

report and at the Daubert hearing. The defendants, of course, will be heard before the Court would grant any such request.

I. Background

The plaintiff, Elizabeth Karen Mause, claims to have used the cleaning product, Maximum Strength X-14 Instant Mildew Stain Remover ("X-14") while cleaning her bathroom on the evening of July 19, 1999. She alleges that after using the product as instructed, she suffered severe and permanent damage resulting from her exposure to the X-14. The defendants deny all liability and deny that the X-14 caused the plaintiffs any damages.

II. Discussion

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. The Rule states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of this case.

Fed. R. Evid. 702. The Third Circuit has held that there are three factors which courts should weigh in determining the admissibility of expert testimony. Those three factors are the qualifications of the expert, reliability, and fit. Elcock v.

Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000).

First, the court must assess the proposed expert's qualifications. An expert witness must have specialized knowledge, beyond that of an average layperson. See Elcock, 233 F.3d at 741. As Rule 702 makes clear, formal education or training is not required; the basis of the witness' specialized knowledge can be practical experience. See Fed. R. Evid. 702; In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 741 (3d Cir. 1994) ("Paoli II").

Second, the court must determine the reliability of the expert's testimony. See Elcock, 233 F.3d at 741. The expert must have "good grounds" for his or her testimony. Daubert v. Merrell Dow Pharm., 509 U.S. 579, 590 (1993). To be considered reliable, an expert's opinion must be based on "reliable principles and methods," as opposed to "subjective belief or unsupported speculation." Fed. R. Evid. 702; Daubert, 509 U.S. at 590.

In determining reliability, the Third Circuit has listed eight factors to be considered by the courts, along with any other relevant factors. Those eight factors are:

- (1) whether a method consists of a testable hypothesis;
- (2) whether the method has been subject to peer review;
- (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness

testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Paoli II, 35 F.3d at 742.

The final requirement of Rule 702 is "fit," that is, whether the expert's testimony would be of assistance to the trier of fact. See Elcock, 233 F.3d at 741. Courts must determine the fit "'between the scientific research or test result to be presented and particular disputed factual issues in the case.'" Paoli II, 35 F.3d at 743 (quoting United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985)).

A. Testimony of Dr. Paul Goldstein

The Court will first address the question of whether Dr. Goldstein may offer causation testimony. In his report, Dr. Goldstein concluded that the plaintiff's injuries were directly caused by her exposure to the X-14. The Court finds that Dr. Goldstein's opinion is unreliable.

Dr. Goldstein, a professor of genetics who has taught toxicology courses, did not discuss his methodology in his report or deposition. In coming to his conclusion that the X-14 caused the plaintiff's injuries, he reveals only that he relied upon his training, education, experience, and materials provided by plaintiffs' counsel, including medical reports about the plaintiff and scientific literature. In the opinion section of his report, he only refers to the plaintiff's medical history and

the reports prepared by the defendants regarding the X-14. He cites to no specific articles, textbooks, or studies to support his conclusions, nor does he set forth a scientific methodology.

During the Daubert hearing held on September 18, 2003, Dr. Goldstein introduced an excerpt from a textbook that described the Bradford Hill criteria for determining causation. He said that he used the criteria in his report. Sept. 18, 2003 Hr'g Tr., at 47. He did not refer to those criteria in his report or deposition, however, even though he was repeatedly asked to provide his methodology and any supporting textbooks. Dep. Tr., at 62-66. Nor did the defendants have an opportunity to prepare a rebuttal to the criteria first introduced in the Daubert hearing. It appears to the Court that the reference to the Bradford Hill criteria is an after the fact attempt to buttress an opinion that was not formed as a result of any scientific methodology.

In Dr. Goldstein's four page report, he provides only the alleged facts of the case and his opinions. He provides no explanation of how each of his assumptions about the facts support his causation opinion. He provides no references to textbooks or articles that support his causation opinions. With no basis nor methodology for his opinions, his conclusion is no more than a "subjective belief or unsupported speculation." See Daubert, 509 U.S. at 590.

The defendants also raise serious issues concerning the fit between Dr. Goldstein's opinion and the factual issues of the case. Dr. Goldstein was unable to explain several facts. He could not explain why there was an absence of irritation in the plaintiff's nose or mouth. Nor could he offer a reason why she did not believe she swallowed, inhaled, or otherwise ingested the X-14, or why she did not taste the product while using it. He gave no explanation of how the X-14 got through the mask and into the plaintiff's lungs. His only attempt at an explanation of any of these points was to say that the plaintiff was wrong in her account. Sept. 18, 2003 Hr'g Tr., at 75-77. These problems with fit, coupled with the lack of discernible methodology, lead the Court to find that Dr. Goldstein's causation opinion is unreliable under Daubert.

B. Testimony of Dr. George Bedon

The Court will next address the question of whether Dr. Bedon may offer causation testimony and testify in support of the plaintiffs' claims of a defective or unreasonably dangerous product and whether he may offer testimony in support of the plaintiffs' claims of permanent damage. Dr. Bedon is qualified in pulmonary medicine and as the plaintiff's treating physician. His opinion is reliable and has sufficient fit.

Dr. Bedon, a doctor practicing pulmonary medicine for over thirty years, gives both causation and diagnosis opinions. The Court must analyze the reliability of the opinions separately. Medical physicians often use differential diagnosis in order to determine the accurate diagnosis for a patient. This method involves performing physical examinations, tests, and reviewing the medical history in order to rule out other potential diagnoses and finding the appropriate diagnosis. See Kannankeril v. Termanix International, Inc., 128 F.3d 802, 807 (3d Cir. 1997). Causation, at least as used in the legal field, refers to the outside factors which produce the diagnosed problem and symptoms. See Holbrook v. Lykes Bros. S.S. Co., Inc., 80 F.3d 777, 781-83 (3d Cir. 1996).

Dr. Bedon used differential diagnosis to come to both of his conclusions regarding the plaintiff. He ordered tests, examined the plaintiff, took her medical history, and referred her to other doctors. Dr. Bedon examined the plaintiff's medical history and the events leading up to her hospitalization. He looked at chest x-rays, and he listened to her chest and heard a lot of wheezing. A test revealed her oxygen was low. Dep. Tr., at 48-50. The plaintiff was admitted to the Intensive Care Unit of the Greater Baltimore Medical Center and hospitalized for ten days. She was prescribed several medications and underwent continuing pulmonary functioning testing.

Although causation is distinct from diagnosis, Dr. Bedon's methods were reliable for both. The defendants argued at the Daubert hearing that Dr. Bedon's methodology in diagnosing the problem does not relate to causation at all. The defense counsel hypothesized that treatment of a medical problem like a burn might rely on the cause of the burn, but that the diagnosis in this case does not rely on the cause. A burn caused by exposure to sulfuric acid, counsel conjectured, would be treated differently than a burn caused by an open flame. Oct. 1, 2003 Hr'g Tr., at 130-31. The illustration offered by defense counsel is not unlike what Dr. Bedon did in this case. For example, he referred the plaintiff to an allergist. He did so in order to rule out any diagnosis of allergies and to rule out an environmental allergen as the cause. Oct. 1, 2003 Hr'g Tr., at 44-46. Dr. Bedon also looked at the plaintiff's chest x-rays in order to rule out pneumonia and emphysema, each having different causes. See Dep. Tr., at 50. In this case, the methodologies to determine cause and diagnosis are the same, and Dr. Bedon's opinion is reliable.

C. Testimony of Dr. Robert Cunitz

Finally, the Court will address the question of whether Dr. Cunitz's testimony as a warnings expert should be excluded. Dr. Cunitz is a human factors psychologist. He makes three main

conclusions in his report to which the defendants object. First, he concluded that the X-14 should have contained "bleach" in its label. Second, the label should have recommended the use of a respirator when using the X-14. Third, the label should have included risks such as possible coma, pulmonary edema, and fatality. Dr. Cunitz also concludes that these three problems in the X-14 label constitute a mislabeling and violation of the Federal Hazardous Substances Act ("FHSA"). 15 U.S.C. § 1261-1278.

Dr. Cunitz's report has sections purporting to explain his basis, the methodology of human factors, and assumptions he made in coming to his conclusions. He listed his basis for his opinion as including his education, training and experience, as well as literature in the field of warnings. Dr. Cunitz admitted in his deposition that he did not specifically read or rely on any of the articles he had listed in coming to his opinion in this case. Dep. Tr., at 51. He reviewed documents providing him with the alleged facts surrounding the plaintiffs' claim. He then cited to Material Safety Data Sheets ("MSDS") of other products containing sodium hypochlorite.

Dr. Cunitz made three assumptions in coming to his conclusions. He assumed that the plaintiff's injuries were caused by her exposure to the X-14. Second, he assumed that the defendant knew or should have known about the chance of serious

injury. Finally, he assumed that a proper respirator or avoiding the product entirely would have prevented the plaintiff's injuries.

There are several problems with Dr. Cunitz's opinion which leads the Court to find his testimony to be unreliable. Dr. Cunitz does not demonstrate that he utilized any reliable methodology in coming to his conclusions. He generally explained the field of human factors in his report, but he did not explain how that methodology was used in this case or leads to the conclusions he reached in this case.

Dr. Cunitz concluded that the label of the X-14 was insufficient, because it violated the FHSA and because the plaintiff testified that she would not have used the X-14 had it been labeled as bleach. As to the first basis for his opinion, he provides no account of why he, as a human factors psychologist, is specialized to give this opinion. See Milanese v. Rust-Oleum Corp., 244 F.3d 104, 111 (2d Cir. 2001) (approving the trial court's exclusion of Dr. Cunitz's testimony based upon his lack of qualifications in offering an opinion if a product was misbranded under the FHSA). It is for the Court, and not an expert, to decide whether the law is violated.

As to the second basis for his opinion, Dr. Cunitz did not survey any other consumers or otherwise test this assertion at all. Dep. Tr., at 125-26. Other than looking at the

plaintiff's deposition transcript, there is no basis for his opinion.

Another reliability issue centers on Dr. Cunitz's reliance on other products' MSDSs. His report lists these MSDSs as a basis for his conclusions. However, Dr. Cunitz admitted in his deposition that MSDSs are used more in workplace settings than for home use. Id. at 54. He also admitted that he surveyed only the MSDSs of certain products and not those products' labels. Id. at 162. He is not aware of any similar products that reproduce the MSDS on its product label. Id. at 163. Dr. Cunitz offers no evidence that the comparison of other products' MSDSs to the X-14's label is a reliable methodology used in his field. His conclusions, being based on unreliable methods, must be excluded under Daubert. See, e.g., Allen v. IBM, 1997 U.S. Dist. LEXIS 8016, at *133 (D. Del. 1997), aff'd, 1999 U.S. App. LEXIS 3286 (3d Cir. 1999) (excluding Dr. Cunitz's testimony because it had no basis in fact); Tyler v. Sterling Drug, 19 F. Supp. 2d 1239, 1244 (N.D. Okla. 1998) (excluding Dr. Cunitz's testimony because he relied on the general theory of informed consent rather than "qualified scientific methods" or "reliable data"); Walker v. Yellow Freight Sys., 1999 U.S. Dist. LEXIS 16128, at *24 (E.D. La. 1999) (excluding Dr. Cunitz's testimony because he based his opinion on deposition testimony and general theories rather than appropriate industry standards).

In concluding that the X-14 should have suggested the use of a respirator, Dr. Cunitz does not provide any reliable methodology. He makes his conclusion based upon what other products' MSDSs say, but he did not survey the labels in order to determine if other products suggest using a respirator. When Dr. Cunitz was asked specifically in his deposition how he applied a human factors analysis in concluding that the label should have suggested respirator use, he responded that he believed that, if warned, almost every person using the product would use a respirator because they would know of the risks. Dep. Tr., at 134. The Court sees no analysis or methodology here. Instead, Dr. Cunitz offers only his subjective belief.

For similar reasons, his conclusion that the label should have included such risks as death or coma is also unreliable. He again relied upon MSDSs from other products without examining other labels. His report states no clear methodology in making his conclusion. Also, Dr. Cunitz admitted that the plaintiff did not suffer from the symptoms which he claims the defendants were at fault for excluding. Id. at 157, 163.

Dr. Cunitz's conclusions that the defendants did not appropriately label the product as a bleach, advise the use of a respirator, or warn of other possible risks are unreliable and must be excluded under Daubert. With no methodology offered in

Dr. Cunitz's expert report, the Court is left only with his unsubstantiated opinions. Indeed, in his deposition when asked what an adequate label would say, he had no recommendations. Id. at 168-69, 176. See Allen, 1997 U.S. Dist. LEXIS at *130. In fact, Dr. Cunitz stated that to write a warning label for the X-14, he would have to meet with physicians and industrial hygienists and others with knowledge about the hazards and techniques to avoid those hazards, review MSDSs, and apply his field's expertise. Dep. Tr., at 176. He did none of that, and, yet, the plaintiffs ask that he be allowed to testify that the label was inadequate. The Court sees no scientific basis for such testimony.

Another problem in Dr. Cunitz's report focuses on the assumptions upon which he relies in coming to his conclusions. There is an issue with his assumption that the defendant knew or should have known about the chance of serious injury when sodium hypochlorite was used as the X-14 label directed. Dr. Cunitz relies upon no evidence that suggests the defendants knew that the X-14, when used according to the instructions provided, could cause such severe and permanent injuries as the plaintiffs allege.

Several courts have ruled that a warnings expert needs to provide some evidence, rather than merely an assumption, of a causal link in order to substantiate their opinions. In the

Allen case, the District Court of New Jersey found that there was an insufficient link between the evidence of injuries occurring after use of the defendants' keyboards and the assumptions made by Dr. Cunitz. The court excluded his testimony because he could not address any design defect or causal association between the keyboard and injury. Allen, 1997 U.S. Dist. LEXIS at *130, *134. See also Schneck v. IBM, 1996 U.S. Dist. LEXIS 17486, at *75 (D.N.J. 1996) (excluding a warnings expert for similar reasons). In a District of Maryland case, the court excluded a warnings expert because he assumed, without providing any evidence, that a powdered bleach product caused the plaintiff's injuries. Higgins v. Diversey Corp., 998 F. Supp. 598, 604 (D. Md. 1997).

There is no indication that Dr. Cunitz applied any expertise in coming to his conclusions in this case. Because his opinion has no reliable methodology and is based on an unsupported assumption, the Court excludes the testimony of Dr. Cunitz.

This memorandum accompanies the Order dated October 15, 2003.