Independent Women's LAW CENTER

— LEGAL POLICY FOCUS —

She Blinded Me With Science: Unreliable Expert Testimony in American Courtrooms

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EXECUTIVE SUMMARY

- In courtrooms across the nation, predatory trial lawyers use shaky science to manipulate juries into awarding millions (sometimes billions) of dollars to sympathetic plaintiffs.
- But when juries hold companies liable for harm that the companies did not cause, they undermine the truth-seeking function of the American judicial system.
- Verdicts that are not based on careful, fact-based determinations of causation impose unfair economic burdens on the manufacturers of safe and beneficial products.
- Ultimately, it is the consumers that pay the price in the form of higher prices and reduced access to useful products and potentially life-saving medications and vaccines.
- Trial judges must take seriously their role as evidentiary gatekeepers to ensure that unreliable expert testimony does not unduly prejudice outcomes.

MORE INFORMATION

What You Should Know

Expert testimony is a critical component of proof in any product liability or toxic tort case. But what if the expert's opinions are based on spurious "science" or unrepresentative studies? What if the studies offered are scientifically valid but not relevant to the plaintiff's circumstances?

How are juries, composed of lay people from various walks of life, supposed to weigh such testimony?

In the American legal system, trial judges are responsible for determining the admissibility of evidence on the basis of whether it is reliable and helpful to the jury. But when judges admit unreliable expert testimony, they confuse the jurors, making it difficult for them to ascertain the truth. In cases that pit sickly plaintiffs against large corporations, scientifically unsound testimony can mislead well-intentioned juries into compensating David by punishing Goliath—even when Goliath is not at fault.

Unfortunately, when juries get it wrong, consumers pay the price. Two recent examples illustrate the point:

- **RoundUp Weed Killer—**Scientific regulatory agencies in the United States, Canada, Japan, Australia, and the European Union, as well as the Joint Meeting on Pesticide Residues of the United Nations, have concluded that glyphosate, the active ingredient in RoundUp, is likely not a human carcinogen. Nevertheless, attorneys have brought thousands of lawsuits in state and federal courts, seeking damages from Bayer, the maker of RoundUp, for plaintiffs' non-Hodgkin's lymphoma. And three juries have found Bayer liable to the tune of $289 million, $80 million and $2 billion, respectively.
- **Johnson's Baby Powder**—Multiple studies, including **a recent study of over 250,000 women published in JAMA**, have found no statistically significant increase in the risk of ovarian cancer in women who use talcum powder. The FDA has consistently found insufficient evidence to mandate an ovarian-cancer warning label for such powder. And the CDC does not list talcum powder use as a risk factor for ovarian cancer. Although at least 8 different juries in 2019 rejected claims that Johnson's Baby Powder caused plaintiffs' ovarian cancer, others have found Johnson & Johnson liable, awarding billions in damages. Verdicts like these raise questions about the ability of juries to evaluate scientific data in context and to determine causation properly.

Why You Should Care

Now, more than ever, it is important to understand the relevance of scientific data. Advocates and partisans often try to bolster their positions by telling us to "believe science." But not all scientific studies are reliable. And, sometimes, even reliable studies are not relevant to a particular case or problem. Unfortunately, lay people often find it easier to accept expert opinion than to examine the data critically. This is particularly dangerous when expert testimony is used to support claims for monetary damages in court. And it is equally dangerous when the media report on outlier jury verdicts in a way that scares consumers.

Forcing a person or a company to pay for harm it did not cause is unjust and undermines the rule of law. The purpose of the American tort system is to require people or companies to compensate those whom they have injured. It is not the job of the tort system to redistribute wealth from unpopular companies to sympathetic people whose injuries the companies did not cause. When juries hold defendants liable without proof of causation, they impose unfair economic burdens on companies whose products are safe. This also undermines the truth-seeking function of American courts and the legitimacy of the judicial system.

Verdicts based on unreliable science harm consumers. When juries force the makers of safe and legal products to pay plaintiffs large sums of money, they create unnecessary consumer fear and unwarranted confusion. Consumers may hesitate to purchase life-enhancing products. Or they may worry needlessly about previous product use. Holding companies liable for damage they did not cause also raises the cost, and sometimes the availability, of safe, desirable, and previously affordable products. Longer term, concern about baseless liability judgments stifles innovation and the development of new, and potentially life-saving, products and medicines. For example:

- In May 2020, Johnson & Johnson announced that, because of recent litigation blaming its talc-based baby powder for ovarian cancer, it is **discontinuing** North American sales of the product.
- In 2002, lawsuits forced SmithKline Beecham to **pull from the market** a vaccine against Lyme disease, an often severely debilitating illness, in spite of overwhelming evidence that the vaccine was **safe and effective**. Pharmaceutical companies have remained reluctant to develop vaccines for the disease ever since. As a result, Americans today can get their dogs vaccinated for Lyme disease, but not themselves.

Legal Causation And Expert Testimony

In a typical product liability case, plaintiffs seeking to recover damages must prove, by a preponderance of the evidence, that the defendant is at fault for their injuries. This means that the injured party must prove that the defendant's product is *capable* of causing the type of injury that he or she sustained (***general causation***) and that the defendant's product, more likely than not, caused the plaintiff's particular injury (***specific causation***).[1]

In order to demonstrate general and specific causation, plaintiffs rely on expert witnesses who offer opinions based on scientific evidence. Defendants offer their own experts to dispute plaintiff's theories of causation.

> ***"Now, more than ever, it is important to understand the relevance of scientific data."***

The parties to litigation select their expert witnesses after extensive research to identify experts who will support their legal theory of the case. This is problematic for a variety of reasons, not the least of which is potential bias.[2] Our adversarial system compounds this problem by creating the impression that the weight of the evidence on each side is, more or less, equal. In fact, in most cases, the overwhelming majority of scientific opinion supports one side. Yet, juries will perceive the opinions of outliers as being on equal footing with the opinions of experts who are within the scientific mainstream.

Daubert *And Federal Rule Of Evidence 702*

Prior to 1993, under what was known as the *Frye*[3] standard, most courts allowed expert witnesses to offer novel scientific theories, so long as the experts based their conclusions on studies generally accepted in the relevant scientific community.[4] Judges tended to apply the *Frye* standard liberally without making an independent determination as to the relevance of the studies to the case at hand or the reliability of the testimony.[5]

In 1993, the United States Supreme Court for the first time addressed concerns about the role of the judge in cases involving expert testimony. In ***Daubert v. Merrell Dow Pharmaceuticals***,[6] the Court held that Federal Rule of Evidence 702, not *Frye*, governs

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1 *See* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 Brook. L. Rev. 51, 52-53 (2008).

2 *See* Bradford H. Charles, *Rule 706: An Underutilized Tool to Be Used When Partisan Experts Become "Hired Guns"*, 60 Vill. L. Rev. 941, 941 (2016) ("[O]ur adversarial paradigm does not translate well to scientific analysis and may be detrimental to a court's fundamental truth-gathering purpose in a science-dependent dispute.").

3 Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923).

4 *See* Victor E. Schwartz and Cary Silverman, *The Draining of* Daubert *and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 220-21 (2006) (explaining the pre-*Daubert* landscape).

5 *Id.* at 221.

6 509 U.S. 579 (1993).

the admissibility of expert testimony in federal court. While expert testimony need not be based on scientific certainty in order to be admissible, the Court held that expert testimony must be "not only relevant, but reliable."[7]

Daubert and its progeny[8] left some ambiguity as to the admissibility of scientific testimony. But in 2000 Congress amended Federal Rule of Evidence 702 and clarified the standard. **Federal Rule of Evidence 702** now provides that:

> *A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:*
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> *(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;*
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> *(b) the testimony is based on sufficient facts or data;*
>
> *(c) the testimony is the product of reliable principles and methods; and*
>
> *(d) the expert has reliably applied the principles and methods to the facts of the case.*[9]

In other words, an expert's testimony must be based on sufficient facts or data derived from reliable scientific methods, *and* there must be a sufficiently reliable "fit" between the underlying science and the specific facts in the case.

The Problem With Juries: Confusing Hazard And Risk

Jurors are lay people, not scientific experts, and lay people often confuse "hazard" and "risk." In fact, many people use the terms interchangeably, although their legal meanings are significantly different.

"Hazard" is the possibility that, *at some exposure level and under some circumstance,* a substance *might* pose a risk. **"Risk,"** on the other hand, refers to the likelihood that *actual* exposure in the real world *will* cause harm.

When jurors see a sick plaintiff sitting before them and hear evidence that a substance that the plaintiff used is hazardous, they may wrongly assume that the substance

7 *Id*. at 589.

8 *See also* Gen. Elec. Co. v. Joiner, 522 U.S. 136 (1997) (noting that even where underlying studies are reliable, a judge may still reject expert testimony if there is an insufficiently reliable *connection* between evidence and conclusion); Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137 (1999) (holding that *Daubert* applies to all technical or other specialized expert testimony, not just scientific evidence).

9 Fed.R.Evid. 702.

caused the plaintiff's illness. But hazard does not prove causation. For a jury to find causation, there must be ***risk*** and ***actual exposure***.

Consider the example of weed killer. Weed killer, by definition, is toxic to weeds. It may also cause harm to a human if she bathes in it repeatedly or drinks it. Weed killer, in other words, poses a ***hazard*** to humans. This does not tell us whether normal use of weed killer poses a significant ***risk*** to humans of developing cancer.[10]

> ***Judges must strictly enforce evidentiary rules in order to prevent unreliable expert testimony from unduly prejudicing the outcome.***

The Problem With Experts: Blinding Us With Science

Excellent scientists can sometimes make poor witnesses. And bad scientists can sometimes be excellent actors on the witness stand. It is precisely because jurors are easily influenced by an expert's demeanor or paper credentials that judges must take extra care to screen out testimony with the potential to mislead. In so doing, they must consider both the reliability of both the methodology *and* the fit between the methodology and the facts of the case.

1. Unreliable methodology—In the first instance, courts typically consider whether the methodology has been tested; whether it has been subjected to peer review and publication; the known or potential error rate; the existence and maintenance of standards controlling its operation; and whether the methodology has attracted widespread acceptance within a relevant scientific community.[11] This list of factors is not exhaustive, and courts retain broad flexibility to consider any factor that implicates the validity of the data.

Testimony based on a study that has not been replicated is particularly suspect.[12] Thus, in 2020, a federal district judge in New Jersey refused to allow an expert to testify that Johnson & Johnson's talc baby powder contains ultra-trace amounts of asbestos where the testimony was based on a single unreplicated study and other scientific reviews came up negative for asbestos.[13] Excluding such testimony is

10 *See* Guy-Andre Pelouze, *How Do You Assess if a Chemical Causes Cancer?,* Slate (Jan. 24, 2018), available at https://slate.com/technology/2018/01/years-of-testing-shows-glyphosate-isnt-carcinogenic.html (last visited, June 10, 2020).

11 *Daubert*, 509 U.S. at 593-94.

12 *See* David E. Bernstein, *The Misbegotten Judicial Resistance to the* Daubert *Revolution,* 89 Notre Dame L. Rev. 27, 60 (2013).

13 *In re Johnson & Johnson*, C.A. No. 16-2738(FLW) at 55-57 (Dist.N.J. April 27, 2020).

necessary in order to avoid creating the false impression that a scientific outlier is a representative study.

***2. Unreliable fit*—**Even where the studies themselves are reliable, an expert's application of the studies to the facts of the case may not be.

Consider an expert's conclusion, based solely on high-dose animal studies, that a product can cause a particular type of cancer. The animal studies may be scientifically valid, but they are not relevant to humans if humans respond to the substance differently than the tested species or if humans are typically exposed to the substance in far lower doses than those used in the study.[14] High-dose animal studies may provide a basis for concluding that a product is hazardous. But they cannot provide a reliable basis for testimony about general causation.[15]

> ***"The purpose of the American tort system is to require people or companies to compensate those whom they have injured, not to compensate David by punishing Goliath when Goliath is not at fault."***

There are many other situations in which experts attempt to rely on scientifically valid studies to justify speculative testimony. For example, an expert might offer her opinion that Substance A caused plaintiff's cancer on the basis of studies that show Substance B, a "chemically similar" substance, poses an elevated risk of cancer to humans. Where plaintiff never used Substance B, however, there is an insufficient fit between the study and the facts to support the expert's conclusion.

Likewise, an expert might rely on studies that show the product in question causes a certain reaction in the human body to support a claim that the product is a human carcinogen. Without evidence that the identified reaction leads to cancer, however, the expert's testimony is mere speculation.[16] Thus, studies that show that the use of talcum powder causes inflammation in certain cells is insufficient to support

14 *See Joiner*, 522 U.S. at 144 (District Court did not err in excluding expert testimony that was based on high-dose studies of infant mice where plaintiff was an adult human.).

15 *See* Bernstein, *Judicial Resistance to* Daubert*, supra* note 12, at 49-50 (explaining that Rule 702 prohibits testimony based on "informed speculation and educated guesses").

16 *But see Id.*, at 60 (distinguishing between the regulatory context, where decision-makers might properly rely on speculative scientific evidence to protect the public from potential risks to public health, and the tort context, where the plaintiff has the burden of proving that a particular risk did, in fact, cause him harm).

the conclusion that talcum powder causes ovarian cancer absent evidence that inflammation leads to ovarian cancer.[17]

3. Can an unreliable fit be made more reliable by the weight of the evidence?— Experts sometimes try to bolster unreliable conclusions about human risk with other evidence related to the individual plaintiff's actual exposure. (In other words, they try to show specific causation without evidence of the crucial initial showing of general causation.)

For example, an expert might rely on "anecdotal case reports,"[18] which show the plaintiff was exposed to the substance shortly before suffering harm. Or an expert might argue that he should be allowed extrapolate from high-dose animal studies where all other known causes of the plaintiff's illness have been ruled out.[19]

> ***"Jury verdicts based on unreliable science harm consumers by raising prices and reducing access to safe and previously affordable products, medications, and vaccines."***

In such cases, plaintiffs argue, essentially, that an expert's testimony should be considered holistically.[20] The problem, however, with allowing experts to offer opinions based on the totality of evidence, none of which is sufficiently reliable on its own, is that it "leave[s] the evidentiary gates wide open"[21] with tremendous potential to confuse jurors and prejudice the case.

Evidence of specific causation should, therefore, be excluded where there is insufficient proof that the product or substance in question is capable of injuring humans in the first place.

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17 *In re Johnson & Johnson*, C.A. No. 16-2738(FLW) at 24, ("[Expert's] extrapolation from inflammation to ovarian cancer is a step too far to constitute a reliable scientific opinion and, therefore, that opinion will be excluded from his testimony.").

18 "Anecdotal case reports" demonstrate a temporal relationship between exposure and harm, such as when a doctor prescribes a patient a particular medication and the patient subsequently develops the illness in question. *See* Bernstein, *Getting to Causation*, *supra* note 1, at 61.

19 The process by which experts identify a probable cause of a person's disease by ruling out all other known possibilities is known as "differential etiology." *See id.*, at 64.

20 *See* Bernstein, *Judicial Resistance to* Daubert, *supra* note 12, at 58.

21 *Id.* at 62-63 ("Every quack and huckster claiming that he is relying on an evidentiary mosaic to invent causation without reference to reliable scientific evidence could claim he is utilizing a 'weight of the evidence methodology.'"); *see also Joiner*, 522 U.S. at 137-38 (District Court entitled to conclude that the studies upon which plaintiff's experts relied were insufficient, both individually and in combination, to support the conclusion that the substance at issue caused plaintiff's cancer.).

Myths About Science In The Courtroom

MYTH #1—Juries are capable of determining the credibility of expert scientific witnesses, just as they determine the credibility of lay witnesses. In the American legal system, it is the role of the jury to judge the credibility of the witnesses. Juries are generally competent to assess the credibility of a lay witness because the subject matter of the testimony is ordinarily something within the scope of an average juror's knowledge or understanding. By contrast, the subject matter upon which an expert offers his opinion is outside the scope of the average juror's experience. As a result, jurors are likely to judge an expert's credibility on the basis of his performance on the witness stand, rather than on the validity of his conclusions.

MYTH #2—The validity of expert testimony can be tested through vigorous cross examination, as opposed to the outright exclusion of testimony. Once an expert testifies, it is impossible to "unhear" his conclusions. Where the expert's credentials are impressive and undisputed, juries may defer to the expert even after vigorous cross-examination reveals that the science is shaky or the expert's conclusions are speculative. It is precisely because the content of expert testimony is outside the realm of an ordinary juror's knowledge[22] that *Daubert* requires the judge to make critical determinations about reliability and applicability in the first instance.

The Gatekeeping Function

Trial judges play a unique gatekeeping function in determining the admissibility of expert testimony. Although *Daubert* and the amended Federal Rule of Evidence 702 require judges to admit only reliable expert testimony, some courts have interpreted that requirement loosely in order to let the jury hear as much evidence as possible.[23] This is particularly true where the expert's testimony is based, not on obvious junk science, but on speculative theories proffered by well-credentialed scientists. Yet, it is in precisely these cases that the gatekeeping function is most important.[24]

> "*Americans can get their dogs vaccinated for Lyme disease, but not themselves.*"

22 *See* Schwartz and Silverman, *supra* note 4, at 220.

23 *See* Bernstein, *Judicial Resistance to* Daubert*, supra* note 12, at 50-52 (noting that many judges ignore the text of Rule 702, and instead rely on lenient precedents that predate the current rule and conflict with *Daubert*); Schwartz and Silverman, *supra* note 4, at 230 (noting that some trial judges misinterpret their "flexibility" to apply the *Daubert* factors "to the point of abdication").

24 Bernstein, *Judicial Resistance to* Daubert*, supra* note 12, at 59.

Recommendations

- Trial judges should hold pre-trial *Daubert* hearings to assess admissibility of proposed expert testimony before the jury is empaneled. Decisions about whether to admit expert testimony are complex and difficult to make in the midst of a trial. A pre-trial hearing allows trial judges to take their time considering the evidence and to make an informed and deliberative decision.[25]

- Trial judges must consider not only whether the expert has the relevant credentials and whether the expert's methodology is reliable but whether the expert "reliably *applied* the principles and methods *to the facts of the case*."[26] It is not enough that the underlying science be valid; there must be a sufficient fit between the methodology and the expert's conclusions.[27]

- Trial judges should exclude testimony regarding specific causation where the evidence of general causation is lacking.

- To avoid bias and increase reliability, trial judges should appoint independent experts pursuant to **Federal Rule of Evidence 706**, which allows a court to appoint an expert "*of its own choosing*."[28] A judge may use her own expert to evaluate the testimony proposed by the parties and guide her decisions as to admissibility,[29] or she may ask the independent expert to testify at trial.[30]

Conclusion

A jury is not supposed to hold a defendant company liable without proof that the company's product or actions *caused* harm to the plaintiff. In determining causation, science matters. Judges must, therefore, take particular care to ensure that lawyers do not mislead or emotionally manipulate jurors with scientifically unreliable testimony.

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25 Schwartz and Silverman, *supra* note 4, at 257-58 (explaining the necessity of pre-trial *Daubert* hearings).

26 Fed.R.Evid. 702 (emphasis added).

27 *See Joiner*, 522 U.S. at 146 (Conclusions and methodology are not entirely distinct, and when there is "too great an analytical gap" between the science and the conclusions, testimony is properly excluded.).

28 Fed.R.Evid. 706 (emphasis added); *see also* Charles, *supra* note 2, at 948 (advocating this approach, but noting that most American judges hesitate to invoke this rule, "largely due to a self-perceived fear of interfering with the adversarial process").

29 Andrew W. Jurs, *Balancing Legal Process with Scientific Expertise: Expert Witness Methodology in Five Nations and Suggestions for Reform of Post-Daubert U.S. Reliability Determinations*, 95 Marq. L. Rev. 1329, 1353-54 (2012).

30 Fed.R.Evid. 706 (A court-appointed independent expert "may be called to testify by the court or any party.").