United States Court of Appeals,

Fifth Circuit.

No. 96-30209.

Walter Mixon ALLEN, Jr., et al., Plaintiffs,

Mattie Gayle Allen, Barry Lane Allen, Plaintiffs-Appellants,

v.

PENNSYLVANIA ENGINEERING CORP., et al., Defendants,

American Sterilizers Company, Defendant-Appellee.

Dec. 31, 1996.

Appeal from the United States District Court for the Middle District of Louisiana.

Before WISDOM, JONES and WIENER, Circuit Judges.

EDITH H. JONES, Circuit Judge:

Walter Allen died of a brain cancer known as glioblastoma multiforme after having been a maintenance worker at Baton Rouge General Hospital for over 20 years. During that time, he occasionally replaced cylinders containing ethylene oxide ("EtO"), a chemical that has been widely used in this country to sterilize heat and moisture sensitive medical and surgical devices. Allen's widow and son (the "Allens") filed suit against numerous defendants, including American Sterilizer Company, the manufacturer of EtO. On motions for judgment as a matter of law, the district court held both that two of the Allens' three expert witnesses were not qualified to render opinions that exposure to EtO caused Allen's fatal cancer and that the opinions of all three experts were inadmissible in federal court for lack of sufficient scientific grounding.

We affirm. Where, as here, no epidemiological study has found a statistically significant link between EtO exposure and human brain cancer; the results of animal studies are inconclusive at best; and there was no evidence of the level of Allen's occupational exposure to EtO, the expert testimony does not exhibit the level of reliability necessary to comport with Federal Rules of Evidence 702 and

703, the Supreme Court's *Daubert* decision,[1] and this court's authorities. Moreover, under the circumstances of this case, the fact that EtO has been classified as a carcinogen by agencies responsible for public health regulations is not probative of the question whether Allen's brain cancer was caused by EtO exposure.

This court reviews the judgment as a matter of law on two levels. First we must evaluate the trial court's evidentiary ruling under the manifest error standard, and then, with the record defined, we review *de novo* the order granting judgment as a matter of law. *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1109 (5th Cir.1991) (en banc), *cert. denied*, 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992). If the trial court has excluded evidence essential to maintain a cause of action, the propriety of summary judgment depends, as here, entirely on the evidentiary ruling. *Id.*

In *Daubert,* the Supreme Court meticulously explained the criteria for admitting expert scientific testimony pursuant to Federal Rule of Evidence 702:

> Proposed testimony must be supported by appropriate validation—*i.e.*, "good grounds," based on what is known ... [T]he requirement that an expert's testimony pertained to "scientific knowledge" establishes a standard of evidentiary reliability. (footnote omitted) *Daubert,* 509 U.S. at 590, 113 S.Ct. at 2795.

Further, the Court held that a trial court has a duty to screen expert testimony for both its relevance and reliability. *Id.* An expert's opinion must have a "reliable basis in the knowledge and experience of his discipline." *Id.* at 592, 113 S.Ct. at 2796. Specifically, the court must determine that the reasoning and methodology underlying the testimony is scientifically valid and that the reasoning and methodology can properly be applied to the facts in issue. *Id.* at 592-93, 113 S.Ct. at 2796.

The Court added that under Rule 703, an expert must base his opinion on facts and data of a type reasonably relied on by experts in the field. *Id.* at 595, 113 S.Ct. at 2797-98.

Although the trial court wrote a cursory opinion on the admissibility of Allen's expert evidence, the parties developed a considerable record, and the court heard oral argument before rendering a decision that the experts' evidence, testimony and opinions did not satisfy the standards

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[1] *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

set forth in *Daubert* or relevant authorities of this Court. Those standards may readily be applied to the evidence before us.

Appellants produced three expert witnesses, Dr. Page, Dr. Kelsey and now—Dr. LaMontagne,[2] whose opinions may be summarized as follows. First, human epidemiological evidence "suggests" an association between EtO exposure and an increased risk of brain cancer. Second, scientific studies conducted on rats have shown EtO capable of causing tumors in certain of those animals. Third, EtO is known as a mutagen and genotoxin. Consequently, these witnesses theorize, EtO reaches brain tissue, alkylates DNA and "clearly" causes animal brain tumors. The experts employ a "weight of the evidence" analysis used by organizations such as the World Health Organization's International Agency for Research on Cancer (IARC), OSHA, and the EPA to rate the carcinogenicity of various substances in humans. We will examine each of the types of evidence on which appellants' experts rely: epidemiological studies, animal studies, cell biology, and health organization conclusions. We must also consider the "weight of the evidence" methodology.

First, although occupational exposure to EtO has been studied for many years, not a single scientific study has revealed a link between human brain cancer and EtO exposure. In fact, numerous reputable epidemiological studies covering in total thousands of workers indicate there is not a correlation between EtO exposure and cancer of the human brain. *See, e.g.*, L. Stayner, *et al.*, *Exposure-Response Analysis of Cancer Mortality in a Cohort of Workers Exposed to Ethylene Oxide*, 138 Am.J.Epid. 787, 797 (1993) (concluding that the studies "findings do not provide evidence for a positive association between exposure to [EtO] and cancers of the ... brain...."). The

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[2]Dr. Anthony LaMontagne and Dr. Norbert Page each hold master's degrees in toxicology. At the time of his deposition for trial, Dr. LaMontagne, who had not yet received his doctorate degree, had written a doctoral dissertation concerning the medical surveillance of hospital employees exposed to EtO in Massachusetts. Dr. LaMontagne now has an Sc.D. in Occupational and Environmental Health, and is a research fellow at the Harvard School of Public Health, with a research emphasis on the implementation of OSHA requirements for exposure monitoring and worker training as preventive measures for EtO exposure in Massachusetts hospitals. Dr. Page is a doctor of veterinary medicine, who provides expert consultation on chemical and radiation toxicology. Dr. Karl Timothy Kelsey is a medical doctor and Assistant Professor of Occupational Medicine at the Harvard School of Public Health. He has received several grants to study the effect of EtO on humans and primates.

National Institute for Occupational Safety and Health ("NIOSH") conducted this study. This analysis follows the prior published epidemiological study by the same NIOSH researchers. *See* K. Steenland, *et al., Mortality Among Workers Exposed to Ethylene Oxide,* 324 N.E.J.Med. 1402 (1991). Evidence has been found that suggests a connection between EtO exposure and human lymphatic and hematopoietic cancers, but this is not probative on the causation of brain cancer.[3] This court has said that:

> Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies. *Brock v. Merrill-Dow Pharmaceuticals, Inc.,* 874 F.2d 307, 311 (5th Cir.1989), *modified by* 884 F.2d 166 (5th Cir.1989), *cert. denied,* 494 U.S. 1046 [110 S.Ct. 1511, 108 L.Ed.2d 646] (1990).

While appellants' experts acknowledge the lack of statistically significant epidemiological evidence, they rely on certain studies as "suggestive" of a link between EtO exposure and brain cancer. "Suggestiveness" is not by the experts' own admission statistical significance, nor did the appellants' experts show why and how mere "suggestiveness" scientifically supports a causal connection; this basis for their scientific opinion must be rejected.[4]

Second, the experts rely on two studies that found brain tumors in F-344 rats exposed to inhaled EtO, and on other animal studies that have found EtO-associated increases in the rodents' various solid and hematopoietic cancers. In *Brock,* this court noted "the very limited usefulness of animal studies when confronted with questions of toxicity." *Brock,* 874 F.2d at 313. *Brock* goes on to outline a number of reasons why studies of the effects of chemicals on animals must be carefully

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[3]*See, e.g., Lust v. Merrell Dow Pharmaceuticals,* 89 F.3d 594, 597-98 (9th Cir.1996) (holding that an expert's reasoning, which concluded from the fact that the drug in question caused some types of birth defects that it also caused hemifacial microsomia, was not scientific). The *Lust* court noted that the expert's testimony "was influenced by litigation-driven by financial incentive" and that the expert's premise was not recognized by even a "relevant minority." *Id.*

[4]Courts should particularly pay close attention when expert witnesses depart from generally accepted scientific methodologies. As the Seventh Circuit noted in *Braun v. Lorillard Inc.,* 84 F.3d 230 (7th Cir.1996), *cert. denied,* No. 96-377, 1996 WL 526463 (U.S. Nov. 18, 1996), "A judge or jury is not equipped to evaluate scientific innovations. If, therefore, an expert proposes to depart from the generally accepted methodology of his field and embark upon a sea of scientific uncertainty, the court may appropriately insist that he ground his departure in demonstrable and scrupulous adherence to the scientist's creed of meticulous and objective inquiry." *Id.* at 235.

qualified in order to have explanatory potential for human beings. So it is here. Although in these particular studies, F-344 rats contracted brain cancer after being exposed to EtO, Allen's experts concede that the same effect did not occur in mice studies. As an expert for appellee concludes:

> Thus, the lack of capacity for the F-344 rat to predict how even the mouse model responds necessarily undercuts confidence that the rat will predict accurately how other species including humans will respond [to EtO exposure].

Reliance on these animal studies furnishes at best speculative support for appellants' causation theory.[5]

Third, the cell biology data show only that EtO has mutagenic and genotoxic capabilities in living organisms, not that it necessarily causes brain cancer in humans or in Allen's particular case. That EtO may have these effects on living cells or genes is the beginning, not the end of the scientific inquiry and proves nothing about causation without other scientific evidence.

On examination, none of the scientific data on which appellants' experts rely furnishes a scientifically valid basis for the conclusion they would draw. The paucity of epidemiological evidence, the unreliability of animal studies, and the inconclusiveness of cell biology combine to undercut the expert testimony.

We are also unpersuaded that the "weight of the evidence" methodology these experts use is scientifically acceptable for demonstrating a medical link between Allen's EtO exposure and brain cancer. Regulatory and advisory bodies such as IARC, OSHA and EPA utilize a "weight of the evidence" method to assess the carcinogenicity of various substances in human beings and suggest

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[5]In support of the use of animal studies to establish medical causation, the Allens have cited *In re Paoli R.R. Yard PCB Litigation,* 35 F.3d 717 (3d Cir.1994), *cert. denied sub nom. General Elec. Co. v. Ingram,* --- U.S. ----, 115 S.Ct. 1253, 131 L.Ed.2d 134 (1995), in which the Third Circuit held that the animal studies relied on by the plaintiffs in that case passed *Daubert* muster. *Id.* at 781. However, the *Paoli* court recognized that other cases have held animal studies inadmissible, and distinguished *Paoli* as a case in which the EPA had ruled that the substance in question was a probable human carcinogen, there was "reason to think that [these] animal studies are particularly valuable because animals react similarly to humans with respect to the chemical in question", and the epidemiological data was inconclusive, with some of it supporting a finding of causation. *Id.* at 780-81. In the instant case, in contrast, we note that the animal studies relied on by the plaintiffs are unreliable, and the epidemiological evidence clearly does not support a finding of causation. In any case, *Paoli* is not binding on this court and we do not adopt its reasoning.

or make prophylactic rules governing human exposure. This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is, reasonably, lower than that appropriate in tort law, which "traditionally makes[s] more particularized inquiries into cause and effect" and requires a plaintiff to prove "that it is more likely than not that another individual has caused him or her harm." *Wright v. Willamette Industries, Inc.*, 91 F.3d 1105, 1107 (8th Cir.1996). In addition, in this case, the public health agencies acted at least partly on the basis of epidemiological studies that showed a relationship between EtO exposure and other kinds of human cancer, so their use of a "weight of the evidence" methodology was grounded in stronger probative evidence than appellants' experts have adduced to show a link between EtO annclusion at best weakly supported, if not contradicted, by the evidence on which they rely, but they all declined to say that they would subject their findings to the test of peer review for publication. *Daubert* notes that this is "a component of "good science' in part because it increases the likelihood that substantive laws and methodology will be detected." *Daubert*, 509 U.S. at 593, 113 S.Ct. at 2797 (1993). Dr. LaMontagne, in fact, inadvertently described exactly the problem this court faced in evaluating his and appellants' other expert testimony:

> This is not a scientific study. This is a legal opinion. [Dr. LaMontagne Deposition at 187, lines 14-15.]

Pace Dr. LaMontagne, the goal of *Daubert* and this court's previous cases has been to bring more rigorous scientific study into the expression of legal opinions offered in court by scientific and medical professionals. In the absence of scientifically valid reasoning, methodology and evidence supporting these experts' opinions, the district court properly excluded them.

An additional ground for excluding the opinions lies in Federal Rule of Evidence 703, which requires that the facts on which the expert relies must be reasonably relied on by other experts in the field. In this case, there is no direct evidence of the level of Allen's exposure to EtO. The Kelsey/LaMontagne opinion relies principally on the affidavit of a coworker and on extrapolations concerning EtO handling at the hospital where Allen worked based on conditions in other hospitals in the 1970's. The experts actually knew more about Allen's exposure to EtO through his smoking

a pack of cigarettes a day than they did about his occupational exposure to the chemical. Nevertheless, Dr. Kelsey and Dr. LaMontagne discounted the effect of tobacco, while speculating that the workplace exposure was the cause of his brain cancer.[6] Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case. *See Wright,* 91 F.3d at 1107. Not only was the scientific knowledge absent, but the experts' background information concerning Allen's exposure to EtO is so sadly lacking as to be mere guesswork. The experts did not rely on data concerning Allen's exposure that suffices to sustain their opinions under R. 703. *See Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1114-1115 (5th Cir.1991) (en banc), *cert. denied*, 503 U.S. 912, 112 S.Ct. 1280, 117 L.Ed.2d 506 (1992) (holding that the district court did not abuse its discretion in excluding an expert's opinion that was based on insufficient data regarding the dosage of a harmful substance and the duration of exposure to that substance); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 423 (5th Cir.1987) (concluding that evidence from animal studies is insufficient based in part on the lack of evidence that the plaintiff was exposed to comparable amounts). *See also Wright,* 91 F.3d at 1107-08 (holding expert opinions inadmissible in the absence of evidence of exposure to toxic substance).

The other issue on appeal was whether the district court erred in finding that Dr. LaMontagne (who at the time of his expert deposition had not yet obtained his Sc.D.) and Dr. Norbert Page (D.V.M.) were not qualified to testify as experts on the issue of medical causation in this case. We need not decide this issue, as the testimony of all three experts is in any event inadmissible.

CONCLUSION

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[6]The Eighth Circuit was faced with a similar issue. In *Sorensen v. Shaklee Corp.*, 31 F.3d 638 (8th Cir.1994), the district court in a suit alleging that EtO exposure had caused mental retardation in the plaintiff had criticized an expert witness for, among other things, failing to establish that "no other agent containing ETO, such as ... cigarette smoking, could be a cause." *Id.* at 649. The district court went on to find that the expert's method was therefore "subject to great potential for error." *Id.* The Eighth Circuit expressly approved the district court's observations and concluded that it had properly held the expert testimony inadmissible. *Id.* at 650.

For the foregoing reasons, the judgment of the district court is AFFIRMED.