[J-190-1999]
IN THE SUPREME COURT OF PENNSYLVANIA
EASTERN DISTRICT

JEFFREY BLUM, A MINOR, BY HIS PARENTS AND NATURAL GUARDIANS, JOAN AND FRED BLUM, AND JOAN AND FRED BLUM, IN THEIR OWN RIGHT,	:	No. 1 E.D. Appeal Docket 1999
	:	Appeal from the Order of the Superior Court dated December 29, 1997 at NO. 3711 Philadelphia 1995, reversing the Order of the Court of Common Pleas of Philadelphia County, dated September 15, 1995 at No. 1027, September Term, 1982
Appellants,	:	
v.	:	705 A.2d 1314 (Pa. Super. 1997)
	:	ARGUED: October 18, 1999
MERRELL DOW PHARMACEUTICALS, INC.,	:	
Appellee.	:	

DISSENTING OPINION

MR. JUSTICE CASTILLE **DECIDED: December 22, 2000**

Like Mr. Justice Cappy, I agree with the majority that the Frye[1] test should remain the general evidentiary standard for admitting expert scientific testimony in this Commonwealth. The test is an appropriate vehicle to prevent "junk science" from improperly influencing the jury on matters not within their common knowledge and experience. However, I disagree with the majority's summary conclusion that, under the Frye standard, the trial court here erred in admitting appellants' expert testimony on causation. After reviewing the extensive record here, I am thoroughly convinced that the

[1] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), adopted by this Court in Commonwealth v. Topa, 471 Pa. 223, 231, 369 A.2d 1277, 1281 (1977).

trial judge committed no such error. The majority's selective reference to other decided cases involving the plaintiffs' lead expert witness, rather than consideration of the actual record on the Frye question here, proves no error by the trial court. Accordingly, I respectfully dissent.

The majority states that the trial court admitted the offending testimony here under the test set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). I do not believe that to be so. As Mr. Justice Cappy correctly notes, in point of fact, the trial court itself stated that it was applying the Frye test. Trial Court Slip Op. at 45 & n.130, 50 n. 143. The Superior Court recognized that the trial court applied Frye, while suggesting that the trial judge went on to criticize Frye's limitations on the fact-finder. 705 A.2d at 1321, 1323 (noting that trial judge found that plaintiffs' experts used same four methods and techniques as defense experts, and those were generally accepted; thus, the trial court concluded that "their opinion on causation met the Frye standard for admissibility"). The Superior Court held, not that the trial court erred in **failing** to apply Frye, but that its application was erroneous. Specifically, the Superior Court agreed with Merrell Dow that the way in which plaintiffs' experts "utilized" the four generally accepted techniques was itself a scientific "method" that had to be generally accepted before it could be heard. 705 A.2d at 1323-24.

The trial court's analysis of this difficult question was far more thoughtful and sophisticated than the majority, or the Superior Court, acknowledges. A fair reading of the trial court's exhaustive opinion reveals a court acutely aware that this was a close case under traditional Frye analysis, and concerned with the further limitation on scientific testimony suggested in the Commonwealth Court's rather novel opinion in McKenzie v. Westinghouse Electric Corp., 674 A.2d 1167 (Pa. Cmwlth. 1996), alloc. denied, 547 Pa. 733, 689 A.2d 237 (1997). McKenzie would require that the expert's opinion as to the **causal relationship** at issue, and not just the expert's methodology, must find general

acceptance in the relevant scientific community before it may even be heard. In effect, under McKenzie, minority opinions and conclusions on causation may never be heard, no matter how sound the underlying methodology. The trial court felt bound by McKenzie but concluded that McKenzie was wrongly decided. See Trial Court Slip Op. at 77-82.

The trial court strongly believed that the evidence at issue here was admissible, and its opinion attempts to explain why that is so, or should be so, under any test -- a not-at-all unreasonable approach for the court to take given the age of this twice-tried case,[2] given that the court felt bound by McKenzie, and given that the dichotomy of Frye/Daubert is a question that this Court had made a point of not yet deciding. In addition, and perhaps of more importance, the trial court felt that the Frye issue in this case was "unique," i.e., that the expert testimony at issue did not lend itself to an easy application of Frye. The trial court went to great lengths to explain why it believed that this was so.

The gravamen of Merrell Dow's Frye objection was that the plaintiffs' scientific experts' **conclusions** on causation (or, as Merrell Dow would have it, the manner in which they reached those conclusions) should themselves be viewed as a separate scientific "methodology" that must be "generally accepted" in the relevant scientific community before they may even be admitted under Frye. The trial court disagreed for two reasons: first, because it did not believe that conclusions on causation are a separate methodology needing general acceptance (a would-be classic Frye formulation rendered questionable by McKenzie); and second, because, at least in the litigation-driven Bendectin "scientific community" described to the court in this case, the notion of "general acceptance," or scientific "orthodoxy," if you will, on the question of causation was a questionable proposition to begin with. This was so because the trial court had heard extensive evidence concerning Merrell Dow's active and deliberate role, motivated by its litigation

[2] The lawsuit was filed in 1982 and was first tried in 1986.

interests in defending lawsuits involving Bendectin, in actually creating and influencing the scientific orthodoxy that would then operate to suppress any contrary opinion that might harm its Bendectin litigation interest. As the trial court succinctly put it: "The testimony in this case demonstrates how 'scientific consensus' can be created through purchased research and the manipulation of a 'scientific' literature, funded as part of litigation defense, and choreographed by counsel." Trial Court Slip Op. at 46.

The court generally summarized the evidence of Merrell Dow's influence that supported this conclusion as follows:

> Articles were intentionally inserted into 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. The testimony revealed that 'follow-up' studies were solicited by the defendant through intermediaries, funded by the defendant.
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> 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.

Id. at 67-68, 70-71.[3] In such an instance, where the supposed "consensus" of "scientific opinion" in the relevant "scientific community" had been manipulated by the financial and litigation interests of an interested party, the trial court determined that cross-examination of contrary scientific conclusions, rather than their outright exclusion, was sufficient gatekeeping under Frye. Id. at 71-72.

In short, the trial court did not, as the majority inaccurately suggests, ignore Frye in favor of Daubert. Its analysis derived from the specific and extensive record made in the case before it, as well as the unsettled status of the law since McKenzie, and was far more sophisticated than acknowledged by the majority opinion.

The majority never discusses why it believes appellants' expert causation testimony here was inadmissible, instead offering only that it agrees with the Superior Court's conclusion in that regard. The published opinion of the Superior Court, however, states that there are two ways to analyze admissibility under Frye, one focusing on whether the methodology employed by the testifying expert was generally accepted in the scientific community (a classic Frye analysis), and a second, more restrictive test, deriving from the Commonwealth Court's opinion in McKenzie, which requires that the expert testimony as to the specific **causal relationship** also find general acceptance in the relevant scientific community. The Superior Court held that, under either version of the Frye test, the trial court abused its discretion in admitting the expert testimony here. 705 A.2d at 1322-25.

The majority does not identify which of the Superior Court's independent analyses, and hence, which version of the Frye test, it is approving. Since McKenzie represents a

[3] A "teratogen" is an agent that causes the production of physical defects in the developing embryo. The "discipline" teratology refers to the study of the causes and effects of abnormal growth and development in the developing embryo. There is no degree program or certification process in the field of teratology. The journal Teratology, the official journal of the Teratology Society, was edited by Dr. Robert L. Brent, Merrell Dow's lead expert witness.

novel extension of Frye never discussed or approved by this Court in the past, and it is difficult to conceive that the majority intends to radically change the law by such an oblique reference, I assume that the majority intends to adopt only the Superior Court's traditional Frye "methodology" analysis. I would specifically disapprove and overrule McKenzie. Like Mr. Justice Cappy, I believe that the Frye test in this Court's jurisprudence has only required, and should only require, that the methodology employed by the testifying scientist, and not his or her ultimate conclusions or opinions as to causation, be generally accepted by the relevant scientific community. See Commonwealth v. Blasioli, 552 Pa. 149, 713 A.2d 1117 (1998).

Having said this, I believe that the trial court's admission of appellants' expert causation testimony here should be affirmed both because the trial court properly concluded that the disputed testimony consisted of expert conclusions not subject to Frye's methodology screening[4] and, even if those conclusions were a separate "methodology" generally subject to Frye, I do not believe that consensus (or "general acceptance") should be required in exceptional cases like this, where the scientific consensus derives largely from the proprietary influence and litigation interests of the adverse party. To explain my view on both points, a close consideration of the record in this case is necessary.

While pregnant with her son Jeffrey, appellant Joan Blum ingested Bendectin, a drug manufactured by Merrell Dow and promoted by it as a safe drug for pregnant women to control morning sickness. Jeffrey was born with clubfeet, a crippling condition that has already required multiple surgeries. The Blums sued Merrell Dow, alleging that Joan Blum's ingestion of Bendectin was a legal cause of Jeffrey's birth defect. The Blums pursued theories of product liability, negligence, fraud, and breach of warranty. A first trial

[4] See Trial Court Slip Op. at 15 ("Dr. Done relied upon acceptable scientific methodology in reaching his opinion").

ended in a jury verdict in favor of the Blums on January 20, 1987, awarding $1 million in compensatory damages and $1 million in punitive damages. On Merrell Dow's appeal, however, the Superior Court ordered a new trial because the verdict had been returned by an eleven-person jury, after the twelfth juror had become ill. 385 Pa. Super. 151, 560 A.2d 212 (1989). This Court affirmed, holding that Merrell Dow had been deprived of its constitutional right to a trial by jury. 534 Pa. 97, 626 A.2d 537 (1993).

After a seven-week retrial, a second jury found that Merrell Dow had acted negligently, failed to provide proper warnings, breached express and implied warranties, and acted fraudulently. The jury awarded $4 million to Jeffrey, $200,000 to his parents for medical expenses, and $15 million in punitive damages.

The question of causation was hotly contested at both trials and came down to the proverbial battle of the experts. There was no serious question as to the qualifications of the competing experts. Merrell Dow's experts categorically opined that Bendectin could not cause Jeffrey's birth defect (notwithstanding that they agreed that no scientific study could prove such an absolute conclusion), while the Blums' experts held contrary opinions. Each expert was subject to searching cross-examination and, obviously, the jury ultimately accepted the testimony of the Blums' experts.[5]

Having lost the causation issue before a jury for the second time, Merrell Dow complained post-verdict that the jury never should have been permitted to hear the Blums' expert testimony that Bendectin caused Jeffrey's clubfeet and that, absent that evidence, Merrell Dow was entitled to judgment notwithstanding the verdict.[6] The tack taken was to

[5] Two of the Blums' experts, Drs. Done and Gross, were deceased by the time of the second trial. Their testimony from the first trial was read to the jury due to their unavailability.

[6] Notably, Merrell Dow had made no such argument after the first trial.

suggest that the expert plaintiffs' testimony on causation reflected a minority view, not "generally accepted" in the scientific community of researchers and experts who studied Bendectin's potential to cause birth defects in general, and clubfeet in particular. Further refining its analysis, Merrell Dow suggested that the manner by which the plaintiff's experts, and in particular their lead expert, Dr. Alan K. Done, arrived at a contrary conclusion on causation constituted a separate "scientific methodology" that was inadmissible because it was not "generally accepted" in the relevant scientific community. What Merrell Dow wanted, effectively, was a finding that, as a matter of law, its product does not cause birth defects. That finding would be accomplished in the guise of an evidentiary ruling, i.e. a holding that any expert who looked at the "scientific studies" -- studies that Merrell Dow often subsidized and which concluded that there is no causal connection -- and reached a conclusion contrary to Merrell Dow's experts, should not be permitted to testify because that conclusion must result from a methodology that is not "generally accepted."

By approving the Superior Court's conclusion, the majority apparently finds merit in Merrell Dow's analysis. Going even further, the majority takes pains to dismiss Dr. Done's testimony by citing to other cases where Dr. Done had testified, in particular by quoting one appellate court that labeled him a "professional plaintiff's witness," whose opinion "was influenced by a litigation-driven financial incentive" and whose testimony, precisely because it involved conclusions not shared by other scientists, should be viewed with caution. Majority Slip Op. at 5 n. 5, quoting Lust v. Merrell Dow Pharmaceuticals, 89 F.3d 594, 598 (9th Cir. 1996).[7] But the majority could just as easily cite to a case where the testimony of

[7] It bears noting that Lust is the only case cited by the majority that questioned Dr. Done's objectivity. In Lee v. Richardson-Merrell, Inc., 772 F. Supp. 1027 (1991), Dr. Done did not even testify or participate. In Richardson v. Richardson-Merrell, Inc., 649 F. Supp. 799 (D.C. 1986), the court concluded that the quantity of the defendant's evidence, especially the FDA's approval of Bendectin, prevented Dr. Done from testifying concerning his contrary conclusion. Importantly, in that case, unlike here, the plaintiff did not offer (continued…)

Merrell Dow's leading expert, Dr. Robert L. Brent, was found to be incredible. See Wells v. Ortho Pharmaceutical Corporation, 615 F. Supp. 262, 291 (N. Dist. Ga. 1985) (finding Dr. Brent incredible because, inter alia, the absolute terms in which he expressed his conclusions detracted from his believability; Brent's "testimony and manner suggested a degree of conviction in his own conclusions unwarranted in a discipline in which, according to other competent experts from both sides, explanations are only more or less probable. For these reasons, Dr. Brent lacked credibility as a witness"). The Wells court noted that Brent's slanted testimony also might be a result of his litigation interest:

> [A]lthough Dr. Brent's credentials were most impressive, he was not a convincing witness. His criticisms of plaintiffs' attorneys and of expert witnesses who testify for plaintiffs in malformation lawsuits strongly suggest a distinct prejudice against plaintiffs and a corresponding bias in favor of defendants in such cases.

Id.

By preferring citation to unrelated cases -- and selective citation at that -- to the actual record presented to the trial court here, the majority proceeds upon what is at best a half-truth. The plaintiffs' experts certainly were impeachable, and were impeached, because of their "litigation driven" interest. But, unperceived by the majority opinion is the countervailing fact that Merrell Dow's experts -- experts who testified to the "orthodoxy" that would render the plaintiffs' experts' "minority" conclusions inadmissible -- themselves were

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(…continued)
evidence of Merrell Dow's fraudulent failure to disclose information to the FDA. Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir. 1990), simply followed the Richardson decision. Lynch v. Merrell-National Laboratories, Inc., 830 F.2d 1190 (1st Cir. 1987), likewise did not involve an allegation of fraud. Finally, Wade-Greauz v. Whitehall Laboratories, Inc., 874 F. Supp. 1441 (D.V.I. 1994), did not even involve Bendectin. More importantly, in Wade, Dr. Done testified that it was not clear that Primatene Mist caused birth defects.

impeachable, and were impeached, because of their own financial and litigation-driven biases.

What should be of central importance, but is ignored by the majority, is the Frye record here. That record shows not only that Merrell Dow's experts were as liable to criticism for having a "litigation driven" financial interest as were the Blums' experts, but also that much of the "science" in this area, held up by Merrell Dow as the objective, generally accepted scientific view that requires exclusion of the plaintiffs' experts' "contrary" conclusions, **itself** was a product of Merrell Dow's litigation-driven influence. For example:

- The lead defense expert, Dr. Brent, had been retained as an expert by Merrell Dow for some eighteen years, N.T. 6/8/94 at 2612, and thus had a financial incentive to testify favorably for Merrell Dow. Brent was described as the originator of the field of teratology, a scientific subspecialty studying the causes and effects of abnormal growth and development in the embryo. Brent also edited the would-be "peer review" journal Teratology, which published many of the works relied upon by Merrell Dow to establish the favorable consensus of the scientific community. Id. at 2602. The trial court noted that there was ample evidence of a "sycophantic relationship between Brent and the attorneys representing Merrell Dow," which necessarily called into question the scientific validity of materials published by Teratology. Trial Court Slip Op. at 40. Remarkably, Brent actually submitted draft "scientific" articles on Bendectin for review and approval by the attorneys representing Merrell Dow. As the trial court aptly noted, such a relationship "clearly affected the objectivity of his approach and the validity of his writing." Id. Somehow, this practice caused Brent no ethical qualms.

  Brent also claimed a curious expertise in legal matters involving birth defect claims. For example, Brent had published an article in Teratology entitled, "Litigation-Produced Pain, Disease, and Suffering: An Experience With Congenital

Malformation Lawsuits," in which he claimed a rather unique ability to determine who told the truth, and who lied, in congenital malformation lawsuits. He found that seventeen out of seventeen plaintiffs lied and 82.6% of plaintiffs' lawyers "distorted" the facts, while, in his fantastical opinion, only 25% of defendants distorted the facts and only one in twenty-one defense attorneys made any distortions. N.T. 6/8/94 at 2662, 2669-76. He also opined that there was a sycophantic relationship between the plaintiffs' medical experts in those cases and the plaintiffs' counsel. Id. at 2681. It is unlikely that Brent's obvious bias and eccentricities, and the irony of his indictment of the relationship of the plaintiffs and their experts in these cases, went unappreciated by the jury.

- Another defense expert, Dr. Samuel Shapiro, also had a direct financial incentive to testify favorably for Merrell Dow regarding the scientific "consensus" on whether Bendectin caused birth defects. Shapiro began by overstating his qualifications in the field of epidemiology, the area in which he was supposedly an expert -- a misstatement he was forced to acknowledge. N.T. 5/27/94 at 1756-62, 2537-61. Shapiro was the head of the epidemiology department of Boston University. Merrell Dow approached Shapiro to study Bendectin while Shapiro's group was studying other drug compounds. At that time, Merrell Dow only offered Shapiro $5,000 to complete the study. After the favorable results of the study were released, Merrell Dow increased their support of Shapiro's studies to $1.8 million. N.T. 5/20/94 at 1043.

  Shapiro testified to his unwavering belief that Bendectin could not cause birth defects, despite admitting that his study of the issue was flawed. In the study, he grouped together women who took the chemical compound found in Bendectin during the time of fetal limb formation and women who took the drug after fetal limb formation. N.T. 5/23/94 at 1297-98. By including both of these women in his study,

he admittedly diluted the number of women who could possibly show any effect from use of the drug. Id. at 1298. Not only did subsequent scientific literature criticize his methodology, but Shapiro himself was critical of his group selections. Id. at 1298-1302. Shapiro testified that "[t]he major criticism that we had among ourselves is that we recognized that this would introduce some miscalculation; that if there were any drug that were causal that would result in an underestimate of the magnitude of the effect." Id. at 1301. Nevertheless, he stubbornly refused to attribute any significance to his underestimation: "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." N.T. 5/23/94 at 1317 (emphasis added). As the trial court aptly noted, the circularity of Shapiro's logic is obvious: "It demonstrates justification science not inquisitive science." Trial Court Slip Op. at 30.[8]

- Another defense expert, Dr. James Newberne, was directly connected to Merrell Dow, having formerly served as a vice president responsible for animal testing and drug safety. N.T. 5/26/94 at 1660. In this case, which included a theory of fraud,

[8] The Superior Court's failure to recognize Shapiro's "litigation driven" role in this litigation made its Frye analysis fatally erroneous. The Superior Court finds fault with Dr. Done's conclusions because they were arrived at by "reanalyzing" the results of a single study, referred to by the Superior Court as the "Heinonen" study. 705 A.2d at 1324-25. It was Done's method of reanalyzing that study, to conclude that it helped prove causation, that the Superior Court felt was an "improper" utilization of data that rendered his conclusions inadmissible. What the Superior Court failed to realize, however, was that the so-called Heinonen study was inextricably connected to Dr. Shapiro. The study was published in the textbook, Birth Defects and Drugs in Pregnancy, authored by Shapiro, Heinonen and a Dr. Slone. It was the very study that the obviously biased Shapiro himself admitted was flawed. Dr. Done was not obliged to accept the results of that flawed study, produced by scientists connected to Merrell Dow, as gospel.

Newberne admitted that Merrell Dow had failed to report numerous musculoskeletal defects in data submitted to the United States Food and Drug Administration ("FDA") to obtain approval of Bendectin. As the trial court described, Newberne under-represented the incidence of clubfeet found in animal studies, overstated the number of animals studied, failed to disclose that an insufficient number of animals were studied and that the animals died due to improper care. Gross' Testimony at 1673a-12/8/86 at 73. Newberne also failed to report that the company's tests were "scientifically inadequate due to insufficient dosing levels." Trial Court Slip Op. at 2; Gross' Testimony, N.T. 12/8/86 at 71. The following exchange provides just a flavor of Newberne's remarkable testimony:

> Q [the plaintiff's counsel]: Sir, it has been the pattern and practice 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 is correct.

N.T. 6/1/94 at 2266.

Newberne also testified to the proprietary link between Merrell Dow and other studies that came to comprise the exclusionary "scientific consensus" concerning whether Bendectin caused birth defects. One study, conducted by a Dr. Roll in Germany, concluded in a 1982 report to the German Official Health Agency that Bendectin caused birth defects in rats. N.T. 6/1/94 at 2259. After learning of this unfavorable study, Newberne contacted Roll through an intermediary, sending a copy of the correspondence to Merrell Dow's lawyers. Following this contact, Roll undertook a second study using a different breed of rats. Id. at 2262. The second report concluded that there was not an increased risk of birth defects associated with Bendectin use. This was not surprising, for the rats chosen in the second study

had an increased natural incidence of diaphragmatic hernia that masked any increased malformations caused by Bendectin. Trial Court Slip Op. at 33-34.

Finally, Newberne testified to a second instance where Merrell Dow directly influenced a "scientific" study. In the early 1980's, a Dr. Hendrickx performed an animal study that showed a significant increase in heart defects in monkeys from the use of Bendectin. N.T. 6/1/94 at 2313. Once again, Merrell Dow funded, with more than $300,000 from the company's litigation defense budget, a second study that achieved much more positive results for the company. Id. at 2314-15, 2321. When Hendrickx wrote to the company regarding funding for the study, he indicated that he would be willing to discuss or modify his proposal to "meet a common objective." Id. at 2320.

- Dr. Mark Hoekenga, Merrell Dow's former Vice President, Medical Liaison Worldwide, testified to facts that suggested that Merrell Dow had influenced the outcome of yet another study on Bendectin, this one conducted by a Dr. Smithell, which concluded that Bendectin was not the cause of birth defects. The study was rejected by the widely respected medical periodicals New England Journal of Medicine, British Medical Journal and Lancet, before, predictably enough, it was accepted by Brent's journal Teratology. Hoekenga Testimony at 142a-144a. Smithell's obvious bias and incentive were reflected in the fact that he was actively soliciting funds from Merrell Dow at the time of his study. Thus, Smithell wrote to the company that:

> Much clearly depends upon the value of this publication 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 [monetary] figure you suggest as generous and welcome.

Plaintiffs' Exhibit 200, Hoekenga Testimony at 165a. In another, equally remarkable letter, Smithell noted that he would "appreciate any gesture Merrell felt inclined to make," but imagined that if he could give Bendectin "a clean bill of health with regard to teratogenesis, this would be of substantial help in the courtrooms of California." Plaintiffs' Exhibit 185, Hoekenga Testimony at 170a.

- Finally, two other defense experts, Dr. Mark Klebanoff and Dr. Rochelle Tyl, published their findings on Bendectin in Teratology, the journal controlled by Dr. Brent. N.T. 5/18/94 at 890, 892-3. Those studies were undertaken after Merrell Dow had removed Bendectin from the market. Klebanoff's study had been rejected by the New England Journal of Medicine, yet Teratology published it. Id. Klebanoff met with Merrell Dow attorneys after his article had been published in Teratology to discuss aspects of it. Also invited to the meeting by Merrell Dow was one of Merrell Dow's consultants, Dr. Berendes, who was also a Division Director at the National Institute of Health and Dr. Klebanoff's superior. N.T. 5/20/94 at 1031-32.

In short, in rushing to dismiss Dr. Done's testimony as that of a biased, "professional plaintiff's witness," both the majority and the Superior Court overlook not only the bias of Merrell Dow's equally "professional defendant's witnesses," but also the record fact that the "scientific" orthodoxy on Bendectin held up to silence the appellants' experts was in many instances bought and paid for by Merrell Dow to further their litigation needs. The trial court found, and the record amply demonstrates, that, with untold millions of dollars at its disposal, and untold millions more at stake, Merrell Dow was able to create and influence a scientific subdiscipline devoted to result-driven studies that Merrell Dow could then cite to defeat lawsuits brought by those who alleged that their birth defects were caused by Merrell Dow's Bendectin.

The trial court, which labored under this entire sordid picture, was of the view that there was, in fact, no difference in methodology between the dueling experts. The only dispute involved their conclusions on causation. The record here -- a record never discussed by the majority -- overwhelmingly supports this finding. Indeed, even Dr. Brent admitted that the four scientific methodologies employed by appellants' experts -- chemical structure analysis, in vitro analysis, in vivo animal studies and human epidemiological data[9] -- were the generally accepted methodologies utilized by the relevant scientific community to examine whether Bendectin caused birth defects such as Jeffrey Blum's clubfeet. Merrell Dow's experts employed the same methodologies. Trial Court Slip Op. at 6, 9, 47.

The Superior Court recognized that the studies and data relied upon by the appellants' experts were universally accepted as "good science," but concluded that the way those experts utilized that science to draw conclusions on causation was not. 705 A.2d at 1323. The flaw in this reasoning is that it conclusively determines that no opinion other than the initial researcher's may ever be heard. In a situation, as here, where so much of the underlying research and interpretation was in the control of a party driven by a litigation incentive, such a holding would be, and is, absurd.

The absurdity is well-demonstrated here. Even if some justification was needed to explain why the appellants' experts interpreted the data differently, the explanation was forthcoming. The appellants' evidence demonstrated that the conclusions in the studies that Bendectin was not a teratogen -- studies often subsidized by Merrell Dow -- were

[9] Chemical structure analysis determines whether a chemical compound fits into a class of compounds that have certain effects. In vitro studies determine the effect of chemical compounds on cells or parts of tissues. Trial Court Slip Op. at 42. In vivo animal studies determine how a chemical compound affects a living animal. Epidemiological studies consider whether causation may be inferred by comparing the incidence of a disease in a group of humans who have been exposed to the substance in question with the incidence in a group who have not been exposed.

based upon severe underestimates of the significance of Bendectin's association with birth defects. This resulted from both poor study designs as well as a fraudulent failure to report data. For example, in Merrell Dow's Bunde-Bowles epidemiological study, the women taking Bendectin in some cases were also designated as the control match for themselves. Furthermore, some women in the control group had taken Bendectin while some women in the Bendectin group had not taken Bendectin. Done Testimony at 2121a, 2151a. In another epidemiological study that received funding from Merrell Dow, the Jick study, the researcher calculated his results using only part of the data he collected -- omitting data obtained between 1976 and 1977 -- which obviously undermined the conclusions on causation suggested in that study. Id. at 2169a, 2998a. Furthermore, with respect to Merrell Dow's animal studies, the appellants' evidence showed that the company did not report certain malformations and did not analyze whether dead animal fetuses had malformations. N.T. 5/31/94 at 2094-95, 6/1/94 at 2266. Given the basic flaws in the methodology of the Merrell Dow studies testified to by qualified experts, the appellants' experts were not required to accept the conclusions in those studies.

Further evidence that the appellants' expert testimony on causation was not renegade science may be found in Dr. Done's testimony concerning the Shapiro-Heinonen study, another study held up as proof of the generally accepted scientific view that Bendectin did not cause birth defects. The Shapiro-Heinonen study examined the effects of ingestion of certain drug compounds (including the compound in Bendectin) during the first four months of pregnancy. Dr. Shapiro's statistical analysis of the data concluded that 63% more children had birth defects when their mothers ingested the chemical compound in Bendectin within the first four months of development than when they had not taken Bendectin. N.T. 5/23/94 at 1182. Dr. Shapiro reached this number by reducing the raw

numbers of cases involving birth defects by accounting for hospital-by-hospital deviation[10] and comparing the hospital standardized data against the control group. The effect of Shapiro's "standardization" was to reduce the instances of an apparent causal relationship between Bendectin and birth defects. Dr. Shapiro did not believe the incidence of birth defects detected in his interpretation of the data was statistically significant and, accordingly, concluded that Bendectin was not a teratogen.

Appellants' expert, Dr. Done, fully explained why he reached a different conclusion from this same data. First, the Shapiro-Heinonen study underestimated the probability of Bendectin's causing limb malformations because the study included women who took the drug beyond the period in pregnancy where limb bud development occurs. N.T. 5/23/94 at 1298. In addition, Dr. Done recalculated this data, the major difference being that he did not repeat Shapiro's decision to reduce the number of positive associations outright by excluding results from certain hospitals, i.e. Shapiro's "hospital standardization." When Dr. Done recalculated the data, he simply compared the raw number of positive associations received in Shapiro's data against the control group. This analysis of the data resulted in a finding that the likelihood of having a child with clubbed feet was 2.1 times greater if the chemical compound in Bendectin had been ingested during the first four months of pregnancy. N.T. 5/23/94 at 1476.

Far from being junk science, Dr. Done's recalculation of the data and his use of a non-hospital standardized comparison, while different from Dr. Shapiro's approach, were nevertheless the same "methods" of analysis that had been employed in other studies relied upon by Merrell Dow. In Merrell Dow's Bunde-Bowles study, for example, the

[10] The studies' data had been collected from various hospitals. Dr. Shapiro accounted for "hospital deviation" by considering the impact of a woman being treated at a particular hospital as relevant in determining what caused the malformations being studied.

company did not standardize the data for hospital deviation. See e.g., Defendant's Exhibit 251. Merrell Dow had also relied upon a study completed by a Dr. Paul Stolley that used the recalculation "methodology" to analyze a study completed by Dr. Smithell. See Defendant Exhibit 3057; Hoekenga Testimony at 152a. In fact, Merrell Dow vice president Dr. Hoekenga maintained that the recalculation performed by Dr. Stolley was relevant and reliable information and that Merrell Dow would have produced this type of information to the FDA. Id. at 152a.

In short, both Drs. Done and Shapiro utilized generally accepted, albeit different, methodologies to analyze the raw data. The only difference is that the scientists took into account different factors, which produced different results and led to different conclusions on causation. On the record here, the trial court did not err in concluding that the plaintiffs' expert's methodology was generally accepted.

The Superior Court's suggestion that Dr. Done's statistical analysis was not "generally accepted" also is not supported by this record. As the trial court noted, even among Merrell Dow's experts, there were differences of opinion on this point. For example, Dr. Newberne maintained that no statistical analysis was required to make sense of Merrell Dow's animal studies; whereas, Dr. Tyl specifically rejected such an approach. Trial Court Slip Op. at 63-66. As the trial court aptly noted, there is not even a "scientific consensus" among the defense experts as to the statistical methodologies that Merrell Dow claims disentitle Dr. Done from testifying. Id. at 63.

Thus, contrary to the Superior Court's finding, there is nothing in this record to suggest that the manner in which the appellants' expert witness interpreted or "utilized" the raw data was a "methodology" that is not "generally accepted." Rather, there is ample support for the trial court's conclusion that there was a single, accepted scientific methodology at issue here, with the parties' experts, predictably enough, differing only as to the conclusions on causation. As to this hotly contested issue, each side accused the

other's experts of reaching conclusions that were biased by their litigation interests. This issue was a classic matter for the jury to resolve and the trial court properly left it to the jury.

Finally, I would note that, even if the appellants' experts' conclusions could be viewed as a separate methodology requiring a Frye analysis, I believe that the trial court properly admitted this testimony. As I have detailed above, the record here shows that Merrell Dow largely created the "generally accepted orthodoxy" that would freeze out viewpoints contrary to their litigation interests. Merrell Dow subsidized or otherwise influenced most of the studies that concluded that Bendectin does not cause birth defects. Merrell Dow's role in virtually creating, and then slanting, the "scientific community" should be a relevant factor in the Frye analysis. Accordingly, I would create a limited exception to Frye that would permit the introduction of expert opinions contrary to those opinions generally held by the "scientific community," when those opinions are a result of proprietary research influenced by an interested party.

There is something not a little offensive about an entity, creating a biased, litigation-driven scientific "orthodoxy," and then being permitted to silence any qualified expert holding a dissenting view on grounds of "unorthodoxy." Where the would-be relevant scientific community is a community beholden to the defendants' litigation interests, that biased community should not be permitted to squelch dissenting opposing opinions. The trial court here properly refused to allow that unjust result to occur.

Hence, I respectfully dissent.