IN THE COURT OF COMMON PLEAS
OF PHILADELPHIA COUNTY

CIVIL TRIAL DIVISION

ROBERT PORTER AND KATHERINE PORTER, INDIVIDUALLY, AND AS PARENTS AND NATURAL GUARDIANS OF ROBERT T. "BO" PORTER, A MINOR:	:	SEPTEMBER TERM, 2007 NO. 03275
Plaintiffs	:	
vs.	:	
SMITHKLINE BEECHAM CORPORATION, and PFIZER, INC.,	:	CONTROL NO. 15081504
Defendants	:	

MEMORANDUM OPINION

Plaintiff filed suit against Pfizer alleging that the ingestion of Zoloft by Katherine Porter during her pregnancy caused Minor plaintiff to be born with the serious birth defect omphalocele. On August 14, 2015 Defendant filed Frye Motions seeking to preclude the Expert Testimony of Dr. Freedman and Dr. Cabrera.[1] On august 26, 2015 Plaintiff filed a response. A two day hearing was held on September 16 and September 17, 2015. At that hearing the court heard from Dr. Freeman and Dr. Kimmel and received into evidence numerous documents including the written report of Dr. Cabrera.[2]

[1] A Third Frye motion as to Dr. Healy was withdrawn in Court upon the representation that he would not be called at trial

[2] Plaintiff bears the burden of proof that their proposed witness may testify. *Grady v. Frito-Lay*, 576 Pa. 546 839 A.2d 1038 (2003).

Minor Plaintiff Bo Porter was born with a giant omphalocele. A giant omphalocele is an abdominal wall birth defect in which an infant's intestine or other abdominal organs are outside of the body. During pregnancy Mrs. Porter took the anti-depressants Paxil and Zoloft for depression. Both these drugs are classified as SSRIs. Plaintiff proposes to call Dr. Freeman and Dr. Cabrera on the question of General and Specific causation The defendants claim the testimony of these experts fail to meet the consensus methodological requirements for the admissibility of scientific opinion testimony and should be precluded at trial.

The *Frye* test, adopted into Pennsylvania in the case of *Commonwealth v. Topa*,[3] has been clearly explained by the Supreme Court of Pennsylvania in *Grady v. Frito-Lay*,[4] and the Superior Court in *Trach v. Fellin*.[5]

The *Frye*[6] 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[7] is not applicable to all expert testimony. Although the proponent of evidence bears the burden of proving admissibility,[8] this admissibility standard applies only when "novel science" is proposed.[9] 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.[10] 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

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[3] 471 Pa 223, 369 A,2d 1277. (1977)
[4] 576 Pa. 546 839A.2d 1038 (2003)
[5] 817 A.2d 1102 (2003).
[6] Initially formulated in *U.S. v Frye,* 293 F. 1013 (D.C. Cir, 1923.
[7] See Pa.R.E. 702.
[8] *Grady v. Frito-Lay*, 576 Pa. 546 839 A.2d 1038 (2003).
[9] *Trach v. Fellin,* 817 A.2d 1102 (2003).
[10] See *Trach v. Fellin,* specifically overruling *Mackenzie v. Westinghouse,* 674 A.d 1167 (Pa. Cmwlth. 1996)

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 Pennsylvania *Frye* test for admissibility does not require this Court to independently determine the Judge's understanding of the science of epidemiology as applied to the facts of Bo Porter's birth defects. Unlike Courts which have adopted the *Daubert* [11] 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."
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> "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."
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> "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

[11] *Daubert v. Merrill Dow Pharmaceuticals Inc.*, 509 US 579, 113 S.Ct. 2786, 125 L.Ed 2d 469 (1993).

perform fact finding only as to the synchronicity of proposed expert testimony with acceptable scientific investigation.[12] 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.[13] 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 permissable for jury evaluation the methodology employed by the expert must be scientifically acceptable.[14] The Frye test recognizes that proper scientific methodology is not dependent upon the perspective of the court analyzing science or the jurisdiction involved in a case.

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:

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[12] 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).

[13] *General Electric Co., v. Joiner, et ux,* 118 S.Ct. 512, 177A.L.R. Fed. 667, 139 L.Ed.2d 508, 66 USLW 4036.
[14] Perfect or ideal is not the standard, See *Trach v. Fellin,* 817 A.2d 1102 (2003).

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?

The Plaintiff seeks to have Robert M. Cabrera, Ph.D. testify as to general and specific causation of the birth defects of this case. Within Dr. Cabrera's forty-seven page report, are five pages devoted to his training, education, and experience and twelve pages devoted to animal studies concerning SSRIs, Zoloft, and birth defects. The most recent animal study referenced is from 1998, seventeen years ago. Animal studies can be instructive in determining the teratogenicity of a pharmaceutical and indeed may possibly be the basis for a valid extrapolated scientific opinion in the absence of human studies.[15] However, animal studies are of limited utility in determining teratogenicity where a significant body of human exposure studies exists in the published medical literature. Dr. Cabrera does not acknowledge these limitations.

Dr. Cabrera's opinions relies on a limited number of the peer review published literature. Dr. Freeman relied on these same studies and formed a comparable analysis. Dr. Cabrera's analysis suffers from many of the same methodological defects set forth in this Court's Memorandum Opinion precluding Dr. Freeman from testifying. These methodological defects are incorporated herein.

[15] See *Trach v. Fellin,* 817 A.2d 1102 (2003).

Dr. Cabrera's report reveals other methodology failings. Dr. Cabrera finds that the studies show that SSRIs significantly increase the risk of birth defects in human studies and opines that SSRIs are teratogenic. However, he does not specifically analyze SSRIs results excluding the pharmaceutical Paxil. This is necessary because Paxil has been identified as having significantly different effects from Zoloft and the other SSRIs and is a causal factor in birth defects. Dr. Cabrera's opinion as reflected in his report does not contain an adequate discussion of the differences between Paxil and Zoloft with respect to causation of birth defects.

Dr. Cabrera opines that the mechanism of action resulting in birth defects is that an "alteration of serotonin signaling by sertraline, can impact embryonic development resulting in several different congenital malformations." This opinion must be considered speculation without basis. Dr. Cabrera presents no information as to the baseline serotonin level in the developing fetus or in the change caused by Zoloft. Without this date there can be no valid opinion as to whether the level of serotonin changes in positive or negative manner or has any outcome determinative effect. Likewise, Dr Cabrera performs no dose response analysis necessary to draw a valid scientific conclusion that a medication causes a specific biological mechanism.

For the reasons set forth in the previously issued Memorandum Opinion precluding the testimony of Dr. Freeman and the summary recitation herein, Dr. Cabrera is precluded from offering causation opinions in this matter.

BY THE COURT

10/6/15

DATE

MARK I. BERNSTEIN, J.