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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, a minor, Plaintiffs, v. MERRELL DOW PHARMACEUTICALS INC., and DOES 1 through 50 Inclusive, Defendants.	CASE NO. 84-2013-G(I) CASE NO. 84-2929-G(I) NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT ON THE ISSUE OF CAUSATION DATE: September 5, 1989 TIME: 10:30 a.m. DEPT: Courtroom 7 Judge Gilliam

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on September 5, 1989, at 10:30 a.m., before the Honorable Judge Gilliam, in Courtroom 7 of the United States District Court for the Southern District of California, located at 940 Front Street, San Diego, California, defendant Merrell Dow Pharmaceuticals Inc. will move this court for an order granting their motion for summary judgment on the issue of causation pursuant to Rule 56 of the Federal Rules of Civil Procedure.

This motion is based upon this notice, the accompanying memorandum of points and authorities in support thereof, and all matters on file herein, and upon such further documentary and oral evidence as may be presented at the time of the hearing.

Dated: 8/2/89

DICKSON, CARLSON & CAMPILLO

By George E. Berry
George E. Berry
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WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, a minor, Plaintiffs, v. MERRELL DOW PHARMACEUTICALS INC., and DOES 1 through 50 Inclusive, Defendants.	CASE NO. 84-2013-G(I) CASE NO. 84-2929-G(I) DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT ON THE ISSUE OF CAUSATION
MICHAEL SCHULLER, ANITA DE YOUNG, and ANITA DE YOUNG as Guardian Ad Litem for ERIC SCHULLER Plaintiffs, v. MERRELL DOW PHARMACEUTICALS INC., and DOES 1 through 50 Inclusive, Defendants.	

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LAW OFFICES OF
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STATUTES

COMES NOW defendant Merrell Dow Pharmaceuticals Inc., (hereinafter "Merrell Dow") and submits the following memorandum in support of its motion for summary judgment.

There is now nearly universal scientific consensus that Bendectin does not cause birth defects and as such, plaintiffs in this case can offer no admissible evidence that proves otherwise. Consequently, the evidence regarding causation proves that there is no genuine issue of material fact, and therefore summary judgment is appropriate.

STATEMENT OF MATERIAL FACTS

In this action, plaintiffs seek damages from the defendant, Merrell Dow, for injuries allegedly sustained by the infant plaintiffs as a result of their mothers' ingestion of Bendectin during pregnancy. Bendectin is a prescription pharmaceutical product previously manufactured by Merrell Dow, indicated solely for the treatment of nausea and vomiting during pregnancy.

Of the twenty-seven Bendectin cases litigated on the merits, there are no final judgments in favor of plaintiffs, and seven cases have granted Merrell Dow's motion for summary judgment on the issue of causation.

Furthermore, there are now three circuits in agreement that Bendectin does not cause birth defects. Those circuits are: the First, Fifth, and D.C. Circuits. Indeed, every circuit that has entertained this issue is in agreement that plaintiffs' evidence is insufficient to establish causation. Simply stated, there is not only nearly universal scientific consensus that

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Bendectin does not cause birth defects, but there is also a vast amount of legal authority agreeing with this proposition.

Bendectin first obtained FDA (Food and Drug Administration) approval in 1956, and since that time has been used in over 33 million new therapy starts worldwide. During the 1960's, the annual use of Bendectin rose sharply to more than one million pregnancies per year. By the end of that decade, Bendectin use rose to two million pregnancies a year. However, despite these vast increases in the use of the Bendectin, there was no corresponding increase in the rate of birth defects reported. (Dr. Steven H. Lamm's Affidavit; attached as Exhibit A.)

Due to the fact that the normal incidence of birth defects in the general population is approximately three to four percent of all live births, there is obviously a possibility that this phenomenon can occur coincidentally with the use of Bendectin. Furthermore, given the vast use of Bendectin, this possibility becomes even more likely. Yet, despite this fact, even when Bendectin use was at its highest, the worldwide rate of birth defects did not increase. (Dr. Lamm's Affidavit.) Additionally, when Merrell Dow ceased production of Bendectin in 1983, solely for financial reasons, there was also no change in the rate of birth defects worldwide. Bendectin remains approved by the FDA today.

Additionally, plaintiffs' experts admit that the cause of the vast majority of birth defects is unknown. They also concede that there is no scientific consensus that Bendectin causes birth defects.

1.

ARGUMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Merrell Dow moves for summary judgment on the issue of causation as to both plaintiffs in this case.

In order to survive a motion for summary judgment, plaintiffs must establish every element of their claim, and ultimately that Bendectin caused their birth defects to a reasonable degree of medical certainty. Celotex Corp. v. Catrett, 477 U.S. 317, 321 (1986).

Plaintiffs can produce no evidence sufficient to meet their burden, and indeed, other courts have recognized that plaintiffs' evidence is "woefully inadequate" with regard to causation. As such, defendant is not requesting this court to rule upon the credibility of plaintiffs' experts but merely to determine the sufficiency and admissibility, or more appropriately the insufficiency and inadmissibility, of plaintiffs' evidence.

2.

EXPERT TESTIMONY MUST BE BASED ON PRINCIPLES THAT HAVE GAINED GENERAL ACCEPTANCE IN THE SCIENTIFIC COMMUNITY

Federal Rules of Evidence, Rule 703, restricts the permissible factual basis of an expert's opinion. This restriction was recognized by the Ninth Circuit in U.S. v. Kilgus, 571 F.2d 508 (9th Cir. 1987). In Kilgus, the court stated:

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> "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have gained general acceptance in the field to which it belongs.'" Id. at p. 510. (Following Frye v. United States, 293 F.2d 1013 (D.C.Cir. 1923).

In addition, expert testimony must be more than merely helpful. Clearly, an opinion that is not based on facts or data "of a type reasonably relied upon by experts in the particular field", is not only not helpful but it is in fact confusing or misleading and should therefore be excluded. See, Fed.R.Evid. 403. Following this rationale, the court in Barrel of Fun, Inc. v. State Farm Fire and Casualty Co., 739 F.2d 1028, 1033 (5th Cir. 1984), excluded an expert's opinion based on a polygraph test because it was not reasonably relied upon and it was also misleading and confusing.

a. The Necessity of Epidemiological Evidence

Recently, the Fifth Circuit in Brock v. Merrell Dow Pharmaceuticals Inc., 874 F.2d 307 (5th Cir. 1989) (Petition for Rehearing pending), held that Bendectin did not cause plaintiff's birth defects, specifically, a limb defect known as Poland's syndrome. The jury had returned a verdict in favor of the plaintiffs. This was reversed and judgment was rendered in favor of Merrell Dow by the Court of Appeals. In discussing the adequacy of plaintiffs' evidence regarding causation, the court stated:

> "Confronted, as we now are, with difficult medical questions, courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." Id. at p. 310.

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"We find, in this case, the lack of conclusive epidemiological proof to be fatal to the Brock's case. While we do not hold that epidemiologic proof is a necessary element in all toxic tort cases, it is certainly a very important element. This is especially true when the only other evidence is in the form of animal studies of questionable applicability to humans." Id. at p. 314. (Emphasis added.)

In Richardson v. Richardson-Merrell, 857 F.2d 823 (D.C. Cir. 1988) (Petition for Rehearing denied 4/10/89), and Lynch v. Merrell-National Laboratories, 830 F.2d 1190 (1st Cir. 1987), the Court recognized the vital role of epidemiological evidence in dealing with the principle that absent a scientific understanding, causation may only be shown through reliance upon epidemiological evidence.

In this case, plaintiffs' causation expert, Dr. Palmer, relies on exactly the same evidence that was rejected by the courts in Lynch, supra, Richardson, supra (Petition for Rehearing denied 4/10/89), and Brock, supra, i.e., chemical, in vivo, and in vitro studies.

In Lynch v. Merrell National Laboratories, 830 F.2d 1190 (1st Cir. 1988), the court emphatically decided, in affirming defendant's motion for summary judgment, that no correlation, much less a causal connection, has been demonstrated between the use of Bendectin and limb reduction. Just as in Lynch, both infant plaintiffs, in this case, also have limb reduction defects. In Lynch, the infant plaintiff was born without a right hand and without the lower portion of her right forearm. With respect to this type of birth defect, i.e., limb reduction defect, the court noted:

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> "We face then a situation in which limb reductions are a fairly unusual subspecies of defect, in which the origin of most limb reduction is unknown, in which worldwide scientific investigations of Bendectin have produced no evidence establishing that Bendectin causes limb reduction, and in which the irrelevance of Bendectin to the incidence of limb defects has been demonstrated." Id. at p. 1194. [Emphasis added.]

The court in Lynch went on to discuss at length the evidence available on Bendectin, and recognized that because the etiology of most birth defects is unknown, a great deal of "gossip and guess work abound". Id. at p. 1194. The court warned that as a result of such gossip, the "courts must carefully control the basis for testimony pointing to a particular cause." Id.

In Richardson, supra, the Court of Appeals affirmed the District Court's judgment NOV in favor of the defendant manufacturer. Just as in the case at hand, Richardson involved the alleged ingestion of Bendectin as being the cause of plaintiff's limb reduction defects. While plaintiff's causation expert in that case was Dr. Done, Dr. Palmer relies on exactly the same studies as Dr. Done to conclude that Bendectin causes birth defects. As such, the court's language in Richardson is particularly pertinent to this case.

The court in Richardson cautioned that:

> "[T]he question whether Bendectin causes limb reduction defects is scientific in nature, and it is to the scientific community that the law must look for the answer. For this reason, expert witnesses are indispensable in a case such as this. But that is not to say that the court's hands are inexorably tied, or that it must accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify.
> ... .

> Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." Id. at p. 829. (Emphasis added).

Dr. Done relied on 1) chemical structure activity analysis; 2) in vitro (test tube) studies; 3) in vivo (animal teratology) studies; and 4) reanalysis of epidemiology studies.

Concluding that Dr. Done's testimony lacked an adequate basis, the court determined:

> "These three types of studies - chemical, in vitro, and in vivo - cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." Id. at p. 830.

With regard to the epidemiological studies that Dr. Done relied upon, the court noted that his testimony could be better characterized as a rejection and reanalysis of the epidemiological studies. Additionally:

> "Dr. Done further admitted that no one who had published work on Bendectin had concluded that there was a statistically significant association between Bendectin and limb reduction defects ... . Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for peer review." Id. at p. 831.

The Dr. Done scenario, of recalculation and rejection of published peer reviewed studies, is duplicated by plaintiffs' expert in this case, Dr. Palmer. Both these experts readily criticize other people's published works but have never published on this subject themselves. Indeed, in their motion to substitute Dr. Palmer for Dr. Done, plaintiffs state that "the

evidence relied on by Dr. Palmer to reach his opinion regarding Bendectin is the same as the evidence relied on by Dr. Done," and also that "[h]e will not testify to any new aspects of the case". (See Exhibit B; Plaintiffs' Motion for an Order to Compel Further Discovery, Para. 5, lines 15-21). This evidence was of course rejected by the Court in the Lynch, Richardson, and Brock decisions.

In excess of twenty-five epidemiology studies on the safety of Bendectin have been published in the scientific literature. This comprises data on more than any other drug used in pregnancy. Taken as a whole, the studies have demonstrated a lack of any statistically significant association between Bendectin and the incidence of limb reduction defects. (See Affidavit of Dr. Lamm; Exhibit A.)

In each of the epidemiological studies performed on Bendectin, none of the authors have concluded that Bendectin is connected with an increased risk in birth defects.

Plaintiffs' experts ignore this wealth of scientific data and choose instead to re-organize and re-calculate the available data to support their preconceived beliefs. The rationale for this is obvious since even Dr. Palmer admits that he knows of no published epidemiological study that concludes that Bendectin causes limb defects in humans. (Palmer depo. at pp. 192 and 193; Exhibit C.)

Not only does Dr. Palmer's testimony lack the adequate basis to be admissible under Lynch, Richardson, and Brock, in that he does not rely on the published epidemiology studies, but Dr. Palmer also lacks the credentials necessary to testify

regarding the issue of causation. Dr. Palmer has never performed any type of research regarding Bendectin or its components (Palmer deposition at p. 312; Exhibit C), he has never examined the minor plaintiffs in this case, and he has never published his opinions or criticisms of any of the studies that have been performed on Bendectin. Indeed, Dr. Palmer has never performed or designed an epidemiological study of any sort. (Palmer deposition at p. 15; Exhibit C.)

Dr. Palmer violates basic epidemiological principles by ignoring the author's conclusions, and instead, manipulating the data and making adjustments in order to reach a preconceived result.

Despite purporting to be an expert on causation in Bendectin cases, prior to becoming involved with the Bendectin litigation, Dr. Palmer had never consulted with a patient and advised them that their birth defect was caused by exposure to a drug, chemical, or environmental agent (Palmer depo. at pp. 461, 462; Exhibit C).

The case at hand is similar to Thompson v. Merrell Dow Pharmaceuticals Inc., 229 N.J. Super 230, 551 A.2d 177 (1988), another Bendectin case, in which plaintiffs offered a pharmacologist (Dr. Aldinger, Ph.D.) as an expert on causation. The Court, in rejecting the pharmacologist's testimony stated:

> We are satisfied that Aldinger sadly lacked the credentials necessary to support his testimony as being reliable enough to aid the jury in its deliberations. He never performed research concerning Bendectin, never studied the developing embryo, never ventured outside the cardiovascular field and never examined the infant plaintiff, and was not qualified to do so." Id. at p. 185.

The case at hand appears to be remarkably similar, except in this case plaintiffs have named Dr. Palmer, and in that case it was Dr. Aldinger.

Finally, with regard to the admissibility of Dr. Palmer's testimony, following the standard enunciated in Kilgus, supra, that a scientific principle "must be sufficiently established to have gained general acceptance in the field to which it belongs, Dr. Palmer's opinions must be excluded. Dr. Palmer cannot claim that there is a scientific or medical consensus that Bendectin causes birth defects. Indeed, the medical and scientific data is precisely to the contrary. The F.D.A., its professional advisors, and all of the physicians and scientists who have carried out studies on Bendectin have concluded that Bendectin has not been demonstrated to be a human teratogen.

The principle that epidemiological evidence is necessary to prove causation in the absence of scientific understanding regarding causation was also recognized in the "Agent Orange" litigation. Chief Judge Weinstein determined that epidemiologic studies on causation assume a critically important role.

In In Re "Agent Orange" Prod. Liab. Litigation, 611 F.Supp. 1223 (E.D. N.Y. 1985); Aff'd 818 F.2d 187 (2nd Cir. 1987). Judge Weinstein specifically stated that epidemiological studies were "the only useful studies having any bearing on causation." Id. at p. 1231. (See, also, Merrell v. United States, 517 F.Supp. 374, 379 (N.D. Tex. 1981.) Judge Weinstein's findings are particularly applicable to Bendectin litigation

where there exists an overwhelming amount of available epidemiological data.

b. The validity of expert testimony.

It appears abundantly clear that courts are beginning to realize the vital role they must play in determining the qualifications of experts and the soundness of their opinions. In such a scientifically oriented case as this, it is essential that the court step in and take control of the expert evidence. Courts must not be trapped into believing that just because an expert "says it is so", that it must be as he says it is. In In Re Air Crash Disaster at New Orleans, 795 F.2d 1230, 1233-34 (5th Cir. 1986), the court recognized the potential for this problem, and determined:

> "... The ultimate issue in such [products liability] cases too easily becomes what an expert says it is, and trial courts must be wary lest the expert becomes nothing more than an advocate of policy before the jury. Stated more directly, the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument. Indeed, the premise of receiving expert testimony is that it ... will assist the trier of fact to understand the evidence or to determine a fact in issue ... Fed.R.Evid. Rule 702.
>
> Our customary deference also assumes that the trial judge actually exercised his discretion. In saying this, we recognize the temptation to answer objections to receipt of expert testimony with the short hand remark that the jury will give it 'the weight it deserves'. This nigh reflective explanation may be sound in some cases, but in others it can mask a failure by the trial judge to come to grips with an important trial decision. Trial judges must be sensitive to the qualifications of persons claiming to be experts ... .Our message to our able trial colleagues: It is time to take hold of expert testimony in federal trials." Id. at pp. 1233-1234. (Emphasis added.)

In looking at plaintiffs' evidence in this case, only one conclusion can be drawn: It is insufficient to carry this case forward, and plaintiffs' expert opinions are nothing more than "saying it is so."

3.

PLAINTIFFS CANNOT PROVE CAUSATION IN A BENDECTIN CASE BASED UPON THE CURRENT STATUS OF THE SCIENTIFIC EVIDENCE.

Defendant anticipates that in response to this motion, plaintiffs will introduce an affidavit by their primary causation expert (Dr. John D. Palmer) making allegations that Bendectin was the cause of plaintiffs' birth defects.[1] This allegation will be set forth despite the fact that plaintiffs' expert agrees that approximately eighty percent of all birth defects are of unknown origin (Dr. Palmer's Deposition at p. 665); (Exhibit C) and also that no epidemiological study on Bendectin has concluded that Bendectin causes birth defects, and, more specifically, does not cause limb reduction defects at issue in this case.

Plaintiffs' case rests upon "possibilities" and speculation. There is a Ninth Circuit case particularly pertinent to the standard necessary to prove causation. Specifically, that causation must rest on more than mere possibilities.

Neely v. St. Paul Fire and Marine Insurance Company, 584 F.2d 341 (9th Cir. 1978), involved a farmer who brought suit

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1. Plaintiffs' experts in this case are basically the same experts who have testified in other Bendectin cases. Dr. Palmer is the only expert who has not yet testified in a Bendectin case, but he admits that he relies on the same studies as Dr. Done, and that his testimony is substantially the same.

against his vandalism insurer and against an oil company seeking recovery for damages to irrigation engines as a result of contamination from lubricating oil. The District Court entered summary judgment for the defendant. In upholding the summary judgment, the court stated:

> "... that defendant's negligence could possibly have been the cause is not sufficient. The same rule applies, whereas here, the evidence leaves the cause of an accident uncertain." Id. at p. 346. (Emphasis in original.)

In the case at hand, plaintiffs' evidence does not even meet the "possibility" standard, but is clearly the result of guesswork, speculation, and unfounded beliefs.

In Richardson, supra, the court discussed at length the current state of scientific knowledge regarding Bendectin:

> "In September, 1980, the Food and Drug Administration ('FDA') of the U. S. Department of Health and Human Services, the government agency responsible for protecting the public from harmful drugs, convened its Fertility and Maternal Health Drugs Advisory Committee to evaluate the evidence with respect to recurrent rumors of Bendectin related malformations ... Having been furnished the available literature several weeks in advance, the Advisory Committee held two days of hearings in Washington, D.C. September 15 to 16, 1980, to which the public and numerous scholars, including many of the authors of the published epidemiological studies, were invited ... [A]t the conclusion of which, the Advisory Committee went into executive session and deliberated upon the evidence before it. Eight of the ten committee members were convinced that there was nothing to implicate Bendectin in an increased incidence of any birth defects whatsoever, and the other two were simply 'uncertain' as to two species of malformation not involved here. The Advisory Committee reported accordingly to the FDA, and on October 7, 1980, the FDA announced its agreement with its findings, a position it has not changed in the meantime nor been given reason to do so." Id. at p. 803.

The court went on to state:

> "There is now nearly universal scientific consensus that Bendectin has not been shown to be a teratogen, and, the issue being a scientific one, reasonable jurors could not reject that consensus without indulging in precisely the same speculation and conjecture which the multiple investigation undertook, but failed, to confirm." Id.

In addition, the trial court in Lynch, 646 F.Supp. 856 (D. Mass. 1986) (aff'd. 830 F.2d 1190 (1st Cir. 1988) specifically reviewed all the available epidemiological data on Bendectin and birth defects and concluded:

> "As noted above, the epidemiological studies presented by the defendant indicate no statistically significant association between Bendectin and either birth defects generally or limb reduction defects in particular the plaintiffs have presented no epidemiological evidence indicating a statistically significant association between Bendectin and any type of birth defect, and none of the plaintiffs' witnesses has conducted a study of Bendectin and birth defects." Id. at p. 864.

The trial court, in Lynch, also pointed out that even though the number of Bendectin new therapy starts per year changed dramatically, the incidence of limb reduction defects did not change during the same time period concluding: "[t]hus no connection between fluctuations in the use of Bendectin and the incidence of limb reduction defects has been demonstrated." Id. at p. 864. (See, also, Dr. Lamm's Affidavit; Exhibit A.)

The mandate of both the Richardson and Lynch courts was that plaintiffs must come up with some new evidence above and beyond what was presented in those cases, to support their 'belief' that Bendectin causes birth defects.

Plaintiffs in this case have clearly failed to meet this burden. While they have come up with a new expert, he, too,

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relies on the same evidence as the experts in Lynch and Richardson.

Three California Bendectin cases may be informative with regard to the case at hand. Two of these cases were full trials on the merits both resulting in defense verdicts which are now final judgments. Cordova v. Phillips Roxane Labs. Inc., et al., Case No. 432 656 (Sup.Ct. Cal. County of Santa Clara, June 1985), (appeal dismissed) and Bityk v. Richardson-Merrell, Inc., Case No. C302225 (Sup.Ct. Cal. L.A. County, June 1987), (appeal abandoned). The third of these cases was Heath v. Merrell Dow Pharmaceuticals Inc., (U.S.D.C. N.D. Cal., Case No. C81-4362 MHP, 7-15-88), which was dismissed on the morning of trial with Judge Patel stating to Plaintiffs:

> "I don't know where you would get an attorney to represent you, because the success in showing causation has been virtually nil in these cases.
>
> A whole host of experts far more than are ever going to be summoned up or that you could afford to summon up in this case were, in fact, summoned up before Judge Rubin in Cincinnati when a large number of them were tried. In that case, the determination was made that causation had not been established between the use of Bendectin and the resulting birth defects.
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> The overwhelming majority of the cases that have been decided apart from that have reached either the same result or found -- found no liability.
>
> And I think there are very, very few, if any, attorneys, even those who had familiarity with them in the early days, who will now take on these cases. And the reality is that the epidemiology studies don't support the causation showing."; (Attached as Exhibit D); (emphasis added).

In addition to the First, Fifth and D.C. Circuits, the Sixth Circuit has also determined that plaintiffs cannot demonstrate causation in a Bendectin case. See, In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation, 624 F.Supp. 1212 (S.D.Ohio 1985); affirmed on appeal

857 F.2d 290 (6th Cir. 1988); cert. denied, ____U.S.____; 109 S.Ct. 788; 102 L.Ed.2d 779 (1989). In Re Richardson disposed of over 1100 plaintiffs' claims. The three judge panel was unanimous regarding the issue of causation. Even Judge Jones, who dissented in part, wrote:

> "... plaintiffs lost their case because they failed to establish any link between their birth defects and the drug Bendectin, not because of any prejudice to them resulting from the trifurcation order." Id. at p. 327.

4.

THE STANDARD FOR MEDICAL CAUSATION: MORE PROBABLE THAN NOT MEANS A TWOFOLD INCREASE IN RELATIVE RISK

Courts dealing with the swine flu vaccination cases have confronted the same causation problems that are present in the case at hand.

In Cook v. United States, 545 F.Supp. 306 (U.S.D.C. N.D. Cal. 1982), the Court enunciated the following standard in order for plaintiffs to prove causation:

> "Wherever the relative risk to vaccinated persons is greater than two times the risk to unvaccinated persons, there is a greater than 50% chance that a given GBS [Guillain-Barre Syndrome] case among vaccinees of that latency period is attributable to vaccination, thus sustaining plaintiff's burden of proof on causation." Id. at p. 308.

In the footnote that followed, the Court explained their rationale for such a standard:

> "Once the relative risk rises above two, it becomes more probable than not that a given case was caused by the vaccine." (Fn. 1, p. 309.) (Emphasis added.)

To clarify this, the Court in Cook literally determined that, in order to show that plaintiff's illness was more probably

than not caused by the vaccination, there must be a statistically significant relative risk of more than two.

Plaintiffs in this case can in no way demonstrate a relative risk of more than two; thereby failing to meet the more probable than not standard for medical causation.

In addition, the courts dealing with the swine flu cases have consistently held that a theory of causation must be rejected as being purely speculative in the absence of epidemiological evidence or a scientific understanding of causation. See, Perry v. United States, 755 F.2d 888, 891-93 (11th Cir. 1985); Adleson v. United States, 523 F.Supp. 459, 465-467 (N.D. Cal. 1981).

In Novak v. United States, 865 F.2d 718 (6th Cir. 1989), the court recently determined that a trial court's finding that plaintiff's death from dermatomyositis was caused by the administration of a swine flu vaccination, was incorrect and reversed and directed a verdict for the United States.

Specifically, in rejecting plaintiff's experts' evidence, the court held that:

> "... This expert evidence advanced by plaintiff and relied upon by the District Court, was not admissible in light of the totality of the medical evidence and the overwhelming proof that any specific cause of DM/PM is unknown and conjectural at best." Id. at p. 723.

See, also, United States v. Green, 548 F.2d 1261 (6th Cir. 1977) and Heyman v. United Sates, 506 F.Supp. 1145 (S.D.Fla. 1981).

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5.

SUMMARY JUDGMENT ON THE ISSUE OF CAUSATION IS APPROPRIATE IN A CASE INVOLVING BENDECTIN.

Seven cases involving Bendectin have granted summary judgments for the defendant Merrell Dow specifically on the grounds that Bendectin does not cause birth defects.[2/]

The first case in which a summary judgment was granted was Lynch, supra, previously discussed. Significantly, since the Richardson decision, every court that has directly addressed the sufficiency of the causation evidence has followed the Richardson determination that such evidence cannot create a genuine issue of material fact as to whether Bendectin causes birth defects. See, Hull v. Merrell Dow Pharmaceuticals Inc., 700 F.Supp. 28 (S.D. Fla. 1988); Bernhardt v. Richardson-Merrell, Inc., No. D.C. 85-39-B-D, Memorandum Opinion (N.D. Miss. Apr. 24, 1989; Depyper v. Navarro, No. 83-303-467NM, Memorandum Opinion and Order (Cir.Ct. Mich. Mar. 10, 1989); Koller v. Richardson-Merrell, Inc., Case No. 80-1258; Memorandum and Opinion (June 30, 1989); Ambrosini v. Richardson-Merrell, Inc., Case No. 86-0278; Memorandum and Opinion (June 30, 1989); DeLuca v. Merrell Dow Pharmaceuticals Inc., Civil Action No. 87-226(GEB), Memorandum and Order (June 7, 1989); see, also, Hazuga v. Merrell Dow Pharmaceuticals Inc., No. 88-C-146-C, Order at 5,6 W.D. Wisc. (Jan. 30, 1989) (declining to rule on question of whether evidence was sufficient to raise genuine issue of causation but noting that from cases cited by

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2. Three of the decisions are final (Lynch, supra; Monahan v. Merrell National Laboratories, Civil Action No. 893-3108-WD (1987); and Hull v. Merrell Dow Pharmaceuticals Inc., 700 F.Supp. 28 (S.D. Fla. 1988).

Merrell Dow, including Richardson, it appeared that "plaintiffs will have a difficult task in establishing causation").

On Friday, March 10, 1989, the Circuit Court for Wayne County, Michigan, granted Merrell Dow's motion for summary judgment on the issue of causation, in DePyper v. Navarro, Case No. 83-303-467 NM, Memorandum and Opinion, March 10, 1989. (Attached as Exhibit E.) The court in DePyper followed the standard enunciated by the U. S. Supreme Court in Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986), that:

> "A judge is no longer required to submit a question to a jury 'merely because some evidence has been introduced by the party having the burden of proof, unless the evidence be of such character that it would warrant the jury in finding a verdict in favor of that party.' If the evidence is merely colorable, or is not significantly probative ... summary judgment may be granted."

The DePyper court determined that while the teratogenicity of Bendectin was a scientific question, and therefore experts were required in such a case, this did not mean:

> "that the courts 'must accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify ..." Citing Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 at 829 (D.C.Cir. 1988).[3]

Recently, judgments were entered in the cases of Koller v. Richardson-Merrell, Inc., Case No. 80-1258; Memorandum and Opinion (June 30, 1989) (attached as Exhibit F), and Ambrosini v.

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3. Plaintiffs have filed a notice of appeal in DePyper.

Richardson-Merrell, Inc., Case No. 86-0278; Memorandum and Opinion (June 30, 1989) (attached as Exhibit G).

Both Koller and Ambrosini had been stayed pending the decision in Richardson. Following the decision in Richardson, defendant Merrell Dow moved the court to have the stay lifted and to have plaintiffs show cause why these cases should proceed in light of the Court of Appeal's decision in Richardson. Merrell Dow's motion in each case was granted, and plaintiffs were specifically directed to identify specific, admissible, expert evidence of a causal relationship between Bendectin and limb defects, specifically, following the standard enunciated in Richardson. The plaintiffs having failed to do so, the Court entered judgment.

The Court stated:

> "This circuit has found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, in vivo, in vitro studies, or reformulated epidemiological data is not admissible. Consequently, expert testimony in a Bendectin case cannot be presented to a jury unless it is supported by some other type of scientific evidence." (See Exhibits F and G.) (Emphasis added.)

Similarly, Judge Brown granted defendants motion for summary judgment in DeLuca v. Merrell Dow Pharmaceuticals Inc., Civil Action No. 87-226(GEB); Memorandum and Order (June 7, 1989) (appeal pending). (Attached as Exhibit H.)

Specifically, the Court stated:

> "Summary judgment against a litigant is proper if that litigant relies exclusively on expert testimony to prove a material fact, and that expert's testimony has no foundation under F.R.Evid. 703., In Re Japanese Elec. Products Litigation, 723 F.2d 238, 275-78 (3d Cir. 1983); reversed on other grounds, 475 U.S. 574, 1986."

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Furthermore, the Court stated:

> "Determining whether an expert's opinion has sufficient foundation under Fed.R.Evid. 703 is a legal determination to be made by the judge." In re Japanese Prod. Id.

Additionally, in Monahan v. Merrell National Laboratories, Civil Action No. 83-3108-WD, Memorandum and Order, December 18, 1987, (Exhibit I) the court also granted defendant's motion for summary judgment on the issue of causation. Following the standard set forth in Lynch, the court concluded that the plaintiff must produce evidence of a new study showing a statistically significant correlation between Bendectin and birth defects, in order to defeat defendant's summary judgment motion. Specifically, the court stated:

> "Under Lynch, a Bendectin plaintiff may withstand a defendant's motion for summary judgment on the issue of causation if the expert opinion he offers on Bendectin as a cause is based on '[a] new study coming to a different conclusion and challenging the consensus.' Id. at p. 1194. Such a study would have to be supported by 'confirmatory epidemiological data.' Id. And it is likely that it would have to be 'refereed or published in a scientific journal or elsewhere.' Id. at p. 1195." Monahan, Memorandum and Opinion. (See Exhibit I.)

The case at hand is extremely similar to the Monahan case.

Just as here, the plaintiffs in Monahan attempted to offer a new expert, but the court concluded that the plaintiffs had failed to offer a new study, following the mandate of Lynch, and therefore their claim must fail.

In fact, the court concluded that while plaintiffs were offering a new expert qualified in pharmacology, his testimony would be inadmissible since he relied upon 1) studies on

chemicals analogous to Bendectin; 2) the fact that Mrs. Monahan *ingested* Bendectin during the critical period in her pregnancy; and 3) that there was no other known cause.

Similarly, in this case, plaintiffs have no new evidence regarding Bendectin causing birth defects, specifically limb reduction defects. It is also important to note that plaintiffs' primary causation expert in this case is a pharmacologist, just as in Monahan.

While plaintiffs may try to find new experts to enunciate their "belief" that Bendectin causes birth defects, this is insufficient and as such, their evidence is nothing more than speculation and against the great weight of universal scientific evidence and legal precedent.

Finally, summary judgment on the issue of causation was also granted for the defendant Merrell Dow in Hull v. Merrell Dow Pharmaceuticals Inc., 700 F.Supp. 28 (S.D. Fla. 1988). Hull was also a limb defect case.

CONCLUSION

This case does not involve a classic battle of the experts. More than twenty years of human studies have produced a wealth of data regarding the safety of Bendectin. The numerous independent scientists who have reviewed the data on Bendectin, including the FDA, have uniformly concluded that the available information clearly does not support a conclusion that Bendectin causes birth defects in general, or limb reduction defects in particular.

Plaintiffs cannot produce any facts demonstrating a genuine issue as to causation. Therefore, Merrell Dow

respectfully requests that this court grant its motion for summary judgment.

Respectfully submitted,

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