dow's assertion that the scientific community did not support the Blums' experts' conclusions] for two reasons: first, because it did not believe that conclusions on causation are a separate methodology needing general acceptance . . . ; and second, because . . . [a]s the trial court succinctly put it: 'The testimony in this case demonstrates how "scientific consensus" can be created through purchased research and the manipulation of a "scientific" literature, funded as part of litigation defense, and choreographed by counsel.'

Blum, ***supra*** at 13-14, 764 A.2d at 7-8 (Castille, J., dissenting), quoting trial court slip op. at 46.

Blum, ***supra***; ***Thomas v. West Bend Co., Inc.***, 760 A.2d 1174 (Pa.Super. 2000), ***appeal denied***, 566 Pa. 647, 781 A.2d 147 (2001); and ***Wack v. Farmland Industries, Inc.***, 744 A.2d 265 (Pa.Super. 1999), ***appeal denied***, 565 Pa. 649, 771 A.2d 1287 (2001), relying on ***McKenzie***, ***supra***, have followed or referenced the two-bases analysis, we can find no support for doing so in our supreme court's ***Frye*** analysis. Rather, it appears as if the two-bases analysis arose from confusing "principles" with "conclusions." ***See McKenzie***, 674 A.2d at 1172, quoting ***Rodgers***, 605 A.2d at 1234 (opining that the ***Frye***/***Topa*** standard "'assures that those most qualified to assess the general validity of a scientific method will have the determinative voice by requiring that ***the principle or discovery forming the basis for evidence*** presented at trial must have gained general acceptance in the particular field to which it belongs[]'") (emphasis in ***McKenzie***).

¶ 27 In this case, the trial court relied on the two-bases analysis; however, it intertwined methodology and conclusion in such a way that we must discuss both.[10] We begin by observing that there is no question that the scientific community has generally accepted the basic principle Dr. Shane employed, The "Dose-Response" principle. This principle is not as old as the pyramids cited by an ***en banc*** panel of this court in ***Grady v. Frito-Lay, Inc.***, 789 A.2d 735, 742-743 (Pa.Super. 2002) (***en banc***), ***allocatur***

[10] It appears as if the dissent, although purporting to agree with us as to ***Frye***'s limitations, in fact, like the trial court, applies ***Frye*** to conclusions as well as methodology. ***See*** discussion ***infra***.

granted, 569 Pa. 46, 800 A.2d 294 (2002), when referring to crush and compression strength calculations. Nevertheless, the dose-response principle originated in the sixteenth century when Paracelsus, a Swiss physician and alchemist born in 1493 and considered by some to be the "Father of Toxicology," revolutionized the disciplines of chemistry and medicine with his statement, "'Alle Ding sind Gift und nichts ohn Gift; alein die Dosis macht das ein Ding kein Gift ist" [all things are poison and not without poison; only the dose makes a thing not a poison']." William C. Krieger, ***Foreword on Paracelsus—Dose Response***, in Academic Press: Handbook of Pesticide Toxicology, at xxvii-xxxiv (2d ed. 2002).[11] According to Krieger, "With the exception of $E = mc^2$, perhaps no other single statement has wielded such force in establishing the popular notoriety and the professional stature of an individual in the history of science . . . ." ***Id.*** at xxvii.[12]

¶ 28 Next, we address the meaning of "methodology" for purposes of the ***Frye*** test. As The Supreme Court observed in ***Daubert***, ***supra***, "'Scientific methodology today is based on generating hypotheses and testing them to

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[11] In ***Blum***, one of the Blums' experts, Dr. Gross, applied the dose-response principle to determine the effect of Bendectin on humans based solely on animal studies, a relationship which scientists widely acknowledge is not reliable without corroborating human data. ***Blum***, 705 A.2d at 1320.

[12] At least one court has recognized the venerability of this principle. In ***United States v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds, et al.***, 516 F.Supp. 321 (U.S.D.C. Kansas 1981), the court quoted Paracelsus for the proposition that "'the dose determines the poison.'" ***Id.*** at 327.

see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.'" ***Daubert***, 509 U.S. at 593, quoting Green, ***Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation***, 86 Nw. U. L. Rev. 643, 645 (1992). Stated differently, the scientific method is "a method of research in which a problem is identified, relevant data are gathered, a hypothesis is formulated from these data, and the hypothesis is empirically tested." Webster's Encyclopedic Unabridged Dictionary of the English Language ("Webster's") 1279 (1989). Within the meaning of the definition of the scientific method, "empirical" means "provable or verifiable by experience or experiment." ***Id.*** 468. Key aspects of the scientific method include the ability to test or verify a scientific experiment by a parallel experiment or other standard of comparison (control) and to replicate the experiment to expose or reduce error. ***Id.*** 318-319, 1217.

¶ 29 In this case, the trial court accepted Dr. Shane's "methodology" as it related to Trach's immediate adverse reactions to the Doxepin overdose based on the PDR and the epidemiological and other studies underlying its findings. (Trial court opinion, 5/18/00 at 21.) The trial court rejected Dr. Shane's "methodology" as to the long-term effects of Doxepin, however, because Dr. Shane did not refer to studies, texts, and other sources indicating general acceptance of his opinion as to those effects. (***Id.*** at 30.)

As the trial court opined, "Dr. Shane's opinions on these issues were based on his own reasoning from general toxicological principles. There is no evidence that any other members of the medical community share his conclusions or concur in his reasoning process." (***Id.***)

¶ 30 The trial court relied in particular on this court's analysis in ***Checchio v. Frankford Hospital-Torresdale Division***, 717 A.2d 1058 (Pa.Super. 1998), ***appeal denied***, 566 Pa. 633, 781 A.2d 137 (2001), to support its conclusion that an expert's testimony must be based on more than his or her own observations and experience in the field, without reference to outside sources. (Trial court opinion, 5/18/00 29-30, citing ***Checchio***, 717 A.2d at 1062.) We find error in the trial court's analysis for two reasons.

¶ 31 As noted ***supra***, expert testimony is only required where the knowledge is "beyond that possessed by a layperson" and may only be offered by a witness with "reasonable pretension to specialized knowledge on the subject under investigation." Pa.R.E. 702 and Comment—1998. As our supreme court recently observed in the context of the "two schools of thought" doctrine:

> Limiting evidence to medical literature would have the effect of preventing expert witnesses from testifying to the existence of a school of thought based on their experience as practitioners and on information they obtained during their medical training and while attending lectures and other educational programs sponsored by institutions and professional societies. Furthermore, in cases where medical literature is silent with regard to certain techniques or treatments, the lack of written

> materials would necessarily be fatal to the [proponent's] claim.

Gala v. Hamilton, 552 Pa. 466, 472, 715 A.2d 1108, 1111 (1998).[13]

¶ 32 As with the two schools of thought doctrine, ***Frye***'s general acceptance standard requires only that the scientific community generally accept the principles from which the scientist is proceeding and the methodology the scientist is employing to reach his or her conclusions. Assuming the expert is properly qualified to testify, as Dr. Shane was in this case, his or her expertise, appropriately brought to bear on the issue through use of generally accepted scientific principles and methodology, should also pass muster under ***Frye***.

¶ 33 Furthermore, it is clear from the definition of the scientific method, set forth ***supra***, that extrapolation, one of the methodologies Dr. Shane used to conclude that a massive overdose of Doxepin could result in permanent and/or exacerbated adverse effects documented at the recommended dose, is not science: in fact, it is a logical method used "to estimate the value of a variable outside its tabulated or observed range" or "to infer (that which is not known) from that which is known." Webster's 505. The question then becomes whether extrapolation, although not science, is a methodology

[13] In fact, one might reasonably wonder why expert testimony would be needed at all if the parties could merely refer to medical texts and treatises to support their positions.

generally accepted and used by scientists within the relevant scientific community.[14]

¶ 34 While we have found no Pennsylvania cases discussing the admissibility of scientific testimony based on extrapolation, we have found several cases decided by other jurisdictions which have addressed the admissibility of extrapolation evidence under the ***Frye*** test. We recognize that we are not bound by these cases; however, we may use them for guidance to the degree we find them useful and not incompatible with Pennsylvania law. ***See***, ***e.g.***, ***Gutteridge v. A.P. Green Services, Inc.***, 804 A.2d 643, 651 (Pa.Super. 2002) (opining that "Federal court decisions do not control the determinations of the Superior Court[]") (citations omitted); ***Commonwealth v. Santarelli***, 483 A.2d 895, 900 (Pa.Super. 1984) (observing, "We receive [out-of-state] decisions as persuasive authority but not binding precedent[]") (citation omitted), ***cert. denied sub***

[14] Pennsylvania appellate courts have apparently not addressed the admissibility of scientific testimony based on extrapolation. Our supreme court, however, recently decided a case in which the defendant attacked the validity of applying a principle of statistical probability to DNA forensic analysis and then admitting the results into evidence. ***Blasioli***, ***supra*** at 153, 713 A.2d at 1119. The ***Blasioli*** court therefore addressed the admissibility of both the results of DNA testing and certain probabilities derived from that testing using two statistical methods, the product rule and the ceiling principle. ***Id.*** at 152, 713 A.2d at 1118. As the ***Blasioli*** court observed, "This court has generally required that both the theory and technique underlying novel scientific evidence must be generally accepted." ***Id.*** at 153, 713 A.2d at 1119, citing ***Crews***, ***supra*** at 522, 640 A.2d at 402. As the ***Blasioli***, court recognized, however, general acceptance of a methodology does not require unanimity. ***Id.*** at 168, 713 A.2d at 1127 (citations omitted).

nom. Steingraber v. Pennsylvania, 476 U.S. 1116 (1986). With the foregoing in mind, we consider these extra-jurisdictional cases.

¶ 35 In ***Donaldson v. Central Illinois Public Service Co***., 199 Ill.2d 63, 767 N.E.2d 314 (2002), for example, the plaintiffs, who were parents of four children exposed to coal tar during the clean-up of a former coal gasification plant site, brought suit against Central Illinois Public Service Co. ("CIPS") and three of its contractors. According to the parents, their children developed neuroblastoma, a rare form of cancer that attacks the peripheral nervous system, as a result of various acts or omissions committed by CIPS and/or its contractors during the clean-up. ***Id.*** at 65-66, 767 N.E.2d at 317-318.

¶ 36 Neuroblastoma is a very rare form of cancer, usually occurring in young children and infants at a rate of nine out of one million. ***Id.*** The community in which the four children lived recorded 520 live births in 1988. Statistically, such a small community would record a case of neuroblastoma once every 29 years; however, between March 1989 and August 1991, the community recorded cases of neuroblastoma in three infants and one teenager. ***Id.*** While published scientific research warned that coal tar was "'among the most powerful carcinogens known to exist[,]'" ***id.*** at 68, 767 N.E.2d at 319, quoting the Handbook on Manufactured Gas, the scientific community had been limited by the small number of neuroblastoma cases in

its ability specifically to link exposure to coal tar with development of neuroblastoma. ***Id.*** at 85, 767 N.E.2d at 328.

¶ 37 Furthermore, as one of the plaintiffs' experts explained, ethical considerations prevented exposing humans to coal tar for research purposes. ***Id.*** at 87, 767 N.E.2d at 330. Additionally, environmental exposure is often not detected until the onset of illness, thereby preventing controlled settings to study the effects of exposure. ***Id.*** As a result, the experts who testified on behalf of the children extrapolated from similar, but not identical, studies and theories to conclude that coal tar exposure caused the children's neuroblastomas. ***Id.*** at 88, 767 N.E.2d at 330. These experts included an epidemiologist specializing in childhood cancers, a toxicologist specializing in molecular biology, and a physician specializing in occupational and environmental medicine. ***Id.*** at 74, 767 N.E.2d at 322.

¶ 38 The jury returned a verdict in favor of the plaintiffs and against CIPS alone in the amount of $3.2 million, and the intermediate appellate court affirmed. On appeal to the supreme court, CIPS claimed, ***inter alia***, that the trial court erred when it admitted the extrapolation testimony because it did not pass muster under the ***Frye*** test. ***Id.*** at 76, 767 N.E.2d at 323.

¶ 39 In its analysis, the ***Donaldson*** court set out the parameters of ***Frye***, much as we have done ***supra***. The court then addressed the admissibility of extrapolation evidence, reviewing prior Illinois cases as well as a federal appellate court case, ***Ferebee v. Chevron Chemical Co***., 736 F.2d 1529

(D.C.Cir. 1984), ***cert. denied***, 469 U.S. 1062 (1984), which upheld the admissibility of extrapolation testimony under facts similar to the facts of this case.[15] ***Donaldson***, 199 Ill.2d at 86, 767 N.E.2d at 328-329. As the ***Donaldson*** court observed, "extrapolation is commonly used by scientists in certain limited instances . . . "; for example, when the medical inquiry is new or the opportunities to examine a specific cause and effect relationship are limited; when the number of cases limits study of the disease; or, as noted ***supra***, when ethical considerations prevent exposing individuals to a toxic substance for research purposes. ***Id.*** at 85, 87, 767 N.E.2d at 328, 330. According to the ***Donaldson*** court, when an expert relies upon scientific literature discussing similar, but not identical, cause and effect relationships, the fact that the expert must extrapolate affects the weight of the testimony rather than its admissibility. ***Id.*** at 85, 767 A.2d at 328 (citation omitted).

¶ 40 As this court and our supreme court have recognized, the rationale behind the ***Frye*** test is to attempt to measure the quality of scientific evidence prior to its admission because "'there is the danger that the trial judge or jury will ascribe a degree of certainty to the testimony of the expert . . . which may not be deserved.'" ***Blum***, 705 A.2d at 1317, quoting ***Topa***,

[15] We will discuss ***Ferebee infra***. We are aware that numerous courts have recognized that ***Cippollone v. Liggett Group, Inc.***, 505 U.S. 504 (1992), abrogated ***Ferebee***'s preemption analysis. ***See***, ***e.g.***, ***Etcheverry v. Tri-Ag Service, Inc.***, 22 Cal.4th 316, 327, 993 P.2d 366, 371-372 (2000) (collecting cases finding that ***Ferebee***'s preemption analysis is no longer good law). Preemption is not, however, relevant to our disposition of this case.

supra at 230, 369 A.2d at 1281. The ***Donaldson*** court, acknowledging this concern, observed, however, that "the method of extrapolation does not concern a technique new to science that may instill a sense of 'false confidence' or carry a misleading sense of scientific 'infallibility.'" ***Id.*** at 86, 767 A.2d at 829 (citation omitted). As the ***Donaldson*** court continued, "[E]xtrapolation by nature admits its fallibility--the lack of specific support to establish the existence of a known cause and effect relationship." ***Id.*** at 87, 767 N.E.2d at 329 (citation omitted). As a result, the ***Donaldson*** court concluded that the trial court did not err in admitting the testimony of the plaintiffs' experts. ***Id.*** at 88, 767 N.E.2d at 330.

¶ 41 ***Ferebee***, ***supra***, involved an employee's long-term exposure to a chemical herbicide, paraquat, which its manufacturer, Chevron Chemical Co. ("Chevron"), acknowledged was "acutely toxic--that is, that any injuries resulting from exposure to paraquat occur within a very short time of exposure . . . and that when exposure ceases, so too does the injury." ***Ferebee***, 736 F.2d at 1535. Ferebee, and later his estate, claimed, however, that Ferebee ultimately died from pulmonary fibrosis caused by long-term exposure to paraquat poisoning. ***Id.*** at 1533.

¶ 42 In support of its theory, Ferebee's estate presented the testimony of Ferebee's treating physicians, who were both specialists in pulmonary medicine, as expert witnesses. They relied on their personal observation of Ferebee and tests they performed on him, as well as "upon medical studies

which, they asserted, suggested that dermal absorption of paraquat can lead to chronic lung abnormalities of the sort characterized as pulmonary fibrosis." ***Id.*** Finding the experts' opinions as to causation admissible, the ***Ferebee*** court opined:

> Thus, a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a 'statistically significant' number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors ***could*** conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That Ferebee's case may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.

Id. at 1535-1536 (emphasis in original).

¶ 43 In ***Ferebee***, substantial scientific evidence existed as to the acute adverse effects of intense, short-term exposure to paraquat, but little if any evidence existed linking low-level exposure over a prolonged period to long-term side effects: in our case, substantial scientific evidence exists as to the

acute adverse effects of Doxepin taken in its recommended dosage, but little if any evidence exists linking an extremely high-level dosage to long-term side effects. Addressing this issue, the ***Ferebee*** court observed:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low-level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony.

Id. at 1534.

¶ 44 We find the facts of this case even more compelling than the facts of ***Ferebee***, ***supra***, or ***Donaldson***, ***supra***, based on the even stronger logical inference that a substance known to cause adverse side effects in its recommended dose is likely to cause a heightened level of the same or similar adverse effects when taken in a massive overdose.

¶ 45 We have set forth the trial court's summary of Dr. Shane's testimony, in which Dr. Shane explained in minute detail how Doxepin works on the brain's chemistry; the adverse effects and contraindications for Doxepin in therapeutic doses as determined through clinical trials and clinical experience; the PDR's description of those side effects and contraindications; the manner in which Doxepin works on vision, especially its "known anticholinergic effect" which, even in its recommended dosage, can cause excessive dilation of the pupil of the eye. Prolonged dilation, in turn, causes

pigmentary loss, thereby causing the pigment to be deposited in the filter system at the Canal of Schlemm, further clogging up the filter and also causing increased pressure in the eye. (Trial court opinion, 5/18/00 at 7-10, citing notes of testimony, 6/16/99 at 198.) The result of the pigmentary loss and clogging is pigmentary glaucoma, the type of glaucoma from which Trach suffers and which both Drs. Moran and Naidoff acknowledged is a form of open-angle glaucoma. (Notes of testimony, 6/17/99 at 116; Naidoff deposition, 6/8/99 at 17.)

¶ 46 With regard to Trach's cognitive difficulties, Dr. Shane testified that the negative results of the neurological tests administered to Trach after the Doxepin cleared his system further supported the conclusion that ingestion of a massive overdose of Doxepin caused his problems. According to Dr. Shane, an MRI or EEG will reflect tumors and some nervous system diseases, but will not reflect chemical changes, such as those induced by a drug overdose. (Notes of testimony, 6/16/99 at 208-215.)

¶ 47 As our supreme court observed, "'[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, ***the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.***'" ***Commonwealth v. Nazarovitch***, 496 Pa. 97, 101, 436 A.2d 170, 172 (1981), quoting ***Frye***, 293 F. at 1019 (emphasis in ***Nazarovitch***).

¶ 48 In this case, we agree with the trial court that the thing from which Dr. Shane deduced that a massive overdose of Doxepin caused Trach's acute symptoms has been sufficiently established to have gained general acceptance in the particular field to which it belongs. In the case of the immediate adverse reactions, "the thing" consists of the clinical trials and clinical experience with Doxepin at therapeutic dosages, documented in the PDR and manufacturer's inserts.

¶ 49 Unlike the trial court, however, we conclude that the dose-response principle Dr. Shane used is generally accepted in the scientific community. We also conclude that extrapolation, the methodology Dr. Shane used to deduce that Trach's chronic symptoms, including glaucoma, were the result of a massive Doxepin overdose, is neither novel nor "scientific" in its strict sense. Extrapolation has, however, gained general acceptance in the scientific community under certain limited circumstances, delineated ***supra***. As the ***Donaldson*** and ***Ferebee*** courts opined, as long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examinations, the scientist may extrapolate from this sound scientific basis when it is either impossible or unethical to perform the sorts of clinical trials that would yield definitive results. ***Donaldson***, 767 N.E.2d at 329, citing ***Ferebee***, 736 F.2d at 1535-1536. As the ***Ferebee*** court continued, "In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific

certainty but legal sufficiency[.]" ***Ferebee***, 736 F.2d at 1536. It was for the jury, aware of the fallibility of extrapolation, to decide whether Dr. Shane's testimony was credible. It was for Thrift Drug, through vigorous cross-examination, to prove that it was not.

¶ 50 The dissent, while agreeing that extrapolation is an acceptable methodology, finds, however, that remand is necessary because Trach purportedly did not have an opportunity adequately to establish the underlying scientific foundation from which Dr. Shane extrapolated, and Thrift Drug did not have an opportunity to challenge that foundation. (Klein, J., dissenting at 17.) We cannot agree. In fact, we find the record complete as to this issue.

¶ 51 As we have already stated, Dr. Shane extrapolated from the known adverse effects of Doxepin in recommended doses, documented in the PDR and the manufacturer's inserts. Trach introduced into evidence a three-column chart showing Trach's symptoms after taking Doxepin, the manufacturer's insert reflecting possible adverse reactions and contraindications for Doxepin, and the PDR's enumeration of the same adverse reactions and contraindications. (Notes of testimony, 9/16/99 at 192-194, and Plaintiff's Exhibit 10.) Based upon this information, as well as Trach's medical records following the Doxepin overdose, Dr. Shane extrapolated to reach his ultimate conclusion.

¶ 52 Additionally, our review of the record indicates that defense counsel cross-examined Dr. Shane as to the underlying basis for his extrapolation testimony, to which Dr. Shane responded:

> Every opinion I have given today is supported very definitely in the medical literature. It's supported in things that are available on every physician's desk like the Physician's Desk Reference. It's supported in the medical literature by the various textbooks. It is supported in the medical literature by the textbook on toxicology written by Randall Bassault. It's supported by other textbooks. Ellenhorn will support what I have said. I said nothing today to this jury that isn't supported by medical literature.
>
> What's not in the medical literature is how does it block that distal end of the synapse? We don't know. . . .

Id. at 220-221. Defense counsel did not object to Dr. Shane's references to the texts or challenge the accuracy of Dr. Shane's representations of that literature. Defense counsel's only challenge came during direct examination, with reference to the specific content of a text to which Dr. Shane referred. (***Id.*** at 206-207.) In response, the trial court stated, "[T]he witness can give his opinion in which he's taken into consideration the authoritative text but he's not to state the specifics of that text. That would be considered a violation of the hearsay rule under Pennsylvania Rules of Evidence." (***Id.*** at 207.)

¶ 53 The dissent also expresses concern that our review has been significantly hampered by the trial court's reversing itself without taking any evidence on the ***Frye*** issue. (Klein, J., dissenting at 15 n.6.) We disagree.

We recognize that "[t]he Superior Court, as an error-correcting court, may not purport to reverse a trial court's order where the only basis for a finding of error is a claim that the responsible party never gave the trial court an opportunity to consider." ***Harber Philadelphia Center City Office Ltd. v. LPCI***, 764 A.2d 1100, 1105, (Pa.Super. 2000), ***appeal denied***, 566 Pa. 664, 782 A.2d 546 (2001).

¶ 54 In this case, the trial court opined, "Dr. Shane's opinions [as to the effects of a massive overdose of Doxepin] were based on his own reasoning from general toxicological principles." (Trial court opinion, 5/18/00 at 30.) As the trial court continued, "There is no evidence that any other members of the medical community share his conclusions or concur in his reasoning process." (***Id.***) We therefore find that the trial court had the first opportunity to address whether the scientific community has generally accepted extrapolation based on the dose-response principle and erred in its conclusion.

¶ 55 Order granting a new trial as to damages is vacated and the jury's verdict of $5 million is reinstated. Order denying j.n.o.v. or a new trial as to liability and damages is affirmed. Case is remanded for the trial court to address Thrift Drug's post-trial motions regarding the excessiveness of the verdict and, in turn, Trach's motion for delay damages. Jurisdiction is relinquished.

¶ 56 Del Sole, P.J., files a Concurring Statement in which Musmanno, J. joins.

¶ 57 Klein, J. files a Dissenting Opinion in which Lally-Green, J. joins.

J. E02003/02

ALLEN TRACH,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
J. FELLIN and THRIFT DRUG/ECKERD STORE, THRIFT DRUG, INC. and ECKERD DRUG CO.,	:	
	:	
Appellees	:	No. 1921 EDA 2000

Appeal from the Order entered May 18, 2000
in the Court of Common Pleas of Lehigh County,
Civil Division, at No. 97-C-1535

ALLEN TRACH,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellee	:	
	:	
v.	:	
	:	
J. FELLIN and THRIFT DRUG/ECKERD STORE, THRIFT DRUG, INC. and ECKERD DRUG CO.,	:	
	:	
Appellants	:	No. 1949 EDA 2000

Appeal from the Order entered May 18, 2000
in the Court of Common Pleas of Lehigh County,
Civil Division, at No. 97-C-1535

BEFORE: DEL SOLE, P.J., FORD ELLIOTT, JOYCE, STEVENS, MUSMANNO, ORIE MELVIN, LALLY-GREEN, KLEIN and BENDER, JJ.

CONCURRING STATEMENT BY DEL SOLE, P.J.:

¶ 1 I join the opinion of my colleague, Judge Ford Elliott but write separately to address a point raised in the dissenting opinion of Judge Klein.

¶ 2 I do not view the majority opinion as "tak[ing] the position that by failing to challenge Dr. Shane's claim that the literature supported his theories during trial, the defense has conceded that the literature does in fact exist and supports Dr. Shane's opinion." Slip Op. at 7 (Klein, J. dissenting). Rather, once Dr. Shane testified that the literature supported his opinion, he could have been cross-examined regarding the literature. While the defense may have made a tactical decision to forgo that cross-examination, as the dissent surmises, it should not now be granted a second opportunity to do so.

¶ 3 The defense did have an opportunity to explore the literature to challenge the basis of Dr. Shane's opinion; it chose not to do so.

J. E02003/02

ALLEN TRACH	:	IN THE SUPERIOR COURT OF
Appellant	:	PENNSYLVANIA
	:	
v.	:	
	:	
J. FELLIN AND THRIFT DRUG/ECKERD STORE, THRIFT DRUG, INC. AND ECKERD DRUG CO.	:	
	:	
	:	
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ALLEN TRACH	:	IN THE SUPERIOR COURT OF
Appellant	:	PENNSYLVANIA
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	:	
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	:	
	:	
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In the Court of Common Pleas of Lehigh County
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BEFORE: DEL SOLE, P.J., FORD ELLIOTT, JOYCE, STEVENS, MUSMANNO, ORIE MELVIN, LALLY-GREEN, KLEIN and BENDER, JJ.

DISSENTING OPINION BY KLEIN, J.:

¶ 1 I agree with the majority that a medical expert can meet the ***Frye***[16] standard in unusual circumstances by extrapolating from generally accepted

[16] ***Frye v. United States,*** 293 F. 1013 (D.C. Cir. 1923).

theories.[17] However, in this case, the trial judge at no point conducted a ***Frye*** hearing, and from the record we cannot determine whether Dr. Shane's testimony did or did not meet the ***Frye*** standard. Therefore, I would remand for a full ***Frye*** hearing. If it is determined that the ***Frye*** standard was met, there would be no need for a new trial. If the ***Frye*** standard was not met, then there should be a new trial.[18]

¶ 2 ***Frye*** itself supports the premise that an expert can make an extrapolation from well-recognized scientific principles. In ***Frye*** the court said:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

293 F. at 1014.

¶ 3 The statement that "courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle" supports extrapolation, so long as "the thing from which the deduction is made [is]

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[17] I also agree that the ***Frye*** objection was properly preserved in the motion *in limine*.

[18] A new trial would be necessary because judgment n.o.v. should not be entered on a diminished record. ***Jones v. Treegoob***, 249 A.2d 352 (Pa. 1969); ***Hughes v. John Hanna & Sons***, 144 A.2d 617 (Pa. Super. 1958).

sufficiently established to have gained general acceptance." ***Id.***

¶ 4 The procedures conducted by the trial judge in the instant case had the result that neither side was given the opportunity to put on the kind of testimony that would enable one to determine whether Dr. Shane's opinion is or is not based on generally accepted underlying principles. The trial judge first ruled on a motion *in limine* without hearing, ruling that the ***Frye*** standard was met and allowing Dr. Shane to testify. Then, on post-verdict motions, again without any ***Frye*** hearing and without any evidence being taken, the judge held that Dr. Shane's testimony did not meet the ***Frye*** standard.

¶ 5 Although Dr. Shane's extrapolations seem reasonable, the record is not clear enough to demonstrate that the underlying basis upon which Dr. Shane relies for his extrapolation meets the ***Frye*** standard. At the motion *in limine* stage, without a hearing, the *defense* was unable to challenge the underlying basis of the literature on which Dr. Shane relied to say that the drug Doxepin caused pigmentary or "open-angle" glaucoma. At the post-verdict motion stage, without a hearing the *plaintiff* was unable to refer to the literature that would support his extrapolations. When Dr. Shane did refer to literature in the course of the trial, the references were precluded because under Pennsylvania law, textbooks are hearsay, not subject to any exception.

¶ 6 Therefore, I would remand the case to the trial court to conduct a full

Frye hearing. If Dr. Shane's testimony passes ***Frye*** muster, there is no need for a new trial. If it does not pass ***Frye*** muster, then a new trial would be in order.

¶ 7 Since the dosage administered to Mr. Trach of the anti-depressant drug Doxepin was far in excess of the recommended dosage, and prescription of the drug had been generally discontinued (R.R. 339a, N.T. 6/16/99, p 185, 196), there were not and will not be any significant studies dealing with humans receiving this massive overdose. (R.R. 385a, N.T. 6/16/99 p. 243-44).

¶ 8 As I view ***Frye***, the basic issue in this case is whether Dr. Shane's testimony that Doxepin caused Mr. Trach permanent injury is sufficiently reliable to be admitted to the jury. As noted by the majority, other jurisdictions have permitted expert witnesses to extrapolate based on generally recognized medical principles. There is no reason why we cannot use this approach in Pennsylvania.

¶ 9 To boil the testimony down to its elements, glaucoma is caused when pressure builds up in the eye. This occurs when the fluid in the eye is not drained through the Canal of Schlemm. The defense experts said that the side effects from Doxepin only cause "closed-angle" glaucoma, when the entry to the Canal of Schlemm is narrowed and for this reason pressure builds up in the eye. According to the defense, the type of glaucoma suffered by Mr. Trach is "open-angle" or pigmentary glaucoma, which

essentially results when pigment is lost from the iris and blocks up the filter system of the Canal of Schlemm.

¶ 10 Dr. Shane testified as to the massive overdose of Doxepin that Mr. Trach received. He testified that in addition to the closed-angle compression of the Canal of Schlemm, there would be pigmentary loss from the excessive dilation of the pupil of the eye, which would clog the filter of the Canal of Schlemm causing the pressure to build. That would result in the kind of permanent glaucoma from which Mr. Trach suffers. (R.R. 340a, 347a, 349a, 367a; N.T. 6/16/99. pp. 198, 205, 207, 225.) This is an extrapolation by Dr. Shane, since with therapeutic doses of Doxepin, the result is usually closed-angle glaucoma.

¶ 11 The extrapolation makes sense if and only if Dr. Shane's basic premise is correct, that is, that Doxepin causes loss of pigment. When asked about this, Dr. Shane referred to several textbooks. However, since his testimony had already been ruled admissible, these background texts were *inadmissible* as hearsay under the Pennsylvania Rules of Evidence.[19]

¶ 12 Dr. Shane attempted to minimize the distinction between open-angle and closed-angle glaucoma, but when he referred to the published literature, using *New York Eye and Ear* as an example, the defense raised an objection and the trial judge ruled that such literature is inadmissible hearsay in

[19] ***See*** Pa.R.E. 803, comment to Section (18), Learned Treatises (noting that Pennsylvania has not adopted the federal hearsay exception for learned treatises).

Pennsylvania state courts. (R.R. 347a-349a, 366a; N.T. 6/16/99, pp. 205-207, 224). When the defense challenged Dr. Shane, saying that there is nothing in the literature to support his opinion, Dr. Shane replied that the *results* were in the literature although *why* Doxepin causes these results was unknown. The testimony (R.R. 362a-363a, N.T. 9/16/99 pp. 220-221) reads as follows:

> Q. But there's nothing in the medical literature which states the opinion that you're giving here in the courtroom today. Is there, sir?
>
> A. [By Dr. Shane] Oh, absolutely. Every opinion I have given today is supported very definitely in the medical literature. It's supported in things that are available on every physician's desk like the Physician's Desk Reference. It's supported in the medical literature by the textbook on toxicology written by Randall Bassault. It's supported by other textbooks - Ellenhorn will support what I have said. I said nothing today to this jury that isn't supported by medical literature.
>
> What's not in the medical literature is how does it block the distal end of the synapse? We don't know. And we don't have a lot of history on massive overdoses because the drug has been out of favor sufficiently long that folks have not overdosed. It has not been a popular -- it has not been an available or popular street drug.

¶ 13 At trial, the defense did not explore the contents of the literature. Therefore, because the literature was not presented by either side at trial, the record neither supports nor contradicts the bases of Dr. Shane's opinion. It is improper to rule that his opinions should be discarded under ***Frye*** when the trial court never explored the literature to see whether or not there is a basis for his extrapolation from the results found from therapeutic doses of

Doxepin.

¶ 14 Likewise, the defense did not have the opportunity to explore the literature to challenge the bases of Dr. Shane's opinion at a post-verdict hearing. There was no hearing at the motion *in limine,* the literature was not at issue during trial, and there was no hearing at the post-verdict stage where the literature could be evaluated to examine this underlying premise.

¶ 15 The majority takes the position that by failing to challenge Dr. Shane's claim that the literature supported his theories during trial, the defense has conceded that the literature does in fact exist and supports Dr. Shane's opinion. However, the majority overlooks the fact that it might not have been strategically wise for the defense to explore the literature at trial. By the time Dr. Shane testified at trial, the defense had already lost the ***Frye*** issue at the motion *in limine* stage. During trial, the defense had to be concerned about winning the case, not about establishing a record to challenge the ruling on the motion *in limine*. In a major malpractice case, lawyers would legitimately not want to focus on a detailed challenge of the literature to distract the jury from other points they make on cross-examination. Having already lost the ***Frye*** issue, it is unfair to hold the defense conceded this point simply because they did not put in enough evidence at trial to support their ***Frye*** arguments. The time to establish a record is at a ***Frye*** hearing, outside the presence of the jury. If this does not take place on a motion *in limine,* it should take place before a ruling on

post-verdict motions. The problem in this case (both for us as an appellate court and for the parties) is that neither side ever had the proper opportunity to develop a record to support their position on ***Frye***.

¶ 16 Therefore, we as an appellate court cannot determine whether or not the basic premise upon which Dr. Shane extrapolated to reach his conclusion is generally accepted science. If it is, then the extrapolation is justified. If it is not, then the extrapolation fails because the basis of the extrapolation is not supported.

¶ 17 We have made the interpretation of the ***Frye*** principle far too complex. We should be able to come up with a common-sense approach to the "gatekeeper" function of the trial court when it comes to scientific evidence.

¶ 18 I believe we can conduct this analysis by following four simple principles.

1. ***Frye*** applies to scientific testimony whenever there is a legitimate dispute as to whether the expert's conclusions or methodology are generally accepted.

2. If the expert's conclusion is generally accepted, then there is no need to evaluate his or her methodology.

3. If the expert's conclusion is not generally accepted, then courts must determine whether the underlying methodology is reliable.

4. The challenger bears the burdens of production and proof. The trial court should deny the motion without a hearing unless the movant has presented and supported a *prima facie* case that the evidence is not generally accepted.

A detailed analysis follows.

1. ***Frye*** applies to scientific testimony whenever there is a legitimate dispute as to whether the expert's conclusions or methodology are generally accepted.

¶ 19 Pennsylvania law often states that the ***Frye*** standard applies to "novel" science. ***See, e.g.,*** Pa.R.C.P. 207.1, Explanatory Comment—2001. As noted in the majority's opinion, "novel" does not necessarily mean "new." A careful consideration of the purpose of the ***Frye*** rationale shows that the Courts are referring to the second meaning of "novel," not the first. While the term "novel" can mean "new;" it can also mean "having no precedent" or "unusual."[20]

¶ 20 The majority states that the evidence must "in some sense" be novel. ***Id.*** Our Supreme Court's decision in ***Blum*** does not address whether ***Frye*** applies only to novel science, and therefore does not concern itself with a definition of "novel." The Supreme Court's opinion dealt with whether ***Daubert*** or ***Frye*** controlled, and for that reason the majority of the Supreme Court did not address that question. Only the dissenters raised it, which obviously does not end our inquiry. Nor have I found any other controlling precedent.

¶ 21 As Judge Beck noted in ***Blum by Blum v. Merrell Dow Pharmaceuticals, Inc.***, 705 A.2d 1314, 1317 (Pa. Super. 1997), ***aff'd***, 764 A.2d 1 (Pa. 2001), ***Frye*** is designed to ascertain whether the scientific evidence is of sufficient reliability to be presented to the jury. Judge Beck

[20] Webster's Third New International Dictionary (1966).

said:

> The ***Frye*** test represents an attempt to measure the quality of scientific evidence prior to admission, so that jurors are not misled by unreliable evidence. Our courts have considered this to be necessary whenever science enters the courtroom because "there is the danger that the trial judge or jury will ascribe a degree of certainty to the testimony of the expert … which may not be deserved."

705 A.2d at 1317 (quoting ***Commonwealth v. Topa***, 369 A.2d 1277, 1281 (1977)).

¶ 22 Just as "novel" is a confusing term, it is also confusing to say that ***Frye*** applies "whenever science enters the courtroom." The better way to phrase it is to say that ***Frye*** applies whenever a party claims that an opposing expert's theory and/or methodology is not generally accepted. The methodology need not be "new" or involve cutting-edge technology. Such a definition of "novel" would be unreasonably narrow. For example, lie detector tests have been in existence for many years, and are certainly not "novel" in the sense of being new or "cutting-edge." Yet even today this technology is still not generally accepted in the scientific community. Moreover, a temporal or technological view of "novelty" would unreasonably hamper the trial judge's gate-keeping function to ensure that all scientific methodology is generally accepted before it is presented to the jury.

¶ 23 At the same time, a broad reading of the phrase that ***Frye*** applies "whenever science enters the courtroom" may conjure up a vision of ***Frye*** hearings in every case. That also is not true. One should not confuse the

issue of the standard to determine admissibility and the issue of whether the trial court should hold a ***Frye*** hearing. Sometimes the expert's opinion is clearly accepted by the scientific community and there is no challenge, and therefore no hearing will occur. For example, no one would ask for a ***Frye*** hearing if an expert would testify that antibiotics are helpful in treating infections. An example in this case is the opinion that if pressure builds in the eye, glaucoma may result. Although theoretically ***Frye*** could apply to all testimony from every scientific expert, in most cases the opponent will raise no challenge. For general medical testimony that is widely accepted, no responsible lawyer would ask for a ***Frye*** hearing and irresponsible lawyers would be sanctioned. Also, if the petition and answer show that there is no real question that the expert's opinion or methodology is generally accepted, the matter can be decided without a hearing on a standard akin to summary judgments.

¶ 24 While I would hope that in the future we would use a term other than "novel" when talking about when ***Frye*** applies, if "novel" is defined as "having no precedent or unusual," this fits with the law as it has developed. I believe that the proper standard, which I think is adopted by the majority, is that ***Frye*** properly governs the admissibility of expert testimony, new or old; whether there is a *legitimate* dispute as to whether it is generally accepted. If that is the case, then the trial court will need hear a challenge and probably hold a hearing. But the need for a ***Frye*** determination will be

relatively rare.

2. If the expert's conclusion is generally accepted, then there is no need to evaluate his or her methodology.

¶ 25 As for how the court should conduct the inquiry, I propose a sensible two-step approach. The first step would be to determine whether the conclusion is generally accepted, as discussed above. Some conclusions (including some relating to causation) are generally accepted: e.g., botulism causes certain symptoms. If the general acceptance of the conclusion can be established, why should courts delve into methods? Once the theory of causation has been admitted by the court above as generally accepted, that will usually be the end of the inquiry and the evidence will be admitted.

¶ 26 However, where there is a claim that the body of opinion has changed, or has become uncertain, the opponent needs an opportunity to prevent the expert's testimony from going to the jury unless it has a reasonable basis. In such a situation, the trial court should conduct a hearing to determine admissibility using ***Frye*** standards.

3. If the expert's conclusion is not generally accepted, then courts must determine whether the underlying methodology is reliable.

¶ 27 When the expert's opinion is not considered generally accepted, then courts must move to a second step. The second step would focus on the underlying methodology. This step would arise where the expert's conclusion has not reached general acceptance, but the testimony is based on generally accepted procedures. As the New Jersey Supreme Court

phrased it, "[A] theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." ***Landrigan v. Celotex Corp.***, 605 A.2d 1079, 1084 (N.J. 1992) (quoting ***Rubanick v. Witco Chem. Corp.***, 593 A.2d 733, 747-48 (N.J. 1991)).

¶ 28 When the opinion of the expert is not generally accepted, the trial court should hold a hearing to examine the methodology, data and information. The court should examine the basis of the methods, and whether the data was the sort that experts in the field reasonably use. If so, the opinion should be admitted.

¶ 29 Both the conclusion and the methodology may be important, but at different points in the analysis.

> 4. The challenger bears the burdens of production and proof. The trial court should deny the motion without a hearing unless the movant has presented and supported a ***prima facie*** case that the evidence is not generally accepted.

¶ 30 These substantive legal principles have a significant impact on the procedural issue of when and how ***Frye*** hearings should be conducted. First, the party seeking to bar evidence under ***Frye*** must identify precisely what is arguably not generally accepted about the expert's opinion. ***See***, Pa.R.Civ.P. 207.1(a)(1). Moreover, the following principles would apply to the ***Frye*** motion.

¶ 31 If the moving party concedes that the expert's conclusion is generally accepted, the inquiry would end. The trial court would deny the motion and allow the expert to testify. Similarly, if the moving party argues that the expert's conclusion is not generally accepted, but concedes that the methodology is generally accepted, the inquiry would end. The trial court would deny the motion and allow the expert to testify. As the Majority cogently explains, if the expert used established, accepted scientific methods to come to a newly-recognized conclusion, the opinion should not be excluded under ***Frye***. The matter is left for the jury to resolve.

¶ 32 Thus, the party seeking to exclude evidence under ***Frye*** has the initial burden of presenting a *prima facie* case that the expert's conclusion and methodology have not been generally accepted. Upon receiving such a motion, the trial court has two options:

1. The court could rule on the pleadings that either the expert's conclusion or methodology is generally accepted. In such a situation, the court would deny the motion and allow the expert to testify. ***See***, Majority Opinion at 14 ("general acceptance" standard can be incorporated into the concept of judicial notice). Because trial courts retain the power to summarily reject requests for ***Frye*** hearings, there is no danger of our trial courts being flooded with ***Frye*** requests every single time that "science enters the courtroom."

2. The trial court could hold a ***Frye*** hearing. After the hearing, if the court determines that the expert's conclusion is indeed generally accepted, the court would allow the expert to testify. (It may often be the case that a trial court does not know if a conclusion is generally accepted until the court takes evidence on this issue.) If the court finds that the conclusion is not generally accepted, that finding would not end the inquiry. Rather, the court would then proceed to determine if the expert's methodology is generally accepted. If so, the court would allow the expert to testify. If not, the testimony would be barred under ***Frye***.

¶ 33 In any event, trial courts are to comply with Pa.R.Civ.P. 207.1, which provides that, where a party files a ***Frye*** motion with the trial court, the court, in its discretion, can hold a ***Frye*** hearing before trial or defer it to trial.[21] Pa.R.C.P. 207.1(a)(3). Where a party does not raise the issue of the admissibility of the testimony of an expert witness prior to trial, and is not ordered by the trial court to do so, nothing in the Rule precludes raising the issue during trial. ***See, generally,*** Rule 207.1(b).

* * * * *

¶ 34 In this case, I do not believe that it is generally accepted that Doxepin causes pigmentary or open-angle glaucoma. However, I agree with the

[21] The wisdom of Rule 207.1, limiting the timing of ***Frye*** hearings, is apparent in the instant case. Here, the trial court summarily reversed itself

majority that it is possible that Dr. Shane's extrapolation from the theory that Doxepin causes a flaking of the eye's pigment can be extended to find that under such a massive overdose, the pigment can obstruct the flow into the Canal of Schlemm. I do not believe the procedure followed by the trial court enables us to determine whether Dr. Shane's extrapolation is based on generally accepted medical theory. Since there never was a ***Frye*** hearing, the record is unclear whether there is general acceptance that Doxepin causes *any* flaking of the pigment.

¶ 35 Here, when the defense questioned the admissibility of Dr. Shane's testimony pre-trial, the trial court denied the motion *in limine* without a hearing. When Dr. Shane referred to his supporting literature in his trial testimony, this body of literature was excluded for the reason that in Pennsylvania, learned treatises are hearsay. When defendants re-raised the issue in post-trial motions, the trial court granted the motion based on the trial testimony without holding a specific ***Frye*** hearing, which could have explored the literature. I believe the testimony at trial was insufficient to support admission of Dr. Shane's conclusion that in this case Doxepin caused permanent loss of vision (and some cognitive functions) because of the failure to support Dr. Shane's statement that even therapeutic doses of Doxepin cause flaking of the pigment. However, Trach was not triggered to

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after trial without taking any evidence on the issue. In doing so, our review of the matter has been significantly hampered.

put on more definitive evidence because the motion *in limine* had already been denied.

¶ 36 The trial court should have held a ***Frye*** hearing, preferably at the motion *in limine* stage, or at least before reversing the jury's decision on the basis of ***Frye.*** If that had been done, then the record would have been fully developed. Trach would have had the opportunity to establish the general acceptance of the basis of Dr. Shane's expert's opinion,[22] and the defense would have had the ability to challenge the underlying theory upon which Dr. Shane relied for his extrapolation. In nearly every case in which a ***Frye*** challenge is raised, a hearing will be needed to assess whether the opinion is generally accepted. Failure to hold a hearing will often result in error, as it did in this case.

¶ 37 I would therefore vacate the trial court's decision and remand for an opportunity for the parties to follow the procedures outlined above, with the trial court giving both sides the opportunity to present evidence, if desired, and to make further argument following the presentation of evidence.

[22] The failure to hold a hearing is contained within Trach's argument that the trial court misapplied ***Frye***.