IN THE COURT OF COMMON PLEAS
OF PHILADELPHIA COUNTY
CIVIL TRIAL DIVISION

CIVIL ADMINISTRATION

RECEIVED DEC 13 1996

JEFFREY BLUM, a minor by his parents and natural guardians, JOAN and FRED BLUM, and JOAN and FRED BLUM, in their own right SEPTEMBER TERM, 1982

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VS.

MERRELL DOW PHARMACEUTICALS, INC.

NO. 1027

OPINION

"Q: Sir, it has been the pattern and practice and custom of the Merrell Company, in reporting to the FDA, to pick and choose selective information over the past thirty years, relating to the drug Bendectin; correct?

A: Yes, that's correct."[1]

Introduction

On the day Jeffrey Blum was born with clubfeet, which would require eleven surgical procedures in thirteen years, James Newberne, Merrell Dow VicePresident for drug safety, was addressing the Maternal Advisory Committee of the Food and Drug Administration. He testified unequivocally that Bendectin was safe for maternal use during pregnancy He under-represented the incidence of clubfeet found in animal studies. He overstated the number of animals studied. He failed to disclose that an inadequate number of animals had been tested, or that test animals had died due to improper care. He did not disclose that dosing accidents had killed test animals. He did not reveal that the tests were scientifically inadequate due to insufficient dosing levels. He did not tell the FDA that he was not proud of Merrell Dow's testing procedures. He did not reveal that Merrell Dow "chose" what information to report to the FDA, or that relevant testing on Bendectin was hidden by being reported to the FDA Decapryn file.[2] Fifteen years later, at this trial, a jury of twelve citizens learned the rest of the story.

After nine weeks of testimony in 1986, a jury found that the drug Bendectin, taken by Joan Blum to control morning sickness in pregnancy,[3] was a legal cause of Jeffrey Blum's clubfeet. That jury awarded one million dollars in compensatory and one million dollars in punitive damages. On June 3, 1993, the Supreme Court reversed that verdict because ". . . Merrell Dow was deprived of its constitutional right of trial by jury when the trial judge overruled its Motion for Mistrial and proceeded to verdict with only eleven jurors, after one juror became ill."[4] The Supreme Court affirmed the order of the Superior Court which had declared that verdict "a nullity."[5]

At the retrial in 1994, after seven weeks of evidence, twelve jurors rendered a constitutionally valid, unanimous verdict awarding Joan and Fred Blum two hundred thousand dollars for medical expenses. They also rendered a constitutionally valid unanimous verdict of four million dollars as compensation for the pain and the disfigurement and the emotional affliction Jeffrey Blum endured during his twelve

years of life prior to trial, as well as for all the injury he will suffer for the remainder of his life. The jury also awarded fifteen million dollars in punitive damages. Following this verdict, damages for delay pursuant to Rule 238 were awarded in the amount of four million, nine hundred eighteen, one hundred forty seven dollars ($ 4,918,147.00).

Defendant seeks Judgment Notwithstanding the Verdict; or, in the alternative, a new trial.

It is obvious that appellate review must be strictly grounded upon the evidence presented at this trial. A reviewing court is precluded from considering "facts" not of record.[6] The essence of the "rule of law" requires that each party has a due process right to present all relevant evidence[7] and to have appellate review based solely upon the evidence as it was presented to the jury. There is no right to base an appeal upon extraneous material outside of the record created in the court below.[8]

II. Issues Presented

The defendant acknowledges that this is a unique case.[9] Despite years of "Bendectin" litigation, this is the only case in which a causal connection between maternal use of Bendectin and clubfeet has been claimed. Nonetheless, ignoring the basic precept of the "rule of law," the defendant offers written opinions of other judges, grounded in materially different factual records from the voluminous and significant factual record created in this case. The defendant offers opinions in other cases, based upon different systems of jurisprudence, in support of the novel proposition that the judge, rather than the jury, should determine the facts in this case."[10]

Plaintiffs' right to appellate review exclusively upon the record as presented to the jury in this trial is as basic a principle of Anglo-American due process as the right of cross-examination.[11] Indeed, the record of this case demonstrates that these two principal rights are inextricably intertwined and both are central to the absolute right to trial by jury reaffirmed by the Supreme Court in their review of the prior trial in this very case.

Defendant claims that plaintiff's experts employed an unscientific methodology in formulating the opinion that the drug Bendectin caused Jeffrey Blum's clubfeet. Through cross-examination, plaintiff demonstrated at this trial that the experts called by the defendant differ from plaintiff's experts not in scientific methodology, but only in their ultimate conclusion. Stripped of a false forensic illusion of scientific infallibility and uniformity, defendant simply claims that the factual findings of the jury, reached after seven weeks of serious study of testimony, including eleven well-qualified experts, should be replaced by judicial fact-finding more to defendant's liking.

Blum vs. Merrell Dow"[12] affirms the inviolate and absolute right to trial by a jury of twelve citizens. In this appeal, the defendant seeks to castrate the same jury held so precious in their prior appeal. The, defendant asks this court to rule that judicial fact-finding is mandated in birth defect cases."[13] Defendant Merrell Dow further asks this court to decree, as a matter of law, that the Bendectin which Joan Blum took at the time of her pregnancy, during the period when Jeffrey Blum's legs were forming in utero, did not cause the bilateral clubfoot condition with which he has been afflicted since birth. In essence, defendant asks this court to declare, as an unalterable precept of Pennsylvania law, that the drug Bendectin cannot cause birth defects.[14]

The proposition that a finding of fact by the jury should be changed into a legal precept of its opposite is unprecedented. The contention stands in stark contrast to long established law that the determination of legal cause is exclusively the provence of the fact-finder. Pennsylvania jurisprudence has consistently affirmed the central role of the jury, leading inexorably to and culminating in the Supreme Court's decision in this very case two years ago.[15] With neither justification in reason nor precedent in law, defendant wants this court to ignore centuries of Pennsylvania jurisprudence and transmogrify the role of the jury. Even if this court would have made different findings of fact, it would be a gross abuse of judicial power to overturn this verdict.[16] The essence of defendant's post-trial motions is the claim that Bendectin cannot cause birth defects and that any opinion to the contrary, no matter how qualified the expert witness who sincerely holds that opinion, must be based upon unscientific methodology as a *matter of law.*

A detailed review of the evidence reveals that plaintiffs experts employed the same methodology as did defendant's experts, and that plaintiffs experts' methodology was specifically approved by several of defendant's expert witnesses. Additionally, plaintiff's expert

conclusions, themselves, were confirmed by defendant's expert witnesses. Defendant's claim for relief is legally insupportable and factually inaccurate.

III. Plaintiffs Evidence

Plaintiff presented the testimony of Dr. Allan K. Done, a board-certified pediatrician and toxicologist; Dr. Adrian Gross, a veterinarian and former FDA official; and Dr. Stuart Newman, Ph.D, a cellular biologist. Plaintiff also read into evidence deposition testimony from experts called to testify by the defense at the first trial. Plaintiffs experts relied upon the same material and employed the same methodology as the defendant's experts.

Plaintiff's experts based their testimony on four recognized and approved scientific approaches employed in analyzing causation in birth defects: chemical structure analysis, in-vitro studies, animal studies, and-epidemiological studies. Plaintiff's experts concluded that Bendectin was a drug capable of causing birth defects; and, in fact, did cause Jeffrey Blum's clubfoot condition.

A. Dr. Gross

Dr. Adrian Gross provided expert testimony concerning animal studies on the effects of Bendectin. Dr. Gross is a doctor of veterinarian medicine with a Master's Degree in pathology, and advanced studies in statistics and biometry. Dr. Gross was employed by the FDA for fifteen years, evaluating animal testing of drug safety. The defendant does not challenge Dr. Gross' qualifications to provide expert testimony.

Dr. Gross extensively reviewed the drug testing performed by Merrell Dow and concluded that significant numbers of abnormalities in test animals had never been reported to the FDA. Included in the abnormalities not reported were animals having the musculoskeletal defect of club limbs. Dr. Gross outlined serious deficiencies in the Merrell Dow studies, including too few animals, too low an experimental dosage and avoidable mishaps to animals studied. Dr. Gross testified that defendant, Merrell Dow actively concealed from the FDA data which demonstrated that Bendectin caused birth defects generally, and clubfeet specifically, in laboratory animals.[17]

Dr. Gross testified: "…….in each of the studies, the agent on test, which was either Bendectin, the three ingredients, Bendectin or doxylamine succinate or one of its ingredients, can be regarded as a teratogen..in that it significantly affects and it increases the frequency of birth defects…in the totality of these studies and it may be manifested somewhat different in each study, but, in sum total, adds up to the same picture. These agents interfere with normal development of the young." [18]

Dr. Gross testified: "…from everything that I have said here for two days, Bendectin does induce such birth defects in animals. That is clear. Such results are significant. They are unambiguous. They are non-equivocal. They are clear beyond anything one could desire. It stares you in the face. The drug itself is a teratogen." [19] Dr. Gross testified that animal studies performed by Merrell Dow specifically Ied to the conclusion that Bendectin causes clubfeet in animals.[20] He testified further that the teratogen effect of Bendectin was manifest at lower doses than the drug Thalidomide, which is known to cause severe birth defects in humans. [21]

B. Dr. Done

Dr. Alan Done is a Board Certified pediatrician and toxicologist. He served as an official with the FDA and on the faculty of a number of medical schools. He has done birth defect research and published three hundred articles in the medical literature. He has taught in the field of "teratology." No general challenge to his qualifications to offer expert opinion on causation in birth defects is presented.

Defendant claims to challenge the scientific validity of his methodology. The reality is, defendant challenges only his conclusion. Dr. Done testified that the chemical structure of Bendectin is similar to other known teratogens. He also testified that in-vitro studies demonstrated the detrimental effects of Bendectin upon cells grown in test tubes. Dr. Done described a scientific study performed by Dr. John Hassell at the National Institute of Dental Health which concluded that Bendectin adversely affected the development of limb bud

cells and had a teratogenic potential comparable to Dilantin, a known human teratogen.[22] Dr. Done testified to other studies which confirmed the teratogenicity of Bendectin, including epidemiological studies which supported his conclusion that Bendectin is a teratogen. Dr. Done evaluated the "Heinonen study, [23] applied his scientific expertise and concluded: "the likelihood of having a baby with clubfeet is 2.1 times as great if doxylamine [the main ingredient in Bendectin] is taken during the first four months of pregnancy than if it is not taken. It's 97 % I likely that this is a real difference that did not occur by chance alone.[24]

Dr. Done referred to a report authored by Dr. Jick: "There was thirteen times the likelihood that a woman exposed to Bendectin with more than two prescriptions worth of exposure would have a malformed baby with a limb disorder, as opposed to those not exposed. And that again is significant as reflected by the confidence intervals.[25] Dr. Done concluded that the Bendectin taken by Joan Blum during pregnancy caused Jeffrey Blum's clubfeet.

Initially, defendant objected to the use of Dr. Done's testimony through the notes of testimony from the prior trial. Pre-trial, defendants sought to preclude Dr. Done's testimony, claiming that the use of his prior testimony precluded them from confronting him with "subsequently published scientific research." Defendant initially claimed that without confronting Dr. Done with these subsequent studies would permit the plaintiff to present misleading testimony to the jury.

Taking this claim as a seriously presented objection, the court insisted that plaintiff make Dr. Done available for a deposition to enable the defendant to question him about studies published subsequent to his testimony at the first trial. Argument on this objection and the insistence of the court that Dr. Done be made available for a deposition recurred over several court days between May 2 and May 9. When plaintiff agreed to make Dr. Done available, and a time and place for Dr. Done's deposition in California was established, the defendant abruptly decided that it did not wish to pose any additional questions at all.[26] This objection has clearly been knowingly, intelligently and voluntarily waived.

No objection to Dr. Done's testimony was raised at the prior trial."[27] The plaintiffs had a statutory right to offer the notes of Dr. Done's prior testimony as presented at the earlier trial by virtue of statute, enacted as 42 Pa.C.S. §5934.

42 Pa.C.S. §5934 reads:

Whenever any person has been examined as a witness in any civil matter before any tribunal of this Commonwealth or conducted by virtue of its order or direction, if such witness afterwards dies, or is out of the jurisdiction . . . and if the party against whom notes of testimony of such witness are offered, had actual or constructive notice of the examination and an opportunity to be present and examine or cross-examine, properly proven notes of the examination of such witness shall be competent evidence in any civil issue which may exist at the time of his examination, or which may be afterwards formed between the same parties and involving the same subject-matter as that upon such witness was so examined.

The Pennsylvania Rules of Civil Procedure also gave plaintiffs a right to present Dr. Done's prior testimony. Pa.R.C.P. 4020 provides:

The Pennsylvania Rules of Civil Procedure also gave plaintiffs a right to present Dr. Done's prior testimony. Pa.R.C.P. 4020 provides:

(a) At the trial, any part or all of a deposition, so far as admissible under the rules of evidence, may be used against any party who was present or represented at the taking of the deposition or who had notice thereof if required, in accordance with any one of the following provisions: . . .
(3) The deposition of a witness, whether or not a party, may be used by any party for any purpose if the court finds . . .

(b) that the witness is at a greater distance than one hundred (100) miles from the place of trial or is outside the Commonwealth, unless it appears that the absence of the witness was procured by the party offering the deposition.

Clearly, if deposition testimony is admissible at a subsequent trial which occurs when the witness is outside the Commonwealth, notes of testimony from a prior trial in the same case involving the same parties must also be admissible. By failing to object to Dr. Done's

testimony at the first trial, the defense has waived objections to the testimony presented pursuant to statute and Rule. Defendant's technical objections to Dr. Done's testimony are entirely devoid of merit. As is demonstrated, Dr. Done relied upon acceptable scientific methodology in reaching his opinion.

C. Dr. Newman

Plaintiffs third expert, Dr. Newman, has a Ph.D. in chemistry and extensive experience in the biological aspects of complex chemical systems. Dr. Newman presented an analysis based on the molecular structure of Bendectin. Dr. Newman testified that one of the active ingredients in Bendectin, doxylamine, can pass through the placental barrier and cause effects in a developing embryo.

D. Dr. Stolley

Plaintiff offered into evidence expert testimony presented by the defendant at the prior trial. Plaintiff read into evidence the testimony of Dr. Paul Stolley. At the time of the first trial, Dr. Stolley was a physician and co-director of the Clinical Epidemiology Unit at the University of Pennsylvania and a Professor of Medicine at the University of Pennsylvania School of Medicine. Dr. Stolley testified there was three times the risk of malformation in the babies of mothers who had filled more than one prescription for Bendectin.[28]

IV. Defense Testimony

The defense called seven expert witnesses. All opined that Bendectin did not cause birth defects. All conceded that some scientific studies confirmed a connection between Bendectin and birth defects.

A. Dr. Bracken:

Dr. Bracken, a professor of epidemiology at Yale University, was presented as an expert in the field of epidemiology.[29] Dr. Bracken published "Bendectin (Debendox) as a Risk Factor for Pyloric Stenosis" in the American Journal of Obstetrics and Gynecology. This study found no significant increase in birth defects among women who had used Bendectin during pregnancy except a statistically significant association with the birth defect pyloric stenosis.[30]Dr. Bracken explained to the jury, in detail, what epidemiologists mean by a " confidence interval,"[31] stating that an association with a 95% confidence interval is generally accepted as proof of causation in the field of epidemiology.[32]

On cross-examination, Dr. Bracken testified that epidemiology, as a science, is incapable of proving that a drug is safe for ingestion.[33] Dr. Bracken's own epidemiological study consisted of interviews with 1,427 mothers, of whom only 122 had taken Bendectin during pregnancy. Dr. Bracken testified that there was a 2.91 increase in the odds of mothers who used Bendectin and smoked having a child with a birth defect:

"Q: Could it be said that a mother who used Bendectin -- that the odds were at least two and a half times -- that they were more two and a half times odds of a mother who used Bendectin and smoked having a child with a birth defect?

A: Yes...

Q: And that was a statistically significant finding; correct?

A: That's correct.[34]

Dr. Bracken was asked to address the concept of scientific peer review journals. Dr. Bracken was asked:

Q: It is true, sir, that an article which is in the category of less than good can pass peer review; correct?

A: Yes." [35]

He testified that his own published study was "less than good.[36]

Nonetheless, based upon his less than good study, he testified that Bendectin does not cause birth defects.

B. Dr. Klebanoff:

The defense called Dr. Klebanoff, a medical officer with the Epidemiological Branch of the National Institute of Child Health and Human Development, part of the National Institute of Health. Long after Bendectin was removed from the market and unavailable for use, Dr. Klebanoff analyzed data on Bendectin. This study was published in the Journal of Teratology as "Bendectin and the Human Congenital Malformations."[37] Dr. Klebanoff collected data on pregnant women from the Kaiser Health Plan in California during the 1970's. Information on 58 different kinds-of birth defects were analyzed. Dr. Klebanoff's study found three statistically significant birth defects associated with Bendectin exposure: congenital cataracts, under-development of the lungs and microcephaly.[38] Despite these statistically significant associations, Dr. Klebanoff testified on direct examination that Bendectin does not cause any birth defects.[39] Dr. Klebanoff further offered his opinion that it is impossible to prove that Bendectin did not cause birth defects.[40]

Dr. Klebanoff confirmed plaintiff 's experts' conclusion on the central issue at the trial and on this appeal. He testified on cross-examination that Bendectin is positively associated with bilateral clubfeet:

Q:Let me ask you this: Isn't it a positive association, in your article, between Bendectin and clubbed feet (sic) based on the same standard that you used for cataracts and vomiting?

A:It's not a statistically significant positive association, but it is-- it is greater than one. Let's call it that.

Q: So it's a positive association; correct?

A:Okay. Yes."[41]

C. Dr. Tyl:

The defense called Dr. Rochelle W. Tyl, research director for the Center for Life Sciences and Toxicology at- the Research Triangle Institute as an expert in the field of developmental biology, teratology and experimental teratology. Dr.Tyl is a developmental toxicologist, who considers herself a "research teratologist." Dr. Tyl defined a "teratologist" as follows:" . . . the term . . . is based on the Greek 'terata,' which means monster or malformations. So the old term for looking at birth defects, as well as other effects from exposure during in utero development, was called teratology. So a teratologist studied the causes and effects of in utero exposure to some agents."[42]
Dr. Tyl does research into birth defects by performing animal studies involving rats, mice and rabbits. Dr. Tyl has a Ph.D. in developmental genetics and is board-certified in toxicology. She has no degree in "teratology." Dr. Tyl has done no scientific work whatsoever on human systems or human cells.[43]

Dr. Tyl testified that when she received her degree in developmental genetics in 1968, there were no courses offered in "teratology."[44] Dr. Tyl testified that even today, there is no degree offered by any institution of higher learning nor any certification by any authority in teratology:

Q: So if one were to say to themselves, "I want to be a teratologist when I grow up," one could not get a degree in Teratology; correct?

A: Not to my knowledge. Can I expand on that?

Q: Sure.

A: . . But you would get training in Embryology. You would get training in Biochemistry. You would get training in all of those fields that bear on development, both normal and abnormal, in test systems. And I did that.

Courses in statistics."[45]

Dr. Tyl further testified that an embryologist, a biochemist, pharmacologist, or a toxicologist who is interested in issues of teratology could have appropriate credentials to offer an opinion as to the teratogenicity of a drug.[46]

The National Toxicology Program, an umbrella agency of the Federal Government, including the Food and Drug Administration, asked Dr. Tyl to perform an animal study on the effects of Bendectin. Dr. Tyl reported the results of this study in "Developmental Toxicity Evaluation of Bendectin in CD Rats"47 and "Final Report, Teratologic Evaluation of Bendectin."[48] Dr. Tyl's study revealed "an increased incidence of a skeletal malformation, which was a short thirteenth rib, but only at the top dose, which killed 17 % of the mothers, caused profound maternal toxicity, profound other developmental toxicity."[49]

Dr. Tyl was specifically asked for her opinion as to whether Bendectin was teratogenic in rats. Dr. Tyl said based on the definition of a teratogen, which says, if you see malformations only at doses where the mothers are severely affected, then the effects on the conceptus may be due to the effect on the mothers. The mothers were sick. Then it is not -- in my estimation, it is not a teratogen in rats, based on my study."[50] Dr. Tyl's study did not segregate clubfeet as a defect studied.

Dr. Tyl was hired by the Federal Government to perform animal studies on Bendectin long after Bendectin had been withdrawn from sale in the United States.[51] At that time, numerous epidemiological studies had been performed on the effects of Bendectin use.[52] Dr. Tyl's opinion is that Bendectin is not a teratogen, but it is a "developmental toxicant."[53] As a result of her study, Bendectin was placed on the "List of Developmental Toxicants"[54] and is listed on the list of reproductive toxicants maintained by the United States Government.[55]

On cross-examination, Dr. Tyl discussed well-established requirements for any scientific animal study. Dr. Tyl testified that maternal toxicity at the highest doses was necessary for a good scientific study and that the animals needed to be carefully selected and cared for to avoid sickness. In Dr. Tyl's opinion, sick animals would invalidate a scientific study.[56] Dr. Tyl believes that even in studies involving small numbers of animals, results cannot be understood without using statistical analysis.[57]

Outside of the jury's presence,[58] the court asked Dr. Tyl a series of general questions concerning teratology as a scientific field. Referring to previous expert testimony which had employed a concept of results "suggesting" a causal association, Dr. Tyl was asked if the science of teratology had any clear definition of the term "suggestion." Dr. Tyl reported that there was no general definition, but in her opinion, the word "suggest" connotated an anecdotal suggestion, a concept of suspicion.[59] Likewise, Dr. Tyl stated that there is no teratological definition of the word "associated." although the witness stated that it was a term routinely used with statistical analysis, she understood it as follows:

"When you see an effect at a -- when you see an effect that is either relatively uncommon in the vehicle control, or not seen in your vehicle control group, and it exhibits a dose response relationship; that is, there's few of them at the low dose, there's more of them at the mid-dose, there's lots of them at the high dose, then you can say with reasonable assurance and that frequency, it is statistically significant, that maybe there's an association between what you administered, if all of the other things are kept equal, and the outcome.

It doesn't say cause and effect. Statistics can never prove causality. And, for example, in developmental toxicity studies, they're a lot tougher because you don't usually get a nice dose response curve. In terms of malformation, you tend to get nothing; nothing; nothing; lots, as you overwhelm the animal's ability to deal with the test material."[60]

When asked whether an association is an evaluation by the principal investigator or a scientific concept determined by the application of clear and specific standards, Dr. Tyl responded: "You can use statistics to show significant associations, or you can look at the data and evaluate whether or not there's an association; and, usually, you do both." 61 Dr. Tyl was asked whether any teratological definition of "proof" existed: "Is there a teratological definition of proving teratogenicity?" Dr. Tyl responded: "I don't think there is. You just beat it to death with a bunch of studies."[62]

Dr. Tyl's opinion is that teratological studies deal with the reality of causation only "indirectly."[63] Dr. Tyl said, "That word is probably rarely used, because cause and effect is so difficult to prove. Most of us don't touch the word 'cause' with a ten-foot pole. We'll use 'results in', 'is associated with'".[64] With respect to Dr. Tyl's specialty of animal studies, Dr. Tyl was asked: "Do teratological animal studies attempt to say something about cause?" Dr. Tyl responded, "Yes. But they rarely use the word 'cause'." The court asked, "What words do they use instead of 'cause'?" and the witness responded, ";Results in' or 'associated with.' But they are tippy-toeing around 'cause'...[b]ecause you can't ever say with absolute certainly that treatment 'X' results in outcome 'Y'. You can talk about statistical association, or biological association."[65]

Dr. Tyl testified that the science of teratology has no generally accepted definition of "aberration" either: "The terms 'aberration', 'variation', 'alteration' [all of which are found in the studies] can be used interchangeable. Some people are trying to give specific definitions to these terms; and it's not really working."[66]

Dr. Tyl did provide a scientific definition of "malformation" that she "assumed" that everyone would agree to. She said that although she would not use an "aberration" interchangeable with the term "malformation", other scientists might. Dr. Tyl further confirmed that there is no generally accepted teratological standard as to whether the term "aberration" includes the term "malformation,"[67] and conceded that the term "aberration," itself, has no clear scientific meaning.[68]

D. Dr. Shapiro:

Dr. Shapiro was called as a witness by Merrell Dow to provide an expert opinion in the field of epidemiology. He is the head of the epidemiology department of Boston University.[69] His formal training was minimal, consisting of only eleven credits towards a Master's Degree in Epidemiology.[70] In his initial testimony, Dr. Shapiro misstated his formal education in the field of epidemiology.[71] Dr. Shapiro is co-author of "Birth Defects and Drugs and Pregnancy." Considering only Dr. Shapiro's true academic qualifications and experience, he is qualified to provide expert testimony. The weight of that testimony is for jury evaluation.

Dr. Shapiro testified that epidemiological studies could never prove the safety of a drug[72] and conceded that there was a positive association between minor malformations, the category in which he classified clubfoot, and the use of Doxylamine Succinate (the active ingredient in Bendectin).[73] Dr. Shapiro stated that absent statistically significant epidemiological findings, no valid conclusion on causation could ever be scientifically reached. Nonetheless, Dr.Shapiro's opinion was that Bendectin could not cause birth defects.[74]

Dr. Shapiro testified that a drug taken by the mother after the time of fetal limb formation in-utero could not possibly cause a limb defect because all limbs had already developed. Nonetheless, the data on which his opinion was based grouped together, in one group, both women who took Bendectin during the time when limb formation was occurring and women who took Bendectin after the baby's limbs]lad already formed. Dr. Shapiro conceded that the data he used to evaluate whether or not Bendectin caused limb defects, diluted. the number of women who could possibly show any effect of the drug[75] by including many women who could show no effect from Bendectin.[76] No scientific basis or justification was ever presented for this illogical grouping.

Dr. Shapiro conceded that to include those women for whom no causal connection between Bendectin exposure and a limb defect was possible would increase the number of women in the group supposedly being evaluated for birth defect causation due to Bendectin. Dr. Shapiro admitted that this illogical grouping resulted in an underestimate of the risk of clubfeet in offspring.[77] He admitted that this resulted in a lower percentage of incidents of clubfoot in the "Bendectin exposed" group.[78] He refused, however, to attribute any significance to this underestimation.[79] Dr. Shapiro's grouping significantly underestimated the risk of birth defects by categorizing women who could not demonstrate the effect together with women who could. Dr. Shapiro admitted that his study underestimated the risk of harm from Bendectin.[80]

Dr. Shapiro testified:

"THE COURT: Did your study underestimate the risk?

THE WITNESS: Yes.

THE COURT: Okay.

THE WITNESS: No, I beg your pardon, your Honor. If there were a causal relationship, that causal relationship would have been underestimated. If there were no causal relationship, which is what I believe, or none that could be demonstrated, I doubt if there could not have been any underestimates."[81]

When asked specifically whether the inclusion of inappropriate women in the total number would change these figures ("would [this] result in an underestimate of the magnitude of the effect?"), his testimony was, "If there were a causal effect, yes."[82]

The circularity of this reasoning is obvious, revealing transparent, pseudoscientific thought. It demonstrates justification science not inquisitive science. Clearly revealed in this testimony is the unalterable preconception from which Dr. Shapiro's "scientific conclusion" was derived. Believing that Bendectin could not cause birth defects his analysis demonstrated his predetermined conclusions and thereby, in his own mind, confirmed his preconceptions with the sanctity of immutable "scientific" truth.

E. Dr. Newberne:

Dr. Newberne was a Vice-President of defendant, Merrell Dow, with responsibility for animal testing and drug safety. Testifying on behalf of the defendant before the Maternal Advisory Committee of the FDA in September of 1980, Dr. Newberne ignored numerous musculoskeletal defects recorded in the original data of his own studies.[83] At this trial, Dr. Newberne acknowledged a consistent pattern of under-reporting to the FDA. Dr. Newberne testified:

"Q: Sir, it has been the pattern and practice and custom of the Merrell Company, in reporting to the FDA, to pick and chose selective information over the past thirty years relating to the drug Bendectin; correct?
A: Yes, that's correct."[84]

Dr. Newberne conceded his testimony as recorded in the official notes of the FDA meeting was false.
"Q: Well, sir, if you added --- first of all, if this statement is true, truly recorded as to what you said, then you, sir, grossly misrepresented the facts; correct?

A: I think so and I don't think that's an accurate -- accurate statement of what I said. . . . these numbers are not in accord with the number I had at all.

Q: These numbers aren't in accord with anything that approaches reality, are they?
A: I think they are inaccurate.
Q: And if the FDA took them down like you said it, then, sir, this would constitute a misrepresentation; correct?

A: If it does, it's an inadvertent one; because I had given these data on a Table to everyone to see at the FDA. I don't understand how the error occurred in the text." [85]

Dr. Newberne reviewed the animal studies on which the defendant relied to market Bendectin as a safe product. One "scientific" study by Dr. Smithells, presented to the medical community to provide evidence for the safety of Bendectin, was rejected for publication in three widely respected peer review journals: the "British Medical Journal," "Lancet" and the "New England Journal of Medicine" before being

finally accepted in "Teratology."[86] During this time, Dr. Smithells was actively soliciting funds from defendant Merrell Dow. In his letters, Dr. Smithells identified his understanding of the purpose of his study. In one groveling letter, he said: *"Much clearly depends upon the value of this publication [87] to Merrell Dow National Labs. If it may save the company large sums of money, large sums in the California court (which is rather what I thought when we undertook this study), they may feel magnanimous. If with the passage of time, the study is of no great significance, I can only regard the figure you suggest as generous and welcome."[88]*
In September of 1975, Dr. Smithells again wrote to the defendant: "I would not like you to think that in writing at this time I am threatening not to publish or any such nonsense. . . . [N]eedless *to say, I should appreciate any gesture Merrell felt inclined to make, but I imagine that if we are able to give Debendox* 89 *a clean bill of health with regard to teratogenesis, this would be of substantial help in the courtrooms of California."[90]*
Through Dr. Newberne, the jury heard testimony about two studies on Bendectin conducted by Dr. Roll in Germany. In 1982, Dr. Roll wrote a report for the German Official Health Agency published in the German Literature. The Roll study of the drug Lenotan, the German equivalent of Bendectin, concluded: "It can be said that Lenotan has teratogenic potential in the animal study under certain conditions."91 The first Roll study using a strain of rats bred for the German Government (Wistar or "government rat") found that Bendectin was associated with the birth defect of diaphragmatic hernia. The study concluded: "Doxylamine has proven itself in the present case to be teratogenic in Wistar rats bred by the Federal Health Agency."[92]

Upon learning that the Roll study determined that Bendectin was a teratogen in Wistar rats, Dr. Newberne hired a third-party "consultant." [93]
Professor Tuchmann-DuPlessis received a letter from Dr. Newberne asking him to meet with Dr. Roll informally.[94] Copies of this correspondence were sent directly to Merrell Dow's lawyers. Following a meeting with Professor Tuchmarin-Duplessis, Dr. Roll did a second study but made significant changes in procedure: he did not use Wistar rats, nor did he examine skeletons, as he had in the first study. [95] Dr. Roll's second study utilized rats whose natural incidence of diaphragmatic hernia was so high that it masked any increased defects created by Bendectin.[96] Not surprisingly, Dr. Roll's second study failed to confirm his first study's conclusion that Beridectin was teratogenic.

In the early 1980's, an animal study was performed by Dr. Hendrickx, a researcher at the University of California in Davis. As did Dr. Roll, Dr. Hendrickx performed two animal studies on the safety of Bendectin. In his first study, Dr. Hendrickx found a statistically significant increase in heart defects in Bendectin treated monkeys.[97] Again, the defendant funded a second study which attained much more positive results for defendant.

In a letter dated September 22, 1981, Dr. Hendrickx wrote to Dr. Newberne discussing funding for a second study. In that letter, Dr. Hendrickx said, "I *also indicated that we would be willing to discuss or modify any part of the proposal with you in order to meet a common objective*." [98] Dr. Newberne denied that the common objective was the defense of Bendectin litigation.[99] However, Plaintiff's Exhibit 328 was presented to the jury. This single line from the defendant's financial records revealed that the defendant funded Dr. Hendrickx' second study in excess of three-hundred thousand dollars. This ledger stated: "Hendrickx' monkey study - defense". The second "scientific" Hendrickx study was funded out of the defense budget for the purpose of defending litigation. Dr. Newberne had no explanation: "As I say, Mr. Klein, I don't how that got on there. It has nothing to do with -- from my perspective, of defending the litigation."[100] Nonetheless, from both Hendrickx studies, Dr. Newberne conceded that "there is… an effect by Bendectin on the developing fetus which delays the closure of the ventricular septum.[101]
Defendant Merrell Dow performed only one epidemiological evaluation, the Bunde-Bowles study."[102] Dr. Newberne testified that this study contained design and supervision problems, as well as other errors and irregularities.

The interaction of "scientific studies" and litigation defense were further exposed in Dr. Newberne's testimony:

Q: And, sir, the Drug Epidemiology Unit up at Boston University, are you generally familiar with that group in your capacity as the Drug Safety Director?

A: Yes.

Q: Five hundred thousand dollars to support Dr. Shapiro and his group, sir. A half-million dollars on this one sheet was also for defense of the litigation, wasn't it?

A: No. It was for studies assigned, from what I know about that Unit. And that's not my -- that's not my role, epidemiology. But from what I know of what was done by the unit, it was purely epidemiology; and they need --- they need money to the -- run the tests.

Q: Yes, sir. They needed money at Boston University to run the tests,and Dr. Hendrickx needed money in California to run his laboratory, and the Merrell Company needed some good data to defend this drug in the courtrooms of the United States of America; correct?

A: No, that was not the purpose of these studies."[103]

Trial in this case continued for eight days after this testimony. Numerous witnesses were called to testify for defendant, Merrell Dow. At no time was any explanation offered as to why legal defense funds paid for these "scientific"studies.

F. Dr. Brent:

The concluding expert witness called by defendant to consolidate disparate studies into a comprehensive refutation of plaintiff's evidence was Dr. Robert L. Brent. Dr. Brent is Board-certified in pediatrics. He has degrees from Rochester Medical School and Ph.D. degrees in radiology, biology and embryology. Dr. Brent was in the Genetics Division of the Atomic Energy Commission during World War II. Board eligible in genetics, he never presented himself for certification testing. He has been a professor, associate professor or assistant professor in pediatrics at Jefferson University Hospital since 1957. He has been Chairman of the Department of Pediatrics since 1966.

Dr. Brent is a member of numerous professional organizations, including the Teratology Society, the European Teratology Society and the Japanese Teratology Society. He has made presentations around the world, and published three hundred articles in the scientific literature and two hundred seventy nine articles in the medical literature. For fifteen years, he was Editor of the Journal of Teratology. For eighteen years, he has been a retained expert for defendant, Merrell Dow. Described as the originator of the field of teratology, his only formal education in epidemiology was an isolated course in statistics in medical school.[104] Nonetheless, Dr. Brent considers himself "very, very knowledgeable in the field of epidemiology.[105] The majority of

Dr. Brent's research work involves animal research.[106]He has never performed any study concerning the drug Bendectin.[107] Dr. Brent was presented as an expert witness in the field of pediatrics, genetics, clinical teratology, "and encompassed in the field of teratology will be expertise in the understanding and analysis of Epidemiology and animal studies."[108]

Teratology, itself, is not a specialty certified by any board. According to Dr. Brent, anyone who believes they have "appropriate training, education and experience" can self-annoint as a teratologist. Dr. Brent classified teratology as a sub-specialty of developmental biology, and agreed that teratologists can have academic degrees in many fields, including pharmacology, toxicology, pediatrics, obstetrics, pathology, anatomy, physiology, nutrition, medicine, or veterinary medicine.[109]

Dr. Brent considers himself the world's only authority in "secular trend data."[110] This, he claims, is a relevant field of science, although not referred to by any other expert who testified during this trial. This "scientific field" has never been subjected to "peer review" and has only one practitioner, the originator of teratology," Dr. Brent himself. Despite the unique nature of this "scientific field," it was presented by the defense as scientific opinion worthy of belief by the jury.

Dr. Brent also claims expertise in legal matters. He has published a number of articles concerning litigation in "peer review" journals. Dr. Brent has published his opinion that congenital malformation lawsuits are rarely meritorious. An article published in his journal, "Teratology," was entitled, "Litigation-Produced Pain, Disease, and Suffering: An Experience With Congenital Malformation Lawsuits."[111] This publication was based on Dr. Brent's personal review of deposition and trial transcripts, and reported his idiosyncratic credibility decisions in a chart entitled "Distortion of the Facts by Participants in Medical Negligence Litigation."[112]

In this article, Dr. Brent concluded that seventeen out of seventeen plaintiffs lied[113] and 82.6% of plaintiffs' lawyers "distorted" the facts."[114] Dr. Brent further concluded that plaintiffs' experts were lying or distorting the facts 61% of the time.[115] According to Dr. Brent, twenty-five percent of the defendants distorted the facts, but only one defense attorney, out of twenty-one, made any distortions.[116] Not surprisingly, Dr. Brent concluded that only two of twenty-seven defense experts distorted any facts."[117] Dr. Brent wrote, "...the medical expert who testifies for the plaintiff usually demands and receives substantial fees resulting in a sycophantic alliance between the expert witness and the plaintiff's attorney."[118]

The testimony in this trial revealed a sycophantic relationship between Dr. Brent and the attorneys representing Merrell Dow, a relationship which clearly affected the objectivity of his approach and the validity of his writing on the drug Bendectin. Dr. Brent submitted draft articles for approval by the attorneys representing Merrell Dow at the trial of this case. Plaintiffs presented to the jury Exhibit 344, an article entitled: "Bendectin: The Most Comprehensively Studied Human Non-Teratogen, and the Foremost Teratogen-Litigen." Dr. Brent expects to publish this article, as if medical literature, in a prestigious peer review journal, such as the New England Journal of Medicine, the Journal of American Medical Association or Obstetrics and Gynecology.[119] The attorneys representing Merrell Dow at this trial had been sent drafts of this

article for editing in June and, again, in July, 1993.[120]Dr. Brent testified he did not know whether it was common practice to permit attorneys to edit articles prior to publication in the medical literature."[121] Dr. Brent perceived no ethical problem in the practice. Plaintiffs Exhibit 349 demonstrated attorney editing of this supposedly scientific literature. Dr. Brent was questioned concerning the substance of the editing of the "scientific" literature by Merrell Dow's lawyers:

"Q: And the lawyer, here, is commenting to you on the scientific issues.

A: No; on the data that he has, which is frequently more than had in some areas.

Q: In other words, the lawyer at Merrell Dow had more data on some of the scientific issues than you, as the purported expert; is that correct?

A: In some areas. And vice versa. And I have more than they do.

Q: And it's a collaborative effort. You get the whole thing together, lawyer and doctor; correct?

A: I wouldn't call it a collaborative effort; but, we have --- provided each other with important information."[122]

Dr. Brent testified, unequivocally, that Bendectin cannot cause birth defects. Dr. Brent believes that the most common causes of birth malformations are due to inappropriate behavior by the mother during pregnancy."[123]

Dr. Brent confirmed the same methodological approaches utilized by plaintiffs experts. Dr. Brent's methodology for determining teratogenicity was grounded in the same four scientific methodologies employed by plaintiffs experts: chemical structure activity; in vitro-analysis; animal studies; and human epidemiological data. Dr. Brent agreed with Dr. Done that "structure activity analysis" can be helpful.[124] Dr. Brent stated, "If you look --- if you look at a compound, a structure of a chemical compound, you can infer that there may be certain types of biological activity to that compound. In other words, it would fit into a certain class or have certain effects."[125] Plaintiff's experts testified, in part, based upon "structural activity analysis."

Dr. Brent testified that he has performed in vitro-studies and they "...can be considered with regard to determining whether there's a mechanism for a known teratogen."[126] In vitro-studies can be considered with regard to "determining whether there's an effect on those cells, or parts of tissues, in an effort to determine the mechanism of, possibly, how a drug or chemical works."[127] Plaintiff's experts testified, in part, based upon "in-vitro" studies.

Dr. Brent acknowledged the use of animal studies as a scientifically valid procedure in determining teratogeni city. Dr. Brent testified:

"...in almost every instance where an agent has produced has been eventually demonstrated to be positive in epidemiologicalstudies, we've been able to take an animal model and duplicate it; in other words, produce birth defects in the animal model, and, very often, very similar to the birth defect in the human and at the dose that the human is exposed to.[128]

Plaintiff's experts relied in part upon the use of animal studies. Dr. Brent explained proper scientific methodology prior to human ingestion of a drug:

"THE COURT: How do you look at a situation, in the science of Teratology, before a drug is given to humans, in order to decide whether the first human should be permitted to take that drug?

THE WITNESS: Three basic parts. The first is, the Food and Drug Administration has an animal-testing protocol.

THE COURT: So the first is animal testing.

THE WITNESS: The second is human testing, but...

THE COURT: No,No, before you give it to humans.

THE WITNESS: Okay.

THE COURT: You agree that there has to be something done beforeyou give it to humans, don't you?

THE WITNESS: Yes. And they do -- at the present time, they do animal testing, very extensive animal testing, and they do toxicological studies and pharmacological studies.

THE COURT: So the science of teratology says that, "before a drug and don't let me say it if it's wrong. Please stop me, or tell me I'm wrong. The science of Teratology says that before a drug is given to humans, animal studies should be performed, toxicology studies should be performed, and what is the third?

THE WITNESS: Actually, the identification of the compounds, so that you know what you're giving.

THE COURT: The biological basic science of the chemical should be...

THE WITNESS: The pharmacology.

THE COURT: The pharmacology.

THE WITNESS: Yes.

THE COURT: And those are the three types of evaluations that should be performed before a teratologist should say that it is now susceptible to human ingestion.

THE WITNESS: Before the testing in humans can begin.

THE COURT: Any human ingestion, that should be done. Those three types of studies.

THE WITNESS: Correct."[129]

Dr. Brent placed preeminent value on epiderniologic results. Plaintiff's experts also relied on epidemiological data. The differences are not of methodology; only of conclusion.

Discussion:

By this appeal, defendant asks that the law of Pennsylvania be transmogrified so that each trial court can preside over a "scientific court whose primary function is to embody, as precepts of law, the current "generally accepted" opinion of any self-identified scientific establishment. Counsel claims that only generally accepted scientific principles and only subjects having "general agreement" should ever be permitted in court.[130] By this view, the trial judge becomes the courtroom door guardian for scientific conformity: and each trial judge creates, as precepts of law, his or her own individual determination of proper scientific orthodoxy.

Scientific understanding necessarily evolves and must continually create new concepts and theories which evolve into a new consensus, overthrowing outdated orthodoxy. From the retrospective of centuries, or possibly only decades hence, today's absolute truth will be seen as inadequate, naive or superstitious. This is the essence of the modern scientific endeavor. Nonetheless, by defendant's legal theory, judges, as doorkeepers, must seal the courtroom until "science," itself, reaches a new consensus. Defendant's principle would have precluded testimony by every seminal thinker in the history of the world, including Newton,

Pasteur, Freud, Darwin and Einstein. The principles espoused by the defense would have precluded testimony on dynamics, noneuclidean geometry, calculus, the germ theory of disease, the subconscious mind, evolution and relativity. The courts, and thereby all society, would be locked into out-moded thought, erroneous principles and false "truths."

If the law becomes the handmaiden of every self-defining "science," each trial judge ran delusionally become the arbiter of ultimate reality; and whatever the judge accepts as a "generally accepted scientific principle" precludes any courtroom challenge. Castrating the fact-finding role of the jury, the judiciary becomes an absolute bar to legal inquiry, until a new "scientific consensus" claims the mantle of the divine revelation required to open the courtroom doors, but only to let in the new established orthodoxy. 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. The courts of Pennsylvania need no self-appointed scientific door guardians in birth defect cases.

IV. Common Ewert Conclusions:

When ruling, on the Motion for Judgment Notwithstanding the Verdict, the court must review all testimony at the trial in the light most favorable to the plaintiff: "[the] evidence must be considered in the light most favorable to the verdict winner, and he must be given the benefit of every reasonable inference of fact arising therefrom; and any conflict in the evidence must be resolved in his favor."[131]

Each of the four approaches in scientific analysis employed by plaintiff's experts were endorsed by defense experts. In-vitro studies were accepted and never attacked by any expert as an unacceptable scientific methodology applicable to birth defect research.[132]Chemical structure analysis was confirmed as an appropriate investigation into the likelihood or compatibility of the substance in question with the potential for birth defect.[133] In-vitro or animal studies formed the basis of defense testimony, and all the research conducted by Dr. Brent and Dr. Tyl: two self-proclaimed teratologists[134] Results from animal studies are relevant even after epiderniologic results are available. Dr. Tyl and her research institute were retained by the FDA to re-examine Bendectin, through animal studies, lona after significant epidemiological data had become available and had been analyzed:

"THE COURT: Then the more general question is, in your expert opinion, what, if any, is the role of animal studies after epiderniologic studies have been done?

THEWITNESS: They will serve - they can be used to clarify mechanism of action , They can be used to clarify the causation of an effect. If you have a human malformation that is relatively common in the background incidence, in the general population, you would have to see a tremendous increase in epidemiological studies for it to be statistically significant. And I am not an expert in epidemiological studies, okay? Because, of all the noise. There's a background level.
If you're looking in an animal model in which you have very clearly defined what the background noises for incidences of malformation and you can increase the dose, you have a better opportunity, if there is a lesion, ascribing it to the treatment. So it may serve to confirm an

unanticipated finding or a hint of something that may have occurred in the epidemiological studies.

THE COURT: This is outside of the presence of the jury. This is for my purposes and for record purposes; and if my questions make no sense, just tell me, because I don't have somewhere I'm trying to get you to. Okay?

THE WITNESS: Okay.

THE COURT: My understanding of what you just said is that an animal studycan be a cleaner or clearer picture of precisely whatever it is you want to study.
THE WITNESS: Yes. Can be.

THE COURT: Can be. If it's a bad study, it's not going to be anything. But it could be.

THE WITNESS: Yes.

THE COURT: So that, again, don't let me just say something because I'm the Judge. If there is a potential problem, it is not surprising to you for there to be a request for an animal study to try to isolate whether or not that's due to Bendectin.

THE WITNESS: Yes, it is not surprising.

THE COURT: Because it's easier to make sure that there's nothing else that's influencing the data.

THE WITNESS: Right. Can I say one thing?

THE COURT: Yes, please.

THE WITNESS: The animal models aren't always perfect replacements for humans.

THE COURT: In your experience, has it ever happened or is it theorectically reasonable that once a drug is on the market and epidemiological studies have occurred, that an animal study would produce results that caused the drug to be removed from the market, either by the law or by choice?

THE WITNESS: It could occur.

THE COURT: Okay. That would not be a scientifically impermissible or an invalid occurrence.

THE WITNESS: I don't think so. Not in my opinion.[135]

The conclusions reached by plaintiff's experts were, themselves, confirmed by expert defense testimony based upon epidemiological studies.[136] Although, the defense asks for adoption as an absolute principle of law that Bendectin can never cause birth defects, the studies and opinions offered at this trial are to the contrary. Dr. Klebanoff testified that Bendectin is positively associated with bilateral clubfeet.[137] Dr. Shapiro admitted that his work underestimated the risks of Bendectin causing birth defects.[138] Dr. Bracken found a statistically significant association between Bendectin with pyloricstenosis and heart failure anomalies;[139] and, in smoking mothers, a statistically significant association with "all defect categories . . . [including] clubbed feet (sic).[140] Dr. Stolley found that the data demonstrated "a woman who is exposed to Bendectin during the first twelve weeks [and took one more than one prescription[141]], is three times more likely to have a malformation than a woman exposed later than twelve weeks. "[142]

The jury was presented with different opinions, not different approaches; different conclusions based upon the same data. In sworn expert testimony, both in the presence of the jury and in colloquy outside of the presence of the jury, this court evaluated the methodology presented by plaintiffs experts and that methodology was affirmed. [143]

V. **It is Not the Methodology of Plaintiff's Experts to Which Defendant Obiects: Onlv the Conclusion that Bendectin Caused Jeffrey Blum's Clubfeet**

The fallacy of the principle that "scientific consensus" must control access to the courtroom is demonstrated by the testimony in this case. The potentially horrendous consequences of this ideological approach for any court system concerned with justice is vividly portrayed in the founding premise of the entire.. science of "teratology."[144] Teratology is the "science" that defendants claim to be the exclusive discipline for the issues raised in this case. Teratology is the science whose father is also the defendant's leading expert guru, Dr. Brent, and whose Bible appears to be the "peer review" journal, "Teratology."

The "science" of teratology was born with a simple basic premise upon which a consensus of teratologists agreed. This founding premise was the *impermeability of the maternal womb."*[145] Only after thousands of babies were born with stubs for arms and legs, doomed to a stunted and frustrating life of misery caused by maternal use of "Thalidomide," did the teratological "scientific community' consider that, possibly, it was mistaken in the basic organizing principle of their "science." Only when the incidence and causation of this human terata[146] became incontrovertible did the teratological establishment modify its consensus and consider the possibility that the placenta did not protect developing babies from harmful drugs. The impermeability of the placenta is a scientific principle tested and proven inaccurate, through epidemiologic studies in human misery.[147] "Science" can wait for its truths to become tested and rejected. No just court system can permit orthodoxy to preclude redress.[148]

VI. Defendant Seeks to Overturn Long-Established Pennsvivania Law

A. Preemption

The defendant claims that plaintiff's failure-to-warn claim is preempted by federal law. Without justification, defendant asked this trial court to overrule the Pennsylvania Supreme Court. In its own brief, defendant Merrell Dow states we recognize that the Pennsylvania

Supreme Court has refused to find such preemption."[149] Defendant presents neither precedent, public policy, or purpose for adopting this extension of Federal preemption. There is no preemption.

B. Defendant Seeks Selective Reinstatement of a Constitutional Nullity

The defendant asks this court to selectively reinstate the 1986 verdict which they had previously successfully contended was a constitutional nullity on appeal. Defendant claims that the prior jury verdict, which found no fraud, nullifies the fraud verdict rendered at this retrial.[150] The right to a jury twelve citizens can be waived. Since Merrell Dow did not waive their right to a jury of twelve in 1986, the verdict was a nullity.[151] The defendant may not now choose which parts of a constitutionally invalid verdict it wishes to retain.[152] This principle was recently reaffirmed by the Pennsylvania Supreme Court: "It has long been the law of this Commonwealth that the grant of a new trial restores the case to its original status to be tried *de* novo as to all parties and all issues."[153]

C. Defendant Claims a Lack of Sufficiency of the Evidence of Fraud

Defendant claims that the evidence was insufficient to support the jury verdict of fraud. As more fully set forth above, the evidence presented demonstrated a manipulation of "scientific" literature amounting to fraud upon the medical community, upon the FDA, upon Joan Blum's doctor and upon Joan and Jeffrey Blum sufficient to sustain the jury verdict.

D. Defendants Claim Error in the Jurv Instruction

Defendant Merrell Dow purports to claim error in the instructions given to the jury. A jury charge must be reviewed in its entirety to determine whether any error was committed; and if so, whether any such error was prejudicial.154 Defendant does not contest any language contained in the charge; but rather, claims that plaintiffs fraud and warranty theories should never have been presented to the jury.

1. Plaintiff Presents a Valid Cause of Action in Warranty Under Pennsylvania Law

There is, of course, no direct connection between any prescription drug and the ultimate consumer, the patient, except that the drug manufacturer "educates" and markets the drug to the medical community. Few patients have any independent ability to evaluate either the usefulness of, or the dangers in the use of any prescription drug. That is why Federal law prohibited Joan Blum from obtaining Bendectin without a prescription from her doctor. Every patient must rely upon the skill and knowledge of her attending physician.

Dr. Jorgenson, Joan Blum's physician, prescribed Bendectin based on her belief that it was both effective and safe for the developing child in utero. This belief was based entirely upon the defendant's representations. As part of their campaign to aggressively market the drug to obstetricians, defendant represented Bendectin as a totally safe drug for the developing child in utero.

The Physicians' Desk Reference is the standard reference on which physicians rely to learn the proper use, efficiency, potential side effects and negative consequences of any prescription drug. Defendant inserted the following language into the PDR entry on Bendectin:

"Precautions: Because of potential drowsiness, Bendectin should be prescribed with caution for patients who must drive automobiles or operate machinery. Studies in rats and rabbits have revealed no suggestion of drug-induced fetal abnormalities at doses of Bendectin up to 90 times the maximum human dose. In addition, several epidemiologic studies in women who received Bendectin during pregnancy have shown that the incidence of birth defects in their offspring is no higher than in women not taking the drug during pregnancy. Nevertheless, like all drugs considered for use during pregnancy, particularly during the first trimester, Bendectin should be used only when clearly needed."[155]

Dr. Jorgenson relied upon the PDR language to conclude that Bendectin was safe:

"Q: . . . did the PDR, in the seventies or eighties, warn you, as a prescribing physician, of any statistically significant relationship between Bendectin and any birth defects?

A: No. It specifically warns that there were none."[156]

Through the language inserted in the PDR, the defendant expressly warranted to the ultimate consumer, Joan Blum, that there was no danger of birth defects in the use of Bendectin. Defendant further warranted that rat and rabbit studies revealed "no suggestion of drug-induced fetal abnormalities". This unambiguous and absolute language was chosen by defendant. The evidence presented at trial clearly demonstrated the inadequate and fraudulent data on which defendant based these assurances to the medical community. This express warranty upon which Dr. Jorgenson relied, to the detriment of Jeffrey Blum, was properly presented to the jury, which appropriately determined it was a legal cause of the injury.

Defendant Merrell Dow further claims that the issue of implied warranty should not have been presented to the jury. No objection to this charge was presented at either the first trial or the retrial of this matter. The issue has not been properly preserved for appeal. Even had objection been timely made, it is without merit. In Mellon vs. Barre-National Drug Co.,"[157] the Superior Court recognized the applicability of an implied warranty theory against a drug manufacturer. The only permissible use for Bendectin was avoiding nausea during pregnancy. The defendant wrongfully warranted Bendectin as safe for its only permissible use.

Likewise, Merrell Dow claims that it was an error to submit any failure to warn claim to the jury, alleging that, thereby, products liability concepts were injected into the case. The charge, as given, presented only a theory in negligence. The court instructed: "A pharmaceutical manufacturer is not required to warn of dangers which were impossible to know, given the state of knowledge at the time; but a pharmaceutical manufacturer is required to warn of dangers of which it knew, or, in the exercise of due diligence, should have known about at the time it marketed the drug in question."[158] The court, in its charge, clearly distinguished between a negligent failure to warn of the possible risks of using the product and any design or manufacturing defect. A fair reading of the entire jury instruction[159] clearly demonstrates the instructions are fully in accordance with the Superior Court ruling in Hahn vs. Richter.[160] There was no error in this charge and the claim of error is a post-trial construction. This claim was waived at trial.

F. Defendant Claims Three Erroneous RulinEs on Evidence

In seven weeks of testimony encompassing over twenty-six thousand pages of transcript, the defendant claims error in three evidentiary rulings. Defendant claims that reversible error occurred when the court permitted reference to the first trial,[161] reference to evidence of three hundred prior lawsuits and to a single reference to the Unisom label as reported in the PDR.

Page 58 is missing

cross-examination to permit the jury to properly evaluate the objectivity with which the study was designed, conducted and reported. There was no error.

With regard to this issue, plaintiff offered the following point for charge: "Members of the jury, you are aware that this is the second trial of the case. The first case, as I have told you, ended in a verdict with eleven jurors. You are to decide this case on the evidence which was presented to you at this trial, without any speculation regarding the outcome of the first trial." Merrell Dow objected to this instruction. The jury was, nonetheless, clearly instructed that the verdict was to be based on evidence presented in this case. There can be no reversible error premised upon this oblique reference to the first trial and to the three hundred prior lawsuits.

Finally, defendant claims error in permitting into evidence the Unisom label as reported in the PDR. The content of this label was testified about by Dr. Done. This issue was discussed extensively at sidebar. The admission of the label, itself, was proper. There was no prejudice to outweigh its evidentiary value.

G. Propriety of the Punitive Damage Award

Finally, defendant Merrell Dow claims error in the court failing to instruct on proportionality in punitive damages. Again, the defendant claims error, even though this court followed the clearly established law of Pennsylvania.[163] It is well-established that the reasonableness of a punitive damage award is not evaluated in relation to the compensatory damages awarded. The jury is granted broad discretion to assess punitive damages to effectuate "punishment deterrence". In Kirkbride, the Supreme Court stated: "If the amount of punitive damages must bear a reasonable relationship to the injury suffered, then those damages probably would not.serve as a deterrent.[164] The punitive damages award must bear a reasonable relationship to "the character of the tortious act, the nature of plaintiffs harm, the extent of the harm suffered, the wealth of the defendant and the deterrent effect of the award.[165]

In determining its punitive damages award, this jury reasonably considered the character of the act, the nature and extent of the harm and the wealth of the defendant. For eight weeks, this jury was presented with a defense premised upon a continuing claim of scientific validity to admittedly inadequate animal studies, the results of which had been fraudulently presented to the FDA on the very day that Jeffrey Blum was born. The jury learned that the wealth of the

defendant was in excess of seven hundred and eighty million dollars.[166] The punitive damages actually awarded is a small percentage of the net worth of the defendant, and less than four times the compensatory damage award.[167]

The jury heard testimony from thirteen year old Jeffrey Blum. The extent of the injury to this child is not limited to the operations he has had, or the future surgeries he faces. The extent of his loss was presented to the jury in his own words, prepared not for litigation, but as homework.

Jeffrey Blum Direct:
"Do you know what is feels like to be me?

Do you know what it feels like to be normal? I don't.

Do you know what it feels like to be picked on every day?

Do you know what it feels like to walk down a street and know everybody was looking at you and wondering what is wrong?

Do you know what it feels like to trip over your own feet in front of everybody in the school?

Do you know what it feels like to be picked on every day, and not be able to do anything except take the abuse?

Do you know what it feels like to be afraid to wear shorts?

Do you know what it feels like to love to participate in sports, and not be able to play them in gym class?

Do you know what it feels like to have shorts on and walk around my school? Around every corner in school, I can almost guarantee a put-down coming my way. (The most common, "nice socks"
Do you know what it feels like to stay up at night and wonder if you're ever going to be normal or not have to wear braces?

Do you know what it feels like to have a dream that you are normal and you don't have clubfeet; then wake up and put on your braces and go to school?

Now I hope you know what it feels like to be me."[168]

For the reasons set forth above, the verdict of the jury should be affirmed.

Honorable Mark I. Bernstein, J.

Date: 12/13/96

APPENDIX A
Scientific Uniformity

The beliefs we call science, in contrast to those we label magic or superstition, derive from conclusions drawn by methodical testing of hypotheses employing precision of definition, accuracy of observation and integrity of dispassionate analysis performed without preconception.

The record of this trial clearly demonstrated imprecision and inaccuracy in "scientific studies", including those which appeared in supposedly "peer-review" journals. Defendant claims there is a uniformity of scientific opinion. The extensive cross-examination of defendant's experts in this case shows this to be a mythological uniformity.[169]

I. Is statistical analysis necessary to draw scientifically valid conclusions from studies?

While marketing Bendectin as a totally safe drug and proclaiming the safety of its use, defendant Merrell Dow relied upon the result of its own animal studies, results were never subjected to any statistical analysis. Thirty years later, at trial, Dr. Newberne testified in 1994 that statistical analysis is not necessary for scientific validity:

Q: For teratology studies of the type that you ran at the Merrell Laboratories, you never used statistics, and you don't believe that you need to use statistics to analyze the data; correct?

A: That is correct."[170]

Dr. Tyl rejected the validity of this "scientific" principle. Dr. Tyl believes that statistical analysis is required. Dr. Tyl testified:

"Q: Have you ever had a teratologist suggest to you that if you only have a hundred and forty-four [animals] in your RTI study, you don't need to do statistics, you know, you can figure out what the trends are without statistics? Was that ever suggested to you?

A: I don't remember.

Q: If it were suggested to you, would you reject that kind of thinking?

A: Yes sir."[171]

Is there no scientific consensus on this basic principle? Is Dr. Newberne, the only representative of defendant to take the witness stand at this trial, scientifically naive? Is this a question for the judiciary, acting as a "science court" to determine and then preclude Dr. Newberne or Dr. Tyl from testifying because one is wrong; or out of step with proper scientific orthodoxy; or is this

the classic situation where a credibility determination (truthfulness and accuracy) should be made by a jury of twelve citizens?

II. Only a "statistically significant" correlation can be used to demonstrate scientifically acceptable causation, and only a 95 % interval can demonstrate statistical significance.

Defendant proposes the proposition that epidemiologic studies that demonstrate statistically significant positive association between the use of Bendectin by a pregnant mother and clubfeet in the progeny must be an absolute prerequisite to a finding of causation in court.[172]

Dr. Shapiro, an epidemiologist called by defendant, testified that a positive association is statistically significant only if it is expressed to a "95 % confidence interval." On cross-examination, however, Dr. Shapiro acknowledged Dr. that Kenneth J. Rothman is a reputable authority in epidemiology. Dr. Shapiro acknowledged that in Dr. Rothman's works, he accepted a "90% confidence interval" as a valid scientific test for statistical significance.[173] In fact, Dr. Rothman wrote: ". . . the notion of 'statistical significance' could be expunged from the lexicon of the epidemiologist with no loss.[174]

Dr. Klebanoff found a "strong positive association" between cataracts and vomiting despite wide confidence intervals.[175] Dr. Klebanoff was also willing to rule out an association between Bendectin and clubfeet despite the same confidence interval he found sufficient to associate cataracts with vomiting:

Q: What you found for Bendectin in clubbed feet (sic) was a 0.9 confidence interval, or a 0.9 lower limit of a confidence interval, didn't you?

A: Yes.

Q: And that's the same bottom confidence interval that you used to rule out -- used to associate cataracts and vomiting; correct?

A: Yeah. Yes.[176]

Can scientists employ intuition and understanding and make exceptions to the confidence interval requirement in their own writings and opinions, but insist that only strict scientific orthodoxy can be presented in court? Are these discrepancies for resolution as a matter of law; or is this not, again, the classic jury question?

III. The "Peer Review" Scientific Method.

The defendant contends that modern scientific inquiry is verified through publication in "peer review" journals which expose opinion to the critical inquiry of the scientific community. The defendant claims that modern scientific methodology and conclusions can only be evaluated through the use of peer review journal articles, and that all "peer review" journals are created

equal.[177] Testimony in this case clearly demonstrated that not all "peer review" journals are created equal. 'Studies on Bendectin., were published in the "Peer review" journal "Teratology "after having been rejected for publication by other more Prestigious journals. The testimony revealed that not all the articles contained in "peer review" journals were even reviewed for scientific validity before publication.[178] Articles were intentionally inserted in peer review journals for use in court. Studies for publication in peer review journals were tailored to the needs of litigation, and paid for out of defense funds. Most significantly, for the integrity of a judicial system, "scientific" articles for publication in "peer review" journals were edited before publication by lawyers litigating the issues presented in the article.[179] The testimony revealed that "follow-up" studies were solicited by the defendant through intermediaries, funded by the defendant: but the scientific methodology changed, to obscure positive findings. Peer review journals publish studies which are not good.

IV. Scientists Understand What is Required for a Proper Animal Study.

Experts Dr. Newberne and Dr. Tyl disagreed on scientifically acceptable dosing techniques in laboratory animals:

Dr. Tyl testified:

"Q: And to perform the animal test -- this animal test properly, you did not choose the human therapeutic dose; correct?

A: Based on testing guidelines, the top dose has to cause maternal toxicity for it to be an acceptable study."[180]

Dr. Newberne disagreed:

"Q: You believe that a high dose in a study such as this one at twenty milligrams per kilogram, is a sufficient dose; is that correct?

A: I think so.

Q: Did it produce maternal toxicity at the highest levels?

A: No. And that is not a necessary factor in every toxicology study.

Q: Is that a necessary factor in a good teratology study?

A: No. In the ideal teratology study, you would like to know what the maximum tolerated dose is; and then you would not go that high, because you don't want maternal toxicity.

Q: In a good teratology study, is one of the aims of such a study to have maternal toxicity at the top dose?

A: That's a debatable point among teratologists.[181]

APPENDIX B
Science and Justice

President Eisenhower warned the nation of a military industrial complex. The testimony in this case clearly demonstrates what a medical industrial complex can accomplish. The testimony demonstrated a medical-scientific peer review journal literature created and manipulated for use in the courts of California, and elsewhere. The testimony revealed that the science of "teratology" centered around a teratological society and the "peer review" journal of "Teratology," is an imprecise discipline, lacking in any common definition of terminology, lacking in academic credentials, lacking in scientific standards, lacking in standards for certification and self-identified only by academic interests.

The testimony demonstrated that articles were inserted in "peer review journals, without review by independent authorities, but edited by lawyers; that "peer review" journals published, as valid, the results of "less than good studies"; that articles were rejected for publication by prestigious journals before being published in the "peer review" journal of "Teratology." The testimony exposed scientific literature created for purposes of legal defense. The testimony revealed a sycophantic relationship between "scientists" and their funding source; the defendant, Merrell Dow. The testimony revealed circularity of reasoning to prove pre-ordained "scientific" conclusions, and the use of litigation defense funds for scientific research manipulation. Finally, the testimony revealed factual editing of supposedly scientific research literature by the very lawyers defending in litigation.

This court draws no conclusion as to the nature of scientific research in the industry generally, or the sanctity of the scientific literature generally, or the activities of any drug manufacturer other than the defendant in this case; however, the testimony presented in this Common Pleas courtroom about the scientific research and literature on Bendectin should raise a red flag for any judge who considers abdicating the courts' historical role in the resolution of disputes to any scientific establishment. Reliance on a "consensus" of "scientific opinion" in the relevant "scientific community" can be, and has been manipulated when the financial stakes warrant the effort.

As Thomas S. Kuhn, writing in The Structure of Scientific Revolutions,[182] describes, scientific advances occur by expanding the envelope of a commonly shared consensus of scientific opinion. A commonly shared consensus or paradigm creates a conservative, self-protective community, with its own power relations and shared financial and career interests. Only those scientists sharing the common consensus and upholding the paradigms receive funding, opprobrium and support from the "scientific community." But the advance of civilization through history demonstrates the failure of every scientific paradigm. When a paradigm fails sufficiently, a "scientific revolution" occurs.

"The study of paradigms . . . is what mainly prepares the student for membership in the particular scientific community with which lie will later practice. Because he there joins men

who learned the base of their fields from the same concrete models, his subsequent practice will seldom evoke overt disagreement over fundamentals. Men whose research is based on shared paradigms are committed to the same rules and standards for scientific practice. That commitment and the apparent consensus it produces are prerequisites for normal science, i.e., for the genesis and continuation of a particular research tradition.[183]

The objects of investigation, and the purposes of science and a system of justice are very different. Science seeks the discovery of "universal" principles and their application. A system of justice seeks the just resolution of specific cases and controversies. The goals are different. The approaches are different. The analysis is different. The timespan within which each sphere is permitted to operate are incompatible. Science can wait a month, a year or a century until a body of knowledge develops and a scientific revolution results in a new consensus or paradigm. Courts are charged with maintaining the fabric of society by the prompt and just resolution of specific claims. As science can never be successfully chained to judicial determinations of "truth", likewise, courts can never abdicate their role as arbiters of dispute to any scientific orthodoxy or hierarchy.

Cross-examination is "the greatest legal engine ever invented for the discovery of truth.[184] Its use "… [is] particularly conducive to the deconstruction of scientific facts, since it provides…. the formal means for bringing out the contingencies in their opponent's arguments.[185] Cross examination ". . . confirms that scientists are often sloppy, that they use covert assumptions and untried techniques, and that they sometimes manufacture data points or gloss-over results that do not quite make sense in the light of theory.[186]

The problem raised by the interaction of the current set of beliefs, characterized as "scientific truths" and judicial decision-making, is the natural desire for absolute certainty. Sheila Jasanoff recognized this tendency in her article, "What Judges Should Know About the Sociology of Science":

The prevalent presumption was that scientific truth or consensus were always "out there" for the law to find and that any failure to accomplish this goal was due to imperfections in the law's machinery. Social studies of science pose a fundamental challenge to this relatively comfortable assessment. The difficulty of locating facts, truth or consensus now seems to be embedded in the way science works. The problem of fact finding originates within science itself, although the law's halting approaches to determining what science has to say on a given issue often add layers of doubt and uncertainty to an undertaking that scientists themselves cannot entirely master. . . . A sociologically informed analysis suggests, by contrast, that scientific claims are intrinsically provisional, contingent and subject to deconstruction under critical scrutiny. Scientific claims, in short, are inherently open-ended, although, this property may be clearly apparent only when science is embroiled in controversy. Legal fact-finding accordingly reproduces at best the still frame out of the continually unfurling motion picture of science, with all the distortions that such compression entails.[187]

Causation is not always the primary interest of science. As Dr. Tyl testified, teratologists "dance" about the question of causation; yet, causation is the critical question presented in this trial and on this appeal. Legal cause is a substantial factor, but not necessarily the only factor. Legal cause

is not fanciful factor, nor an imaginary factor, nor a factor conjured up to avoid an unpleasant duty. Legal cause is only a substantial factor in producing the result. This is not necessarily the same definition of cause employed by a scientific discipline having commonly accepted definitions. The standard of legal proof, a preponderance of evidence, is not necessarily accepted by science as the proper test, nor should it be.

Modern science and its concomitant industrial complex have improved the quality of life. No area of life today shows greater potential for human benefit, or greater potential for human misery, than the medical scientific industrial complex. The drug industry creates and distributes medicine that save lives. There is a cost. There is a purchase cost, and there are costs from the adverse consequences of the modern medical and marketing systems. The function of a court system is to justly allocate those costs.

There are two clubfeet with which Jeffrey Blum will live. There is the financial cost of the medical care for this condition. There is a cost in pain that only Jeffrey will bear, regardless of compensation. There is cost in the loss of his normal abilities and pleasures. The jury in this case, based on properly admitted opinion evidence, allocated these costs to the defendant, because of its improperly marketed product, which was the legal cause of Jeffrey Blum's condition.

It is the proper role of the courts, and the historical role of tort law, to properly allocate the costs of these adverse consequences. The social policy behind this application of law is not solely the proper allocation of costs to the party which should bear responsibility; but also, by example and deterrence, the protection of everyone. Justice Roger Traynor of the California Supreme-Court, often considered a "father" of products liability law, believed that the responsibility..."should be fixed, wherever it will most effectively reduce the hazards to life and health."[188]

When a drug manufacturer markets a drug to the medical community by proclaiming, "studies in rats and rabbits have revealed no suggestion of drug induced fetal abnormalities [at] doses up to ninety times the maximum human dose," society demands that this warranty is supported by studies that are based upon scientific principles, and better than "less than good". When a drug manufacturer presents testimony to a governmental agency charged with regulating that industry, it must do so forthrightly and completely; not selectively and inaccurately. When a drug manufacturer applies its funds for "scientific research", it must do so for the advancement of knowledge, and not for legal defense in the courts of California and elsewhere.[189] When the safety of a drug is challenged in a specific case or controversy, a drug manufacturer must be able to justify its concern for the safety of the unborn and the accuracy of its claim to medical safety before society represented by a jury of its peers; a jury of twelve citizens, sworn to uphold the law and decide the case strictly on the basis of the facts as they find them to be, from the evidence presented, without prejudice or sympathy, in accord with the law that places the burden of proof upon the plaintiff.
"As the primary custodians of individual rights, courts [are] sensitized to threats posed by science and technology to individual safety and autonomy.[190]

APPENDIX C
Frye, Daubert, Policy and Pennsylvania Law

This case, Blum vs. Merrell Dow, will be the subject of review by the Pennsylvania Supreme Court and, possibly, the United States Supreme Court. The responsibility of these ultimate arbiters, unlike this trial court's obligation, is not limited to adjudicating this specific dispute. Appellate courts must discern the legal precepts required by our technological society with an eye to the future, and an appreciation of tradition. Since this case may become a vehicle for the reanalysis and adaptation of legal precepts with dramatic implications, this trial court feels compelled to comment on the pernicious and fallacious conclusions that may be, drawn from an extension of the decision in the recent Appellate Court decision in McKenzie vs. Westinghouse.[191]

Sydney McKenzie, was born with a ventricular septal defect which resulted in death after seven months of life. Plaintiffs claimed this birth defect was due to exposure to trichlorocthylene (TCE) and dichloroethylene (DCE) contained in the family drinking water. The trial court granted a motion in limine to preclude expert testimony; and, on that basis, granted summary judgment. The Commonwealth court affirmed.

In McKenzie, plaintiff presented the deposition and affidavit of Dr. Stanley Goldberg, who based his conclusions as to the teratogenicity of these chemicals on six scientific studies he conducted. He published his results in respected "peer review" journals over a period of four years. He testified that his studies were scientifically valid, and that he employed generally accepted scientific methodologies. This testimony was supported by the testimony of both Dr. Allan S. Goldman, a pediatrician who specializes in teratology, and Dr. Brenda V. Dawson, a Board-certified pathologist, with research interest and experience in reproductive toxicology. Both of these , well-qualified experts testified that Dr. Goldberg's studies employed "classic research methodologies that art generally accepted in the scientific community."[192] Dr. Goldman testified that these studies established that TCE is a human carcinogen. Dr.Dawson stated that publication in peer review journals, highly regarded in pediatric cardiology, ". . . serves as an endorsement in the scientific community of the validity of the study."[193]

The trial court heard from Dr. Brent, whose opinion is that there are only six teratogens proven to cause heart defects; and TCE is not one of them. The defense further presented Dr. Clark and Dr. Day, who described what they considered to be flaws in the published studies. The trial court precluded Dr. Goldberg's opinion testimony, finding, as fact that "Dr. Goldberg's *opinion* was not generally accepted by the relevant scientific community, and was not derived from reliable scientific studies." The trial court concluded that the drug compound in question "is not recognized as a teratogen by the teratologic community."[194]Despite a clear record of disagreement within the relevant scientific community, the trial court made findings of fact properly reserved for the fact-finding jury.
If the words contained in the Commonwealth Court opinion are to be accepted literally, theMcKenzie court bars all expert opinion beyond each individual Judge's factual finding of paradigm science. The Commonwealth Court opinion abdicates the judicial function to a self-identified, self-authenticating "relevant scientific community," and reduces the Judiciary to arbiters of scientific orthodoxy and courts to the guardians of dogma.

In Commonwealth vs. Topa,[195] adopting Frye vs. U.S.[196] into the criminal evidentiary law of Pennsylvania, the Supreme Court ruled that the admissibility of scientific evidence depends on general acceptance in the field to which it belongs. Frye held that lie-detector test results had not been sufficiently, validated to form the basis of opinion evidence. TheTopa court applied the same analysis to other test results. In neither case did an appellate court rule that the opinion, itself, required general scientific acceptance; rather, it was strictly the methodologies and the tests employed which had to pass scrutiny. In each case the underlying test data was rejected for use in court. The Topa decision was premised upon an understanding that this approach "...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."[197] The Frye legal test rejects opinion evidence only because it rejects the validity of the underlying scientific test data on which the opinion is based.

It is an insidious proposition that qualified expert opinion, itself, not methodology or underlying test data, must be subject to scientific orthodoxy. McKenzie opinion citesCommonwealth vs. Dunkle[198] and Commonwealth vs. Miller [199] in support. Both opinions are strictly grounded in requiring general acceptance of *specific methodologies and approaches;* namely, child abuse syndrome in Dunkle and horizontal gaze nystagmus testing in Miller.

The McKenzie court chains Pennsylvania law to the good faith, the honesty, the credibility and the pace of scientific consensus-building within the litigation oriented segment of the "teratology community." The opinion, if literally accepted, never permits minority opinion to be expressed in court. No, new opinion; no, as yet, unaccepted opinion; no changing opinion; no minority view could ever be exposed for factual determination in a court of law. Only the scientific establishment can open the courtroom door. The trial judge in McKenzie,faced with well-qualified experts holding differing conclusions from peer review published studies, decided which opinion represented orthodoxy.

As a matter of public policy, as a matter of protecting the people of Pennsylvania from dangerous drugs, as a matter of the proper and historic role of courts in adjudicating conflicts and disputes, as a matter of proper evidentiary rulings and as a matter of the historic right of Pennsylvania citizens to have a jury determine the facts, the literal reading ofMcKenzie must be rejected.[200]

What does history reveal about orthodoxy and the establishment consensus of scientific principles? Blood letting was once the common consensus of medical opinion for the treatment of disease. Spontaneous generation was the 'Scientific consensus for the existence of vermin. A clear, scientific consensus confirmed the safety of radiation so children's feet were routinely x-rayed in a shoe store. Scientific consensus confirmed that people of color belonged to an inferior class of mankind. Scientific consensus held that the female sex was, by constitution, incapable of the rigors of the disciplines of medicine, law or politics. The primary support of racism has always been politically-motivated establishment scientific consensus. Only an independent court system, accessible to all, [201] can ever be a refuge against an oppressive entrenched establishment orthodoxy, be it 'political, economic or scientific.

Is our collective memory so short that the Judiciary cannot remember the horror of the consensus in the "relevant scientific community" that women were unfit to be lawyers or doctors; that the

negro was a member of an inferior race; or that genocide of the Jewish race improved racial purity?[202]

Before any courtroom door keys are conferred on the scientific establishment, the testimony in this case of Blum vs. Merrell Dow should be studied.