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748 So.2d 1108 (Fla.App. 3 Dist. 2000)
E.I. DU PONT DE NEMOURS & CO., INC. AND PINE ISLAND FARMS, INC., APPELLANTS,
v.
JOHN CASTILLO, A MINOR BY AND THROUGH HIS MOTHER, NEXT FRIEND AND NATURAL GUARDIAN, DONNA CASTILLO, DONNA CASTILLO AND JUAN CASTILLO, INDIVIDUALLY, APPELLEES.
NOS. 3D96-2486, 3D96-2489
District Court of Appeal of Florida, Third District
February 09, 2000

An Appeal from the Circuit Court for Dade County, Amy Steele Donner, Judge. LOWER TRIBUNAL NO. 93-14199

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Greenberg Traurig and Arthur J. England and Joe N. Unger, Miami; Kirkland & Ellis and Edward W. Warren and Jeffrey Bossert Clark and Christopher Landau; Gaebe, Murphy, Mullen and Antonelli and David Kleinberg, Coral Gables for appellants.

James L. Ferraro; Elizabeth Russo, Miami for appellees.

Before Cope, Gersten and Sorondo, JJ.

ON MOTION FOR REHEARING - DENIED

Sorondo, J.

We deny Appellees' Motion for Rehearing, however we withdraw our previous opinion filed February 17, 1999, and substitute the following in its place.

E.I. Du Pont De Nemours and Co., Inc. (Du Pont) and Pine Island Farms, Inc. (Pine Island) appeal the Final Judgment of the lower court entered on the denial of their motions for judgment notwithstanding the verdict and/or new trial.

John Castillo, a minor, by and through his mother Donna Castillo, and Donna Castillo and Juan Castillo, individually, filed this action against Du Pont and Pine Island in July 1993, alleging that Mrs. Castillo had been exposed to Benlate, an agricultural fungicide manufactured by DuPont, from the "u-pick" field owned by Pine Island in the Castillos' West Kendall neighborhood where Mrs. Castillo walked while pregnant with John. Plaintiffs' case was based on the scientific theory that the mist sprayed in the field, to which Mrs. Castillo had allegedly been exposed, contained Benlate, and that benomyl (the active ingredient in Benlate) entered her bloodstream and caused John's microphthalmia, a rare birth defect involving severely underdeveloped eyes.

As relevant to this appeal, the amended complaint sounded in negligence and strict liability against DuPont and negligence against Pine Island. In support of their theories of liability, plaintiffs proffered the expert testimony of Dr. Charles Howard, a senior lecturer/associate professor at the University of Liverpool in England. In pretrial depositions, Dr. Howard testified that he believed that fetal exposure to benomyl at a concentration of twenty parts per billion in the maternal bloodstream would cause microphthalmia in humans, basing his conclusion on two sources: 1) rat gavage studies and 2) lab experiments on human and rat cells.

Defendants moved before trial to exclude Dr. Howard's testimony on the ground that his methodology for determining whether and at what level Benlate could cause birth defects in humans was not "generally accepted" in the scientific community and thus inadmissible. The trial court denied the motion.

A few weeks before trial, plaintiffs' exposure theory changed from exposure through the lungs (inhalation exposure) to exposure through the skin (dermal exposure). At trial, plaintiffs limited their case to a single drenching incident and did not contend that Mrs. Castillo had otherwise been exposed to Benlate during her pregnancy. Dr. Howard provided plaintiffs' causation evidence.

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Over DuPont's objection, the court allowed plaintiffs to refer at trial to an alleged link between Benlate and unspecified "clusters" of children born without eyes in Great Britain.1 Further, over DuPont's objection, the trial court allowed the plaintiffs to show the jury a 19-minute video entitled "A Day in the Life of John Castillo."2

At the close of the evidence, DuPont moved for a directed verdict arguing that plaintiffs had failed to prove that Benlate is defective and that any such defect proximately caused John's microphthalmia. The jury returned its verdict, holding DuPont liable on a strict-liability theory and both DuPont and Pine Island liable on a negligence theory. The jury awarded a total of $4 million in damages, allocating 99.5% against DuPont and .5% against Pine Island. DuPont and Pine Island moved to set aside the verdict and/or for a new trial, which the trial court denied. This appeal followed.

Our analysis will address each defendant's legal arguments individually, but will begin by reviewing the material facts presented by plaintiffs. According to Donna Castillo's trial testimony, she passed by the "u-pick" farm in question on either November 1st or 2nd, 1989, as she walked with her young daughter, Adriana, while pregnant with John. As she walked, she observed a tractor that she described as "bucking and jerking" and spraying "tons" of mist into the air. As the mist drifted over her (she indicated that it was a windy day), it completely drenched her. She returned to her home and did not shower that night. She was in her seventh week of pregnancy at the time.

The plaintiffs established that Pine Island purchased its chemicals from two suppliers: Helena Chemicals and S&M Chemicals. The evidence showed that in 1989, Pine Island purchased Benlate from Helena Chemicals on four occasions: March 20 - thirty-six pounds; April 29 - twenty-four pounds; May 4 - twelve pounds; and December 19 - sixty pounds. Because S&M's records were destroyed by Hurricane Andrew in 1992, there was no evidence of purchases from S&M for 1989. Pine Island's general manager, Lynn Chaffin, testified that S&M was not a major provider of chemicals for his employer because their prices were too high. He likened S&M to a convenience store like "Quick Mart" where only small purchases were made. He further testified that when purchased chemicals were not used it was the company's practice to return them for credit. This practice was confirmed by Dan Daniels, branch manager for Helena Chemicals.3

Additional evidence elicited during the plaintiff's case indicated that Pine Island's

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strawberry and tomato plants arrived from California on October 25, and that the strawberries were planted that day. The tomatoes were planted at some time after that date. There was testimony which established that Benlate can be used prophylactically as early as the first week after planting of tomatoes. If the tomato plants were planted on the same day as the strawberries, or on the next day, such a prophylactic spraying of the tomato plants would have occurred on November 1st or 2nd.4

Both DuPont and Pine Island moved for directed verdicts at the conclusion of the plaintiffs' case and now argue that their motions should have been granted. We address their claims individually.

MOTIONS FOR DIRECTED VERDICT

I.

Pine Island Farms, Inc.

There is one additional fact presented against Pine Island, which is significant to our analysis of one of its claims on this issue. In May of 1993, a British reporter, John Ashton, was conducting an investigation into the relationship between Benlate and children born with microphthalmia in Great Britain. He initially called Mrs. Castillo and asked her if she had ever been exposed to Benlate. More specifically, he asked her if she lived on a farm or near farmland. Castillo said she was unaware of any exposure but told Ashton that she lived near a "u-pick" field and advised him of its location. Later that month, Ashton called Chaffin and asked him if Pine Island had sprayed Benlate on the field in question in November of 1989. Ashton testified in deposition published to the jury at trial that Chaffin then told him that Pine Island had sprayed Benlate in November of 1989. Although Chaffin testified at trial that he did not remember any such conversation, his telephone records confirmed an eight minute telephone call originating in London, England in May of 1993. Regardless of the confirmation, Ashton's testimony established prima facie evidence of a party admission which was admissible against Pine Island under section 90.803(18)(d), Florida Statutes (1995).

Pine Island argues that its motion for directed verdict should have been granted because plaintiffs presented insufficient evidence to establish that Mrs. Castillo was sprayed with Benlate, and/or that, even if they did, plaintiffs' scientific evidence did not satisfy the Frye5 test for admissibility and should never have been admitted into evidence. In the absence of such evidence Pine Island claims its motion should have been granted.

As concerns the sufficiency argument, Pine Island posits that in order to conclude that Mrs. Castillo was sprayed with Benlate, the jury would have to stack inferences that Pine Island was in possession of Benlate on November 1 and 2, 1989, that Pine Island was growing tomatoes on the field in question on those two dates, and that Pine Island sprayed Benlate on the days in question. Pine Island argues that such stacking of inferences is impermissible. See Voelker v. Combined Ins. Co. of America, 73 So.2d 403 (Fla. 1954); Asplundh Tree Experts, Inc. v. Mason, 693 So.2d 44 (Fla. 1st DCA), review denied, 699 So.2d 1374 (Fla. 1997); Reaves v. Armstrong

World Indus., Inc., 569 So.2d 1307 (Fla. 4th DCA 1990). This argument, however, ignores the fact that Chaffin's admission to Ashton was not an inference but direct evidence that Benlate was sprayed on the field in November of 1989. Indeed, it is the only direct evidence presented by plaintiffs that Benlate was, in fact, used during the time in question. This evidence was critical, and when considered in conjunction with the testimony

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of Mrs. Castillo and the other circumstantial evidence presented, constituted sufficient evidence to deny Pine Island's motion for directed verdict on the sufficiency argument.

Pine Island's Frye argument, like DuPont's, is more compelling and is addressed below.

II.

E. I. DuPont De Nemours & Company, Inc.

Like Pine Island, DuPont argues that its motion for directed verdict should have been granted. In support of that argument it has presented several grounds in this appeal. First, DuPont argues that plaintiffs failed to prove that Benlate is defective, as they failed to in any way negate the conclusions of the EPA that Benlate does not pose an "unreasonable" risk to human health. Next, that plaintiffs' exposure theory was based on an unlawful misuse of Benlate inconsistent with a product defect. Benlate's packaging specifically warns (in three places) against using the product in circumstances that could result in drift. We do not address these arguments here because we find each of DuPont's final two arguments dispositive.

DuPont suggests that plaintiffs failed to prove that Mrs. Castillo was exposed to Benlate in their case against DuPont. It argues that the statement of Lynn Chaffin, although admissible against Pine Island as a party admission under section 90.803(18)(d), was inadmissible hearsay as against DuPont. Indeed, prior to trial, the trial court granted DuPont's motion in limine to preclude the use of Chaffin's hearsay testimony against DuPont. This ruling was eminently correct and fatal to the plaintiffs' case against DuPont. As we observed in our discussion of Pine Island's motion for directed verdict, Chaffin's admission is critical to the resolution of this issue. Without his admission, there is insufficient evidence in this record to establish that Benlate was sprayed on the farm on the dates in question. Having correctly granted DuPont's motion in limine, the trial judge was then obligated to decide DuPont's motion for directed verdict without considering Pine Island's admission. In that light, there is insufficient evidence, as against DuPont, to establish that Mrs. Castillo was sprayed with Benlate.

DuPont next argues that the plaintiffs' scientific evidence should never have been admitted into evidence and that in its absence there is insufficient evidence of causation in this record. We find merit in this argument and proceed to discuss it.

III.

THE FRYE ISSUE

Pine Island and DuPont argue that the trial court should not have admitted plaintiffs' scientific evidence as it did not satisfy the test for admissibility set forth in Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).6 We agree.

The admission of expert testimony in this case is governed by section 90.702, Florida Statutes (1995), which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact in understanding the evidence or in determining a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify about it in the form of an opinion; however, the opinion is admissible only if it can be applied to evidence at trial.

In the seminal case of Frye, the court first espoused the requirement that scientific evidence be "generally accepted" within the relevant scientific community:

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Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Frye, 293 F. at 1014.

Florida courts continue to adhere to the "general acceptance" standard of Frye.

[T]he burden is on the proponent of the evidence to prove the general acceptance of both the underlying scientific principle and the testing procedures used to apply that principle to the facts of the case at hand. . . . The general acceptance under the Frye test must be established by a preponderance of the evidence.

Murray v. State, 692 So.2d 157, 161 (Fla. 1997)(quoting Ramirez v. State, 651 So.2d 1164, 1168 (Fla. 1995)); see also Hadden v. State, 690 So.2d 573, 578 (Fla. 1997) ("[I]t is the function of the court to not permit cases to be resolved on the basis of evidence for which a predicate of reliability has not been established. Reliability is fundamental to issues involved in the admissibility of evidence. . . . Novel scientific evidence must also be shown to be reliable on some basis other than simply that it is the opinion of the witness who seeks to offer the opinion."); Brim v. State, 695 So.2d 268, 271 (Fla. 1997); Hayes v. State, 660 So.2d 257, 262 (Fla. 1995); Flanagan v. State, 625 So.2d 827 (Fla. 1993); Stokes v. State, 548 So.2d 188, 193-94 (Fla. 1989)("The underlying theory for this rule is that a courtroom is not a laboratory, and as such it is not the place to conduct scientific experiments. If the scientific community considers a procedure or process unreliable for its own purposes, then the procedure must be considered less reliable for courtroom use.").

In Ramirez, the court outlined a four-step process for determining the admissibility of expert opinion testimony concerning a new or novel scientific principle:

First, the trial judge must determine whether such expert testimony will assist the jury in understanding the evidence or in determining a fact in issue. . . . Second, the trial judge must decide whether the expert's testimony is based on a scientific principle or discovery that is "sufficiently established to have gained general acceptance in the particular field in which it belongs." Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923). . . . The third step in the process is for the trial judge to determine whether a particular witness is qualified as an expert to present opinion testimony on the subject in issue. . . . Fourth, the judge may then allow the expert to render an opinion on the subject of his or her expertise, and it is then up to the jury to determine the credibility of the expert's opinion, which it may either accept or reject.

Ramirez, 651 So.2d at 1167; see also Murray, 692 So.2d at 161.

A review of the record establishes that the trial judge did not apply the test set forth in Ramirez in this case. We are persuaded of this by three statements made by the trial judge at the time she ruled:

Well, I'm still a little confused since I'm the one who has to make the decision on this. This is not like the jury.

This is something like the hearing I had before you came in, which was a probable cause hearing.

There is probable cause for me to let this in. In other words, if I believe that science is reliable and the jury - it would assist the trier of fact, in Frye, I'm going to let it in.

(Emphasis added). The court went on to say:

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The Frye hearing is not to decide the very seminal issue of this case, whether or not it's a teratogen. It's to decide whether or not the scientists who want to talk about it have reliability, and that is the sole purpose of Frye.

(Emphasis added). Lastly, the court said:

I have to tell you I find it a human teratogen too, so you are really going to have a problem. I don't know what is in the levels, but I'm going to tell you that if it's a rat teratogen, most probably it's a human teratogen, and I'm going to make that quantum leap.

From these statements we conclude that the trial judge failed to make the finding required by Frye, to-wit: "whether the expert's testimony is based on a scientific principle or discovery that is 'sufficiently established to have gained general acceptance in the particular field in which it belongs.'"7 Ramirez, 651 So.2d at 1167 (quoting Frye, 293 F. at 1014). During the discussions which surrounded the above quoted statements, counsel for DuPont repeatedly told the court that the admissibility of the plaintiffs' scientific evidence depended on the general acceptance in the relevant scientific community of the methodology used by Drs. Howard and van Veltzen. The trial judge never made a finding on this critical issue. The lower court's last statement quoted above strongly suggests that rather than making the required finding of general acceptance in the relevant scientific community of the methodologies employed by plaintiffs' scientists, the trial judge reached her own conclusions on the merits of their conclusions. It is clear from this record that the trial court did not correctly apply the Frye standard in determining the admissibility of the plaintiffs' scientific evidence.

The standard of review of a Frye issue is de novo. See Hadden, 690 So.2d at 579; Brim, 695 So.2d at 276. A trial court's ruling on the admissibility of expert opinion testimony, which is purportedly based on an underlying novel scientific principle or technique, is reviewed as a matter of law, rather than under an abuse of discretion standard. See Hadden; Williams v. State, 710 So.2d 24, 32 n.13 (Fla. 3d DCA), review denied, 725 So.2d 1111 (Fla. 1998); Berry v. CSX Transp., Inc., 709 So.2d 552, 557 (Fla. 1st DCA), review denied, 718 So.2d 167 (Fla. 1998). The de novo review of the Frye issue includes an examination of three methods of proof: (1) expert testimony, (2) scientific and legal writings, and (3) judicial opinions. See Brim, 695 So.2d at 268; Hadden, 690 So.2d at 579; Williams, 710 So.2d at 32 n.8; Berry, 709 So.2d at 557; Flanagan v. State, 586 So.2d 1085, 1112 (Fla. 1st DCA

1991)(Ervin, J., concurring and dissenting). Appellate courts should consider the issue of general acceptance at the time of appeal rather than the time of trial. See Hadden, 690 So.2d at 579.

Both Pine Island and DuPont raise two arguments in support of their contention that plaintiffs' scientific evidence did not satisfy the Frye test for admissibility. One, that plaintiffs' expert, Dr. Charles V. Howard, is not a teratologist and is therefore unqualified to testify on that subject. Two, that Dr. Howard's scientific testing and results are inadmissible because his methodologies are not "generally accepted" among experts in the relevant scientific community.

We find no merit in the first argument because it is clear that teratologists frequently come from a variety of academic disciplines.8 Dr. Howard is a fetal

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toxico-pathologist with the Fetal and Infant Toxico-Pathology Department of the University of Liverpool. He has been involved in work which falls within the realm of teratology and was acknowledged by one of DuPont's experts as being qualified in this area.

The defendants' second argument is more persuasive. The scientific evidence presented in this case spans the fields of toxicology,9 medicine and pathology, and is primarily concerned with teratology, the specialized study of the causation of birth defects. The general causation question at issue addresses whether Benlate has the capacity to cause the birth defect microphthalmia in humans, and the specific causation inquiry relates to whether Benlate actually caused John Castillo's microphthalmia. The science involves three primary types of evidence that may contribute to an inference of causation: epidemiology (studies to observe the effect of exposure of a single factor upon the incidence of disease in human populations), in vivo testing (animal toxicology), and in vitro testing (analysis of effects of suspected substances on isolated cell systems).

Epidemiological studies are frequently described, in both scientific literature and case law, as the "best source" of information about human response to toxic substances and their potential teratogenic effects.10 Unfortunately, epidemiological evidence is often unavailable regarding substances that are not designed for human consumption (such as Benlate). Large population groups are necessary to ensure the strength of statistical associations in epidemiological studies and scientists uniformly consider it unethical to test potential toxic substances on humans.

In addition to (or in lieu of) epidemiological evidence, researchers rely upon animal studies to determine the toxicity of chemical substances. Many species are used as subjects, although mammals are preferred. While primates such as rhesus monkeys are favored due to their biological similarity with humans, the predominant species used in animal toxicity studies are white rats and mice.11 Animal studies, which are experimental, have several advantages over epidemiological studies. Researchers can control the environment, reduce the likelihood of biases affecting the results, and administer large doses of an agent over a short period of time. However, a causal inference from an animal study to a similar effect in humans is more tenuous than with epidemiology because of physiological variations between the species (such as size, life span, metabolism and the

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ability to accommodate exposure to toxic substances), and because of the uncertainties associated with extrapolation both from animals to humans andfrom high to low doses.12

In vitro studies are generally useful in identifying the potential target organ toxicity and mechanisms of toxic action.13 In vitro teratogenic testing involves the transplantation of fetal cells into a medium where they are subjected to agents to study the effect on the transplanted tissues. However, the mediating metabolic influence of the mother and the placenta are absent in these tests, which results in a layer of uncertainty with regard to extrapolation to humans.14

One of the first and most influential decisions concerning the scientific and evidentiary questions regarding toxic causation is In re "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223 (E.D.N.Y. 1985), affirmed on other grounds, 818 F.2d 187 (2d Cir. 1987). There, the trial judge entered summary judgment against several plaintiffs based on the conclusion that affidavits submitted by their experts failed to present credible evidence of causation. He found that the epidemiological studies conducted on the health effects of exposure to Agent Orange were the "only useful studies having a bearing on causation." Id. at 1231. The court found that the "many studies on animal exposure to Agent Orange . . . [were] not persuasive in this lawsuit" as:

"[L]aboratory animal studies * * * are generally viewed with more suspicion than epidemiological studies, because they require making the assumption that chemicals behave similarly in different species.". . . Dr. Silbergeld further notes that "[a]nimal studies are aimed at discovering a dose- response relationship, while epidemiological studies show an association between exposure and disease."

Id. at 1241 (quoting Hall & Silbergeld, Reappraising Epidemiology: A Response to Mr. Dore, 7 Harv. Envtl. L. Rev. 441, 442-43 (1983)) (citation omitted). The court noted that there was no evidence that plaintiffs were exposed to the far higher concentrations involved in the animal studies. Id. The judge considered the exclusion of animal study evidence to be particularly appropriate as a "false aura of scientific infallibility, coupled with low probative value, increases resistance to admitting evidence since it multiplies the hazards of misleading a jury." Id. at 1255-56.

Both before and since Agent Orange, many cases involving extensive epidemiological studies, which had shown over several years that there was no association between a chemical and a birth defect or disease, have held that contrary epidemiological

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studies are necessary to prove causation and that animal and in vitro studies are inadmissible to prove causation. See Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194 (5th Cir. 1996); Brock, 874 F.2d at 315 ("Assuredly, one day in the future, medical science may have a clearer understanding of the mechanics of tissue development in the fetus. However, that is not the case today, and speculation unconfirmed by epidemiologic proof cannot form the basis for causation in a court of law."); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 832 (D.C. Cir. 1988)("Bendectin . . . has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic. Uniquely to this case, the law now hasthe benefit of twenty years of scientific study, and the published results must be given their just due."); Lynch v. Merrell-National Labs., Div. of Richardson-Merrell, Inc., 830 F.2d 1190 (1st Cir. 1987); Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1451 (D.V.I. 1994)("Regardless of the particular articulation of the teratology community's methodology, positive human epidemiologic studies are always required to reach a conclusion as to whether a specific agent is teratogenic in humans."); Cadarian v. Merrell Dow Pharms., Inc., 745 F. Supp. 409, 412 (E.D. Mich. 1989)("in vivo and in vitro animal studies . . . are insufficient to prove causation in human beings in the absence of confirmatory epidemiological evidence."). Other factors that courts have considered in weighing scientific evidence in the absence of positive epidemiology are the failure of experts to publish or submit their studies for peer review,15 and the fact that tests were performed solely for the purpose of litigation.16

DuPont's primary argument concerns the methodology used by Dr. Howard in reaching his conclusion that Benlate is a human teratogen which caused John Castillo's microphthalmia. While DuPont appears to acknowledge that in vivo and in vitro tests are generally accepted methods for analyzing the toxicology of a chemical such as Benlate, it contends that Dr. Howard's direct extrapolation of data from the in vivo and in vitro testing to conclude that Benlate is a human teratogen is not generally accepted science.17 Castillo responds that when an expert's opinion is based upon generally accepted scientific principles and methodology, it is not necessary that the expert's opinion be generally accepted as well. See Berry, 709 So.2d at 567; Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1111 (5th Cir. 1991).

Although the trial court must analyze the science and not merely the qualifications, demeanor or conclusions of experts, the court need not weigh or choose between two legitimate but conflicting scientific views. The court instead must assure itself that the opinions are based on relevant scientific methods, processes, and data, and not

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upon an expert's mere speculation. . . . [I]t is important to emphasize that the weight to be given to stated scientific theories, and the resolution of legitimate but competing scientific views, are matters appropriately entrusted to the trier of fact.

Berry, 709 So.2d at 569 n.14 (quoting McDaniel v. CSX Transp., Inc., 955 S.W.2d 257, 265 (Tenn. 1997), cert. denied, 524 U.S. 915, 118 S.Ct. 2296 (1998)).

DuPont and Pine Island contend that plaintiffs have not identified any scientific or legal authority to validate Dr. Howard's assumption that a substance can be considered a human teratogen based solely on rat gavage studies, as positive results in animal and in vitro cellular tests are not accepted as proof of human developmental hazards.18 The judge in Wade-Greaux concluded as follows:

While in vitro and in vivo animal studies can be helpful in determining human teratogenicity either by providing information regarding possible biologic mechanisms or by showing a dose/response relationship, I conclude that in vivo and in vitro animal test data are not relied upon by experts in the field of teratology for extrapolating the results found directly to the human experience.

Wade-Greaux, 874 F. Supp. at 1483.

Plaintiff recognizes the general proposition that one cannot extrapolate directly from mammal and chick studies to the human condition but offers that if such studies are the best that exist, a jury nevertheless should be permitted to decide, from data not subject to extrapolation, what scientists admit they cannot prove to be biological

associations in humans. Any extrapolation that is based upon speculation or speculative data can produce only a speculative, and therefore inadmissible, opinion.

Id. at 1485; see also Schudel v. General Elec. Co., 120 F.3d 991, 997 (9th Cir. 1997)("Extrapolation was necessary to make the studies relevant, and there was no showing that the necessary extrapolation was scientifically acceptable."), cert. denied, 523 U.S. 1094, 118 S.Ct. 1560 (1998); Lust, 89 F.3d at 597 ("When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the district court should be wary that the method has not been faithfully applied. . . . [T]he district court can exclude the opinion if the expert fails to identify and defend the reasons that his conclusions are anomalous."); Christophersen, 939 F.2d at 1114 ("If the dosage of the harmful substance and the duration of exposure to it are the types of information upon which experts reasonably rely when forming opinions on the subject, then the district court was justified in excluding Dr. Miller's opinion that is based upon critically incomplete or grossly inaccurate dosage or duration data.").19

The plaintiffs counter that they are only required to prove causation by a preponderance of the evidence, and that courts should not preclude recovery on the basis of the failure to furnish unavailable epidemiological evidence. They argue that some courts have found that when epidemiologic evidence is lacking, thin, inconclusive or of questionable validity, it is unjustifiable to dismiss other toxicological

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evidence. See Ferebee v. Chevron Chem. Co., 736 F.2d 1529 (D.C. Cir. 1984). In Ferebee, the plaintiff alleged that he contracted a disease as a result of long-term skin exposure to dilute solutions of paraquat, a herbicide. Ferebee presented two expert pulmonologists who testified that paraquat poisoning was the cause of his illness and death. Chevron introduced its own experts who espoused a contrary view. The court concluded:

[A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant. That Ferebee'scase may have been the first of its exact type, or that his doctors may have been the first alert enough to recognize such a case, does not mean that the testimony of those doctors, who are concededly well qualified in their fields, should not have been admitted.

Id. at 1535-36.In Richardson, the D.C. Circuit clarified that

Ferebee stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and "stand[s] at the frontier of current medical and epidemiological inquiry." If experts are willing to testify to causation in such situations and their methodology is sound, the jury's verdict should not be disturbed.

Richardson, 857 F.2d at 832 (footnote omitted); see also Ambrosini v. Labarraque, 101 F.3d 129, 138 (D.C. Cir. 1996), cert. dismissed, 520 U.S. 1205, 117 S.Ct. 1572 (1997); Mendes-Silva v. United States, 980 F.2d 1482, 1487 (D.C. Cir. 1993); City of Greenville v. W.R. Grace & Co., 827 F.2d 975, 980 n.2 (4th Cir. 1987); Wells v. Ortho Pharm. Corp., 788 F.2d 741, 744-45 (11th Cir. 1986); Lakie v. SmithKline Beecham, 965 F. Supp. 49, 56 (D.D.C. 1997); Duran v. Cullinan, 677 N.E.2d 999, 1004 (Ill. App. Ct.), appeal denied, 684 N.E.2d 1335 (Ill. 1997).

We do not conclude that epidemiological studies are a mandatory prerequisite to establish a toxic substance's teratogenicity in human beings. We do, however, conclude that where, as here, plaintiffs wish to establish a substance's teratogenicity in human beings based on animal and in vitro studies, the methodology used in the studies, including the method of extrapolating from the achieved results, must be generally accepted in the relevant scientific community. In the present case, plaintiffs' experts conceded at the Frye hearing that the direct extrapolation method they used in their study was new and that they were unaware of any scientific study that has ever purported to determine a human teratogenic exposure level in this manner. Plaintiffs' experts further admitted at trial that no scientific, governmental, or academic publication had ever before relied on direct extrapolation from in-vitro test results to determine a teratogenic exposure level in a living being.20 This testimony was confirmed

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by the affidavits of defense experts Drs. Brent and Lamb.

In reaching our conclusion on this issue we are mindful of the caution which is necessary in this area. As the Supreme Court of Texas has said:

The argument is sometimes made that waiting until an association found in one study is confirmed by others will mean that early claimants will be denied a recovery. . . . A related argument is that history tells us that the scientific community has been slow at times to accept valid research and its results. While these observations are true, history also tells us that valid and reliable research and theories are generally accepted quickly within the scientific community when sufficient explanation is provided and empirical data are adequate. . . . Our legal system requires that claimants prove their cases by a preponderance of the evidence. In keeping with this sound proposition at the heart of our jurisprudence, the law should not be hasty to impose liability when scientifically reliable evidence is unavailable. As Judge Posner has said, "[l]aw lags science; it does not lead it."

Havner, 953 S.W.2d at 727-28.

Based on the record in this case we hold that plaintiffs' scientific evidence, and the conclusions it embraces, should have been excluded, as the methodology used to obtain them is not generally accepted in the relevant scientific community. In the absence of this evidence plaintiffs presented no proof of causation. Accordingly, DuPont and Pine Island's motions for directed verdict should have been granted.

For the reasons set forth above, we reverse the final judgments entered against DuPont and Pine Island and remand with directions to enter judgments for the defendants.

Notes:

1. We agree that this was error. We find that this evidence was vague and indefinite. Whatever relevance it may have had was greatly outweighed by its potential to unfairly prejudice the jury. See §§ 90.403, Fla. Stat. (1995). Additionally, since this case was tried, a report entitled, Geographical Variation in Anaphtholmia and Microphthalmia in England, 1988-94, prepared by the Environmental Epidemiology Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine was published in the British Medical Journal, volume 317, page 905, October 3, 1998. The report, commissioned by the British government, was unable to confirm such clustering. See also Jack Cuzick, Commentary: Clustering of Anaphthalmia and Microphthalmia Is Not Supported by Data, 317 Brit. Med. J. 910 (1998); E.C.M. Mariman, Clustering of Anaphthalmia and Microphthalmia: No Clustering Has Been Found - but a Link Seems to Exist with Population Density, 317 Brit. Med. J. 895 (1998).

2. We find no error in the trial court's admission of this exhibit. Plaintiffs sought to introduce a 2-hour "day-in-the-life video" which the judge limited to the 19-minute version presented at trial. The redaction allowed the jury to view the most relevant aspects of the tape while minimizing any potentially inflammatory effect.

3. Daniels elaborated and stated that this was "everybody['s]" practice. He testified that in June of 1989, Pine Island returned unused Potassium Nitrate, Bucktril, Agri-Dex, and Dual. There was no return of any unused Benlate.

4. There was also a considerable amount of evidence that tomato plants are not sprayed until the first bloom - four to six weeks after planting.

5. Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

6. Although the case against DuPont is resolved by our holding on the sufficiency issue discussed in section II above, because this defendant took the lead in the litigation of the Frye issue below, it will be referred to during our discussion of the scientific evidence.

7. The trial court did determine that the expert testimony would assist the jury and that the plaintiffs' experts were qualified to testify in this area. The court's statement concerning "probable cause" is confusing but appears to be nothing more than an unfortunate analogy. Contrary to DuPont's suggestion, we do not believe that the court misapplied that concept to these facts.

8. In Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1450, (D.V.I.), affirmed, 46 F.3d 1120 (3d Cir. 1994), the court noted preliminarily: "Persons who study teratology come from different medical or scientific disciplines, including pediatrics, obstetrics, embryology, epidemiology and genetics. . . . Nevertheless, physicians and scientists who study the causes of birth defects, regardless of their specific training and experience, comprise a single medical/scientific community and are known as teratologists."

9. "Toxicology is defined as 'the study of adverse effects of chemical agents on biological systems.' . . . One of the central tenets of toxicology is that 'the dose makes the poison' implying that all chemical agents are harmful--it is only a question of dose." Berry, 709 So.2d 552, 559 (Fla. 1st DCA 1998)(quoting Reference Manual on Scientific Evidence, 185 (Federal Judicial Center, 1994))(citation omitted).

10. Many of the "toxic tort" cases either require epidemiologic proof or reject in vitro and in vivo test results that conflict with epidemiologic data. However, these cases primarily concerned birth defects which arose following the

ingestion of the pharmaceutical Bendectin by pregnant women (see cases cited at p. 21), and a "wealth" of epidemiological data was available.

11. Rats, the least appropriate mammalian test species, are used in 90% of long-term animal bioessays due to pragmatic concerns such as availability, size, cost ($3.50-30 as compared to up to $10,000 for a pregnant primate), short life span and lack of a vomiting-reflex. See Jack L. Landau & W. Hugh O'Riordan, Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Torts Litigation, 25 Idaho L. Rev. 521, 532-49 (1988); Michael D. Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substance Litigation: The Legacy of Agent Orange and Bendectin Litigation, 86 Nw. U. L. Rev. 643, 654-57 (1992).

12. See Brock v. Merrell Dow Pharms., Inc., 874 F.2d 307, 313 (5th Cir. 1989)("This circuit has previously realized the very limited usefulness of animal studies when confronted with questions of toxicity. . . . The court noted several methodological flaws which rendered the rat study inconclusive; specifically, the court focused on the small number of rats used in the study, the high (sometimes near-lethal) doses given, and the difficulty of extrapolating those results to humans."); Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 729 (Tex. 1997), cert. denied, 523 U.S. 1119, 118 S.Ct. 1799 (1998).

A highly regarded text on scientific evidence cites an example:

Sometimes understanding the mechanism underlying the species difference can allow prediction of whether the effect will occur in humans. Thus, carbaryl, an insecticide commonly used, among other things, for gypsy moth control, produces fetal abnormalities in dogs but not in hamsters, mice, rats, and monkeys. Dogs lack the specific enzyme involved to metabolize carbaryl; the other species tested all have this enzyme, as do humans. On this basis, it has been reasoned that humans are not at risk for fetal malformations produce by carbaryl.

Reference Manual On Scientific Evidence 202 n.42 (Federal Judicial Center, 1994).

13. See Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, in Reference Manual on Scientific Evidence 181, 203 (Federal Judicial Center, 1994).

14. See Havner, 953 S.W.2d at 730.

15. See Brock, 874 F. 2d at 313 ("While we do not hold that [the failure to publish a study or conclusions for the purposes of peer review], in and of itself, renders his conclusions inadmissible, courts must nonetheless be especially skeptical of medical and other scientific evidence that has not been subjected to thorough peer review."); Lynch, 830 F. 2d at 1195; Havner, 953 S.W.2d at 726-27.

16. See Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 597 (9th Cir. 1996); Berry, 709 So.2d at 561 n.8 (quoting Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995))("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for the purpose of testifying."); Havner, 953 S.W.2d at 726.

We note that the tests conducted by Drs. Howard and van Veltzen in this case were commissioned and paid for by plaintiffs.

17. See Brock, 874 F.2d at 310 ("[C]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.").

18. "There are approximately 2,000 agents that have been shown to be teratogenic in some animal species, but only about 25-30 of those are considered to be human teratogens." Wade-Greaux, 874 F. Supp. at 1480.

19. DuPont's argument is analogous to recent analyses regarding the admissibility of DNA evidence. In the DNA context, the courts have emphasized that the Frye test must be applied, not only to the matching procedure, but also to the testing protocol used in the analysis. See Brim, 695 So.2d at 271 ("The fact that a match is found in the first step of the DNA testing process may be 'meaningless' without qualitative or quantitative estimates demonstrating the significance of the match."); Hayes, 660 So.2d at 263 (emphasizing the application of the Frye test to the testing procedures used in the analysis).

20. As concerns Drs. Howard and van Veltzen's reliance on the rat gavage studies performed by DuPont in order to secure federal certification for Benlate, we note that contrary to the negative conclusions drawn by Howard and van Veltzen from these in vivo studies, the Environmental Protection Agency, which regulates all pesticides distributed or sold in the United States, see 7 U.S.C. section 136a(a), nevertheless approved the product determining that it did not present a danger to pregnant women either through inhalational or dermal exposure.
