IN THE COURT OF COMMON PLEAS

OF PHILADELPHIA COUNTY

CIVIL TRIAL DIVISION

MIA ROBINSON, et al. : JULY TERM, 2011

: NO. 778

vs. :

:

WOLTERS KLUWER :

HEALTH INC., et al. : CONTROL NO. 14123047

MEMORANDUM OPINION

Mia Robinson was born with severe heart defects. During pregnancy her mother took Zoloft for depression. The defendants claim the testimony of plaintiff’s experts on general and specific causation fail to meet the methodological requirements for admissibility of scientific opinion testimony and should be precluded at trial.[[1]](#footnote-1)

The *Frye* test, adopted into Pennsylvania in the case of *Commonwealth v. Topa*,[[2]](#footnote-2) has been clearly explained by the Supreme Court of Pennsylvania in *Grady v. Frito-Lay*,[[3]](#footnote-3) and the Superior Court in *Trach v. Fellin*.[[4]](#footnote-4)

The *Frye[[5]](#footnote-5)* test is an evidentiary standard for determining whether the methodology employed by a proposed witness is considered scientific by others in a relevant scientific field. The *Frye* standard to determine whether scientific expert testimony will “help” the jury[[6]](#footnote-6) is not applicable to all expert testimony. Although the proponent of evidence bears the burden of proving admissibility,[[7]](#footnote-7) this admissibility standard applies only when “novel science” is proposed.[[8]](#footnote-8) The *Frye* standard does not involve any Judicial finding of the accuracy of the ultimate opinion. It is only the methodology employed which is to be evaluated, not the conclusions reached.[[9]](#footnote-9) The initial formulation of the *Frye* Court continues to be instructive:

“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.”

The Pennsylvannia *Frye* test for admissibility does not require this Court to independently determine the Judge’s understanding of the science of epidemiology, teratology or statistics as applied to the facts of Mia Robinson’s birth defects. Unlike Courts which have adopted the *Daubert* [[10]](#footnote-10) standard, this Court may not independently analyze or evaluate peer reviewed journal articles or other scientific material except as they relate to the methodology employed by the proposed expert witnesses in reaching conclusions. Thus as detailed by Justice Cappy in *Grady v. Frito-Lay*, the *Frye* test is comparable to other common Judicial functions.

Writing for the Court in *Grady v. Frito-Lay* Justice Cappy said:

“One of the primary reasons we embraced the *Frye* test in *Topa* was its assurance that Judges would be guided by scientists when assessing the reliability of a scientific method.”

“We believe now, as we did then, that requiring judges to pay deference to the conclusions of those who are in the best position to evaluate the merits of scientific theory and technique when ruling on the admissibility of scientific proof, as the *Frye* rule requires, is the better way of insuring that only reliable expert scientific evidence is admitted at trial.”

“We also believe that the *Frye* test, which is premised on a rule-that of “general acceptance” –is more likely to yield uniform, objective, and predictable results among the courts, than is the application of the *Daubert* standard, which calls for a balancing of several factors. Moreover, the decisions of individual judges, whose backgrounds in science may vary widely, will be similarly guided by the consensus that exists in the scientific community on such matters.”

Although both the *Frye* and *Daubert* standards relate to methodology and not conclusions, the differences are dramatic. Under the *Frye* standard this Court is required to perform fact finding only as to the synchronicity of proposed expert testimony with acceptable scientific investigation.[[11]](#footnote-11) Pursuant to the *Daubert* standard scientific consensus does not per se permit opinion testimony. A scientific consensus that proper methodology was employed is only one of several nonexclusive criteria for determining whether the expert testimony will “assist” the jury. The *Daubert* standard requires the court to make an independent judicial scientific judgment whether the methodology is scientifically sound even if a scientific consensus of propriety exists. Judges with different understanding of scientific processes can make different rulings on the same opinion subject only to an abuse of discretion appellate review standard.[[12]](#footnote-12) Pursuant to the *Frye* standard the Court need only determine whether an appropriate scientific community considers the methodology used to reach an opinion is scientifically sound. To be available for jury evaluation the methodology employed by the expert must be scientifically acceptable.[[13]](#footnote-13)

Real scientific knowledge is not and never has been static. Even using proper methodology scientists routinely disagree and even reach different conclusions while accepting the same underlying data as accurate. Through the interaction of differing but scientifically appropriate conclusions derived from commonly accepted data, knowledge progresses. Likewise different scientific disciplines may properly opine on the same questions using different but proper methodologies.

Thus, the trial court faces two primary questions in any *Frye* analysis:

1. Is the data and other underlying information relied upon the type of data properly relied upon in a scientific discipline appropriate to the question presented for jury determination? And;
2. Was this proper data analyzed in accord with a scientific discipline appropriate to the question presented for jury determination?

In this case Plaintiffs’ expert Dr. Jewell’s methodology used to conclude that Zoloft taken during pregnancy can be the cause heart birth defects is challenged.[[14]](#footnote-14) Dr. Jewell based his analysis upon the same publicly available peer reviewed medical literature used by defense experts and by defendant Pfizer itself in internal documents. Dr. Kimmel, the primary defense expert witness at the *Frye* hearing agreed that the appropriate first step in determining whether Zoloft is teratogenic is to identify the relevant literature.[[15]](#footnote-15) Dr. Kimmel agreed that Dr. Jewell reviewed the appropriate literature: “Yes I listened so I certainly know Dr. Jewell and I looked at the same literature.”[[16]](#footnote-16) Pfizer’s qualified expert employees also looked at that same literature. These expert employees found 81 potentially relevant studies, abstracts, and papers of which 68 were not determined to be useful. The same thirteen studies formed the relevant literature used by plaintiff’s experts, defense experts, and Pfizer scientists.

Dr. Jewell analyzed these peer reviewed published studies which compared different populations and performed different analyses. Defendant Pfizer’s litigation experts and scientists analyzed the same body of literature to their conclusions. Defendant Pfizer’s May 2014 internal document entitled “Response to Pharmacological Risk Assessment Committee (PRAC) cumulative Review of Growth Retardation In Children and Adolescents”[[17]](#footnote-17) describes[[18]](#footnote-18) a comparable methodological review of the same literature and reports a remarkably compatible conclusions to that of Dr. Jewell namely “….a consistently positive association has been found for sertraline exposure and cardiovascular defects, especially septal defects.”

Of these relevant studies, six demonstrated positive associations between sertraline during pregnancy and teratogenic effects.

Dr. Kimmel agreed that some of these studies showed positive associations.

“Q. It says, some studies have found associations between sertraline use during pregnancy and particular birth defects, is that what it says

A. Yes it does.

Q Do you agreed with that?

A. Yes.”[[19]](#footnote-19)

Although Dr. Kimmel disagreed with the Pfizer’s scientists who found an association he provided no description of any differences between Pfizer’s scientific methodology or that used by Dr. Jewell.[[20]](#footnote-20)

Dr. Jewell evaluated the studies which showed positive associations between Zoloft and heart birth defects and also evaluated the studies which revealed negative associations or were inadequate to formulate any scientific opinion. Dr. Jewell considered whether the positive associations were a function of random variation or chance. He evaluated possible confounding factors including detection bias, smoking, obesity, and confounding due to the underlying condition which caused Zoloft to be prescribed. Dr. Kimmel concedes that this next step in a methodological evaluation is also appropriate.

“Q. Dr. Jewell took these positive associations in his methodology and then assessed them for chance, bias, confounding, correct?

1. He did apply those ideas.”[[21]](#footnote-21)

Dr. Jewell evaluated other possible explanations for the association. Although Dr. Kimmel equivocated, he finally agreed that Dr. Jewell’s procedure, although debatable, was acceptable science.

“Q. That was one of the methods by which Kornum attempted to address [confounding by indication]; is that correct?

1. That is.

Q. And that is a generally well-accepted methodology for testing confounding by

Indication, isn’t it?

1. It is a method. It is an inferior method to others, because confounding by –

COURT: Wait, wait, wait. The question was, isn’t it, and the answer is yes, isn’t it?

WITNESS: I would say there’s some debate in the pharmacoepidemiology world.

COURT: Is there a debate in your professional opinion?

WITNESS: Yes.

COURT: So you don’t have an opinion about whether [that’s] acceptable or not?

You’re not certain. Is that –

WITNESS: I am uncertain.

COURT: You can’t testify to a reasonable degree of scientific certainty whether that’s an acceptable methodological method, correct?

WITNESS: Yeah, it’s a method, yes. It’s an acceptable method.”[[22]](#footnote-22)

Indeed Dr. Kimmel admitted that he has used that same methodology in one of his own published peer reviewed articles.[[23]](#footnote-23)

Finally, Dr. Jewell analyzed whether the demonstrated associations represent an actual causal connection. Dr. Jewell evaluated the literature in accordance with commonly accepted criteria for evaluating causation, the Bradford Hill criteria, to determine whether the positive association is a product of chance or bias. Defendant expert Dr. Deepak Srivastava agreed that this is a proper criteria.[[24]](#footnote-24)

Conclusions contained in published peer reviewed literature results have found heart birth defects associated with Zoloft use. Dr. Jewell’s methodology and even his basic conclusions were further confirmed by a power point presentation prepared by Pfizer employee[[25]](#footnote-25) Francesca Kolitsapoulis entitled “Epidemiology Review of published literature on Sertraline Use and Teratogenic Effects in Pregnancy” which says:

“Epidemiological studies have shown that infants born to women who had first trimester paroxetive exposure had an increased risk of cardiovascular malformations….”[[26]](#footnote-26)

The defense concedes that if it had been properly performed, Dr. Jewell’s purported methodology was appropriately scientific. Although Dr. Jewell’s methodology facially comports with defendants view of proper methodology, the defense claims these proper factors were so improperly evaluated that his deviations from proper evaluation rises to the level of no scientific evaluation at all.

Defendant primarily presents three issues.[[27]](#footnote-27) The defense claims Dr. Jewell’s methodology is inadequate because of his improper assessment of confounding. The defense claims that Dr. Jewell’s analysis improperly considered studies which have overlapping populations as if they were separate studies. The defense claims that Dr. Jewell improperly “groups” or “lumps” cardiac birth defects.

The gold standard study is the randomized control trial in which the outcome of two comparable populations are identified and one is exposed to the medication. All agree that this gold standard cannot be ethically done concerning Zoloft in pregnant women. Thus, the studies from which conclusions can be dawn are observational studies. The parties agree on the relevant observational studies and substantially agree on the subgroup of observational studies which find an association between Zoloft and cardiac birth defects. Two Pfizer documents offered into evidence analyzed the same observational studies as plaintiff’s expert and reach comparable conclusions from those studies.

Dr. Kimmel agreed that Dr. Jewell’s methodology in determining whether the studies had replicated results was proper. Nonetheless the defense claims there are problems in Dr. Jewell’s evaluation of replication. The defense contends that since three studies have overlapping populations these studies cannot demonstrate replication.

Dr. Jewell acknowledged the overlapping populations but applied his expertise to determine that since they only partially overlap they nonetheless confirm and replicate the findings. Dr. Kimmel admitted that plaintiff’s experts’ consistency and replication opinions were confirmed by other study authors.

“Q. Dr. Jewell notes in his report that Pedersen concluded in his paper that agreement with data from a different population with a different type design is reassuring for the validity of our results. That shows some consistency in replication correct?

A. That’s what Dr. Pedersen says in his paper.

Q. Correct and that one of the papers you relied upon correct?

A. But its only one of many papers that.

Q. is it correct or incorrect?

A. Yes its correct.” [[28]](#footnote-28)

The question of overlapping populations presents a proper topic for cross examination but not such a methodological defect as to warrant preclusion.

Defendants contend that Dr. Jewell’s use of not statistically significant data as a supporting trend is impermissible. However, Dr. Kimmel agrees that not statistically significant results could, if appropriately evaluated, support consistency.

“Q. Well can a non-significant results ever be used to support consistency in your professional opinion?

A. Sure, as long with all the other data that are inconsistent.”

Although Dr. Kimmel himself does not consider not statistically results as a “supporting trend” he does concede that some experts consider this methodologically appropriate.

“WITNESS: The term supporting trend is something that I actually did teach against because it leaves you up to total interpretation of what you believe of the number, so I cannot say that’s a supporting trend. That would be against my teaching.

COURT: Do others teaching epidemiology teach the supporting trend process that you don’t teach?

WITNESS: Possibly.

COURT: You’re not sure?

WITNESS: I’m not sure. I’m not sure.

COURT: Why do you say possibly then?

WITNESS: Well, I don’t sit in on classes. I don’t know what everybody teaches.

COURT: Yeah, but is there literature about it?

WITNESS: Oh, there are definitely-

COURT: And therefore, some might be using that literature to teach.

WITNESS: People will use that term for those values of P values.”

“Q: Do you believe that this statement as set forth here about statistical significance and nonsignificant results, that you can indeed take significant results and results that are not significant and use those to show a consistent affect?

….

A: I agree that you can do it…”[[29]](#footnote-29)

Q. And so in this paper, you relied upon insignificant results or nonsignificant results to support consistency; is that correct?

A. In this example, yes.

Q. Is that a valid methodology?

A. Assuming you look at all the data and not just pick the ones that are consistent with your theory.”[[30]](#footnote-30)

The defense claims Dr. Jewell improperly “lumped” birth defects because Mia Robinson’s primary cardiac birth defect was transposition of great arteries (“TGA”). The defense contends that causal conclusions can only properly be drawn from studies which showed an association between Zoloft and TGA. The defense claims that only statistically significant results for her most serious heart defects, TGA, should be used to demonstrate causation.

TGA is an exceptionally rare birth defect. The sample of birth defects in published studies segregated as to TGA alone are simply insufficient in number for a statistically significant association to be revealed. Most studies did not segregate TGA as a separate birth defect. Thus grouping or lumping is not claimed to be per se improper. The defense concedes it may be appropriate to lump or group cardiac defects for certain purposes.

Dr. Kimmel specifically testified that “lumping” could be a proper methodology.

Q. “And would it be proper to lump all the heart defects that occur in children births when they’re born, would that be a proper methodology.

A. It’s not improper, but its---

Q. Does not improper mean proper or is that different.

A. It is proper assuming that you also look at the specific defects and treat those in the proper way. It’s one proper way of doing – looking at the data.”

The issue is whether an appropriate grouping was used by Dr. Jewell. The question as to general causation presented in this case is whether Zoloft taken during pregnancy can be the cause of any cardiac defect suffered by Mia Robinson at birth.

Dr. Jewell conceded that there is insufficient information to isolate TGA birth defects. Likewise, the defense agrees that the TGA birth defects isolated in the studies are too few for statistically significant associations to be found. The failure to find statistically significant results is because of the size of the populations in the studies and the infrequency with which TGA birth defects occur. Specific birth defects can be so finely isolated that insufficient numbers exist to ever demonstrate statistically significant results.

Dr. Kimmel agreed that birth defects can be differentiated so finely that no statistically significant results can be demonstrated. Dr. Kimmel further agreed that appropriate and scientific studies properly grouped TGA with other birth defects.

Under those circumstances logic dictates and proper scientific methodology approves the necessity of grouping results. Not only was this methodology used by Dr. Jewell but also used by investigators in peer reviewed published studies, defendants’ experts, and Pfizer’s employees.[[31]](#footnote-31) If adverse consequences are finely differentiated statistically significant cannot be found because of an insufficiently number of examples. As the Superior Court insightfully recognized:

“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… is not scientific certainty but legal sufficiency…. That [a] case may have been the first of its exact type, or that [a plaintiff’s] doctors may have been the first alert enough to recognize such a case does not mean that the testimony of [the experts] …. Should not have been admitted.”[[32]](#footnote-32)

Sometimes proper scientific conclusions must be extrapolated from available data. In *Trach v. Fellin,* the Superior Court held that where the opportunities to examine a specific cause and effect relationship are limited, extrapolation from analogous studies is permissible. A number of applicable studies utilize the EUROCAT classification system which lump or group birth defects. Dr. Kimmel agreed that the EUROCAT classification system was properly scientific.[[33]](#footnote-33) Dr. Kimmel agreed that the studies which demonstrated associations with heart defects generally could not show association with specific heart defects. He explained:

“So one possibility is just a power issue right. So you have fewer numbers of individual defects. And that’s what the EUROCAT was saying, don’t look at every single line items, put them together so you will at least have enough within a physiologic, biologically plausible---.”

Dr. Kimmel agreed the Jimenes-Solom Peer Review articles properly grouped or lumped heart defects.[[34]](#footnote-34) He also agreed that lumping TGA with “other hearts defects” as a category, as in the Huybrechts study was proper.[[35]](#footnote-35)

“Q. So if you wanted to get any information about TGA from these studies you would have to lump that category with others wouldn’t you?

1. That’s what’s been—well that is------well, that’s what’s been done in Huybrechts and some of the other studies, that’s correct.

Dr. Kimmel concedes, as he must, “there is a balance to be struck between lumping together heterogeneous sets of anomalies and splitting so finely that there are few cases in each group.” [[36]](#footnote-36)

The Superior Court decision in *Trach v. Fellin*, is exceptionally instructive where the limitations of scientific studies and the impossibility of ethically having a gold standard methodology requires a practical evaluation. The Court recognized that courts do not require perfection.

In *Trach v. Fellin*, the plaintiff was given the wrong medication by the defendant Thrift Drug. Although the plaintiff was prescribed an antibiotic, he ingested six times the maximum permissible dosage of an anti-depressant. Of course there never could be any studies to determine the long term effects of taking six times the maximum permissible dosage of an anti-depressant medication. Plaintiff’s expert testified by extrapolating from the known side effects of the medication taken to opine as to the long term effects. The *Trach* Court said:

“..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 which is known.”[[37]](#footnote-37)

The *Trach* court discussed at length the case of *Donaldson v. Central Illinois Public Services Co.*,[[38]](#footnote-38) in which:

“the scientific community had been limited by the small number of neuroblastoma cases and its abilities specifically to link exposure to coal tar with development neuroblastoma.”

The experts in that case extrapolated from similar “but not identical studies and theories to conclude that coal tar exposure caused the children’s neuroblastoma.” That court said:

“..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, 262 Ill.Dec. 854, 767 N.E.2d at 328, 330. Accordingly, 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, 262 Ill.Dec. 854, 767 N.E. 2d at 328 citation omitted).”

The Superior Court also quoted favorably from the case of *Ferebee v. Chevron Chemical Co.*[[39]](#footnote-39):

“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.”

The Superior Court concluded:

“as long as the basic methodology is sound the scientist may extrapolate from this sound scientific basis when it is either impossible or unethical to perform the sorts of clinic trials that would yield definitive results.”

Defendants claim that although plaintiff’s experts facially utilize an acceptable methodology the manner in which they applied this acceptable methodology is unacceptable. Thus the question presented by Defendants in this *Frye* motion can be understood as when does a difference in degree become a difference in kind as to require preclusion. This Court concludes that the differences presented here are differences in degree of a proper methodological analysis and not differences in the kind of analysis performed such that the methodology is improper. The issues and considerations presented in defendants’ *Frye* motions are certainly appropriate for effective cross examination but preclusion is not warranted. The *Frye* motions as to general causation are denied.

SPECIFIC CAUSATION

Plaintiffs’ specific causation experts opine that Mia Robinson’s cardiac birth defects were caused by exposure to Zoloft in utero. They base this opinion on their experience and clinical judgment. A physician must use clinical judgment and expertise to determine the possible cause of birth defects. This is vital for the physician to properly advise their patients who may wish to consider a second pregnancy. There is nothing novel about clinical judgment testimony.[[40]](#footnote-40) In *Kendal v.Wyeth, Inc[[41]](#footnote-41).* the Pennsylvania Superior Court said: “certainly differential diagnosis is a generally accepted methodology.”[[42]](#footnote-42)

Dr. Abdullah, plaintiff’s expert ruled out other medications, diabetes, gestational diabetes, obesity, smoking, alcohol use, illegal drug use and second hand smoke as causes of Mia Robinson’s cardiac defects at birth. Dr. Abdullah also ruled out genetics. Likewise, Dr. Vekemans followed a similar approach. Their clinical judgment opinion is admissible.

The Court notes that once the Court concludes that general causation opinion is admissible opinion on specific causation may readily follow. In the case of *Klein v. Aronchick*,[[43]](#footnote-43) plaintiff’s experts had testified to direct causation. Nonetheless the Superior Court found reversible error because the trial court refused to give an “increased risk of harm” jury charge. In that case plaintiff’s expert report stated and the expert testified in court to a reasonable degree of medical certainty that the defendant doctors’ over prescription of medication had directly caused plaintiff’s kidney disease. The trial court refused to allow the expert who had offered such a definitive opinion as to direct causation to also testify that taking too many drugs had also increased the risk of kidney damage.

The Superior court said:

“although preferred the expert is not necessarily required to use the magic words of ‘increased the risk’ so long as the opinion is expressed to the requisite degree of medical certainty.”

The court held the plaintiff should have been permitted to argue increased risk of harm and a jury charge as to increased risk of harm should have been given.

It is of course a logical necessity that anything which actually causes a result must have increased the risk of causing that effect. Thus, the Superior Court instructs that when general causation testimony uses proper methodology and plaintiff presents actual causation evidence, if requested, a charge on increased risk of harm must be given. This jury instruction must be given even if never explicitly mentioned in the causation expert’s reports or testimony.

Since this court has found that the opinion that Zoloft can cause heart birth defects is permissible it is logically and necessarily permissible that specific causation experts be permitted to testify and plaintiff permitted to argue that the ingestion of Zoloft during pregnancy increased the risk of birth defects of the heart. It then becomes a jury question as to whether that increased

risk presented by Zoloft was a factual cause of any specific heart birth defect. Plaintiff’s specific causation experts may testify.

BY THE COURT

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DATE MARK I. BERNSTEIN, J.

1. No challenge is presented to the qualifications of any of the highly qualified experts. [↑](#footnote-ref-1)
2. 471 Pa 223, 369 A,2d 1277. (1977) [↑](#footnote-ref-2)
3. 576 Pa. 546 839A.2d 1038 (2003) [↑](#footnote-ref-3)
4. 817 A.2d 1102 (2003). [↑](#footnote-ref-4)
5. Initially formulated in *U.S. v Frye,* 293 F. 1013 (D.C. Cir, 1923. [↑](#footnote-ref-5)
6. See Pa.R.E. 702. [↑](#footnote-ref-6)
7. *Grady v. Frito-Lay*, 576 Pa. 546 839 A.2d 1038 (2003). [↑](#footnote-ref-7)
8. *Trach v. Fellin,* 817 A.2d 1102 (2003). [↑](#footnote-ref-8)
9. See *Trach v. Fellin,* specifically overruling *Mackenzie v. Westinghouse,* 674 A.d 1167 (Pa. Cmwlth. 1996) [↑](#footnote-ref-9)
10. *Daubert v. Merrill Dow Pharmaceuticals Inc*., 509 US 579, 113 S.Ct. 2786, 125 L.Ed 2d 469 (1993). [↑](#footnote-ref-10)
11. Like preliminary rulings as to authenticity (Pa. R.E. 901 et. seq. or personal knowledge (Pa R.E. 602) the Court may not preclude opinion testimony because the Judge disagrees with the testimony. “Judges in jury trials should not exclude expert testimony simply because they disagree with the conclusions of the expert.” *Betz v. Pneumo Abex, LLC,* 615 Pa. 504, 542-43, 44 A.3d 27, 51 (2012). [↑](#footnote-ref-11)
12. *General Electric Co., v. Joiner, et ux,* 118 S.Ct. 512, 177A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036. [↑](#footnote-ref-12)
13. Perfect or ideal is not the standard, See *Trach v. Fellin,* 817 A.2d 1102 (2003). [↑](#footnote-ref-13)
14. It was agreed in conference that the Court ruling concerning Dr. Jewell also would apply to Dr. Finnell, Dr. Cabera and Dr. Kapper because they use a commensurate methodology. This was incorporated in an Order dated February 10, 2015. [↑](#footnote-ref-14)
15. N.T., 2/18 2015, 74: 21-75:2 [↑](#footnote-ref-15)
16. N.T., 2/18 2015, 75: 6-15. [↑](#footnote-ref-16)
17. P-1 at the *Frye* hearing. [↑](#footnote-ref-17)
18. At pages 42-43. [↑](#footnote-ref-18)
19. N.T., 2/18, 2015 84: 10-15. [↑](#footnote-ref-19)
20. “Q. This paper that you reviewed earlier P-1, also says when focusing on a specific defect a consistently positive association has been found for sertraline exposure and cardiovascular defects especially septal defects. Do you disagree with that conclusion? A. Yes.” N.T., 2/18 15 74/7-13. [↑](#footnote-ref-20)
21. N.T., 2/18 2015 95-15-20. [↑](#footnote-ref-21)
22. Tr. 2-18-2015 p.m. at 19:21-21.3. [↑](#footnote-ref-22)
23. N.T. 2/18/15 21:4 12. [↑](#footnote-ref-23)
24. N.T., 2/13/13 pm at 6:17 21. [↑](#footnote-ref-24)
25. The defense has stipulated that the scientific investigators involved in the internal studies presented by plaintiff at the *Frye* hearing were appropriate Pfizer employees qualified to reach scientific conclusions. [↑](#footnote-ref-25)
26. An “accurate” conclusion reached through an improper methodology should be rejected and not presented for jury evaluation. A conclusion the Court deems inaccurate reached through a proper scientific methodology is admissible in evidence subject to destructive cross examination before a jury. No explanation of any differences between the methodology utilized by Dr. Jewell and the methodology utilized by Pfizer’s employees who reached comparable conclusions was offered into evidence at the *Frye* hearing. [↑](#footnote-ref-26)
27. Other issues have been raised and are therefore preserved for all future purposes but are overruled without need to be specifically addressed in this Memorandum Opinion. [↑](#footnote-ref-27)
28. N.T., 2/18 71/12-24. [↑](#footnote-ref-28)
29. N.T., 2/18/2015 p.m. at 53/16-22. [↑](#footnote-ref-29)
30. N.T., 2/18/2015 p.m. at 53/16-22. [↑](#footnote-ref-30)
31. While the precise methodology of Pfizer employers has not be fully explained, it appears that they have grouped or lumped birth defects. [↑](#footnote-ref-31)
32. *Trach v. Fellin,* 817 A.2d 1102 at 1117 (quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535-36 (D.C. Cir. 1984), cert. denied, 469 U.S. 1062 (1984)). [↑](#footnote-ref-32)
33. N.T., 2/18 15 117 5-7 118: 5-20. [↑](#footnote-ref-33)
34. N.T. 2/18 15 111: 16-25. [↑](#footnote-ref-34)
35. N.T., 2/18 15 8:13-20. [↑](#footnote-ref-35)
36. N.T. 2/18 15 118/5-8. [↑](#footnote-ref-36)
37. *Trach v. Fellin*, 2003 Pa. Super. 33, 817 A.2d 1102, 1114 (2003). [↑](#footnote-ref-37)
38. 767 N.E.2d 314 (2002). [↑](#footnote-ref-38)
39. 736 F.2d 1535-1536 (D.C. Cir. 1984). [↑](#footnote-ref-39)
40. See *Haney v. Panonelli*, Pa. Super. 261, 830 A.2d 978 (2003). [↑](#footnote-ref-40)
41. 1154 EDA 2010, 2012 WL 112609 (Pa. Super. Ct. 2012). [↑](#footnote-ref-41)
42. See also, *Snizavich v. Rohm Haas*, 2013 Pa. Super. 315, 83 A.3d 191 Pa. Super 2013. [↑](#footnote-ref-42)
43. 85 A.3d 487 (2014). [↑](#footnote-ref-43)