IADC COMMITTEE NEWSLETTER

TOXIC AND HAZARDOUS SUBSTANCES LITIGATION

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IN THIS ISSUE

Science is not made in the courtroom and judges are not scientists. Yet concerted efforts to seek relaxation of evidentiary standards for expert testimony would permit courts and juries, in effect, to create science by basing judgments on unreliable scientific theories. To avoid this result, the judiciary's gatekeeping function must require that science precede the law and not vice versa in order to insure fairness in the judicial system.

Science Before The Law or Cart Before The Horse – Protecting Scientific Integrity at the Courtroom Door

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Science is not made in the courtroom. Science is discovered, evaluated, tested, and verified by scientists in laboratories, research institutions, and universities and not by laypeople serving on a jury. However, the relaxation of the reliability standards for admissibility of expert testimony in toxic tort cases risks creating a paradigm in which the law precedes science by permitting the admission of "junk science" into the record upon which lay jurors base precedent-setting legal verdicts. Effectively, lay jurors are thus empowered to create scientific standards by adopting expert "opinions" that are not backed by hard data, generally accepted studies and principles and/or approval by the scientific community. The junk science then becomes the standard in the eyes of the law. Allowing jurors to base their verdicts upon evidence ranging from yet-to-be-proven, novel theories to outright quackery results in unjust, unreliable verdicts and reverses the proper order of things, where science must precede the law and not vice versa.

"Junk Science" refers to "evidence which is not consonant with generally accepted medical or scientific views and which lacks other indicia of reliability." Joseph M. Price and Gretchen Gates Kelly, *Junk Science In The Courtroom: Causes, Effects and Controls*, 19 Hamline L. Rev. 395 (Spring 1996). Thus, even expert testimony based upon new insights, regardless of valid future promise, qualifies as "junk science" in the absence of at least a minimal level of established, general acceptance.[1] The use of junk science in litigation "has resulted in findings of causation which simply cannot be justified or understood from the standpoint of the current state of credible scientific and medical knowledge." *Id., citing* 1986 Attorney General Tort Policy Working Group Rep., *The Causes, Extent and Policy Implications of the Current Crisis in Insurance Availability and Affordability* at 62.

Clearly, permitting junk science to form the basis of legal findings is the antithesis of justice and contrary to the role set out for the courts and our judicial system. As Justice Stephen Breyer stated in his Introduction to the Federal Judicial Center's Third Edition of the Reference Manual on Scientific Evidence:[2]

> we must search for law that reflects an understanding of the relevant underlying science, not for law that frees companies to cause serious harm or forces them unnecessarily to abandon the thousands of artificial substances on which modern life depends.

[1] Although not all new scientific insights and novel theories that are proffered in litigation are incorrect, and acknowledging that some may eventually be proven true with further time, research, and technological development, for purposes of their role in the judicial process, such theories cannot serve as an evidentiary basis for judicial findings until the requisite reliability is established.

[2] Portions of Justice Breyer's Introduction appeared in Stephen Breyer, The Interdependence of Science and Law, 280 Science 537 (1998).

The search is not a search for scientific precision. We cannot hope to investigate all the subtleties that characterize good scientific work. A judge is not a scientist, and a courtroom is not a scientific laboratory. But consider the remark made by the physicist Wolfgang Pauli. After a colleague asked whether a certain scientific paper was wrong, Pauli replied, "That paper isn't even good enough to be wrong!"[footnote omitted] Our objective is to avoid legal decisions that reflect that paper's so-called science. The law must seek decisions that fall within the boundaries of scientifically sound knowledge.

Even this more modest objective is sometimes difficult to achieve in practice. The most obvious reason is that most judges lack the scientific training that might facilitate the evaluation of scientific claims or the evaluation of expert witnesses who make such claims.…

Furthermore, science itself may be highly uncertain and controversial with respect to many of the matters that come before the courts.…

Despite the difficulties, I believe there is an increasingly important need for law to reflect sound science.

Reference Manual on Scientific Evidence, Third Edition (Federal Judicial Center, 2011) at 4-5. Thus, the requirement of science preceding the law, not the opposite, is of greater importance than permitting novel theories to be posited in the courtroom under the unreliable guise of innovation.

The evidentiary standards for the admissibility of expert testimony have evolved over time. David E. Bernstein, *The Misbegotten Judicial Resistance to the Daubert Revolution*, 89 Notre Dame L. Rev. 27 (Nov. 2013). Prior to three decades ago, virtually any expert could testify so long as it was within their area of expertise. *Id*. Experts needed only to be marginally qualified to testify about a subject, so long as the testimony was relevant and the subject matter was "beyond the ken of the jury." *Id.* at 31. Over time, however, Courts realized that too many causation theories were unsupported by scientific evidence. *Id*.

The first major precedent governing the admissibility of expert testimony was delivered in *Frye v. U.S.*, 293 F. 1013 (D.C. Cir. 1923). Under *Frye*, expert testimony was to be governed by a "general acceptance" test – i.e., that "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." *Id.* at 1014. Next, in the seminal trilogy of *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999) the Supreme Court "tightened the standards for

admissibility of expert testimony." Bernstein, 89 Notre Dame L. Rev. at 28. The *Daubert* Court particularly held that the Court has a "gatekeeper" role to ensure that expert testimony is both relevant and reliable. In determining the reliability of expert testimony, the Court articulated five factors which included "general acceptance" and whether the expert relied on "peer reviewed, published studies." *Daubert* at 593-594.

In 2000, Congress amended Federal Rule of Evidence 702 to provide that expert testimony that is otherwise helpful to a jury is admissible only when "(b) the testimony is based upon 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." Fed. R. Evid. 702. In effect, the amendment codified the Supreme Court's holding that all expert testimony be subject to a strict reliability standard. Bernstein, 89 Notre Dame L. Rev. at 49.

Opponents of such a reliability standard argue that qualified experts should be allowed to testify in their general areas of expertise especially in cases of first or early impression where the industry has not yet had the opportunity to engage in formal testing and/or publication of the results of any testing for review and acceptance by the scientific community. *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984). In *Ferebee*, the Court stated that "If experts are willing to testify … it's for the jury to decide whether to credit such testimony." *Id*. at 1535. However, the danger in freely allowing unsupported expert theory is clear – jurors, most of whom do not have formal, scientific backgrounds, are quick to accept an expert's word at the onset solely by virtue of the fact that they are "experts." *Junk Science In The Courtroom, supra,* 19 Hamline L. Rev. at 397. In other words, lay jurors attribute to expert witnesses, particularly scientific expert witnesses, "a special aura of credibility." *Id*. In a lay juror's mind, this immediate trust, during times of confusion or lack of understanding of the scientific principles underlying a theory of causation, can and does lead to verdicts that are based on credibility assessments and empathy, as opposed to the science, when it comes down to a battle of the experts. *Id*. As a result, if the theory propounded by the prevailing expert is in fact "junk science" – the verdict is scientifically unsound and legally unjust. *Id*. The only way to prevent this phenomenon is to exclude unreliable expert evidence at the outset by applying a strict standard of reliability. *Id*.

Courts that understand the risks inherent in allowing lay juries to dictate science have excluded expert testimony that is not properly backed up by acceptance in the relevant scientific community. For example, the United States District Court for the District of Columbia adopted a three-step test (originally employed by the United States District Court for the Eastern District of Virginia) for determining expert reliability on toxicology that requires a showing that the expert evaluated exposure levels

necessary to produce injury in accordance with "published scientific literature." *Young v. Burton*, 567 F.Supp.2d 121, 129 (D.D.C. 2008), *citing Cavallo v. Star Enterprise,* 892 F.Supp. 756 (E.D.Va. 1995). In *Young*, the District Court for the District of Columbia excluded a plaintiff's expert's diagnosis of "mold illness" from certain residential mycotoxins and theories of general and specific causation because they were not sufficiently grounded in scientifically valid principles and methods under *Daubert*. *Id*. at 131. There, plaintiffs failed to present evidence that "mold illness" is an actual illness recognized in the medical community, as opposed to a condition made up by the expert for the sake of the litigation. *Id*. Plaintiffs also failed to present evidence showing that the expert's methodology was supported by any peer-reviewed medical literature. *Id*. at 130. In fact, the expert utilized a dubiously self-designed diagnosis procedure that invoked a 2-tiered analysis of 9 potential factors. *Id*. at 124. Although the expert himself had published three peer-reviewed articles in support of his methodologies and theory of "mold illness," the Court rejected them as reliable evidence of acceptance in the scientific community because of the lack of any independent evidence showing a causal relationship between mycotoxins and human illness in general and the "lack of peer-reviewed medical literature on 'mold illness' and its [alleged] causes." *Id.* at 130.

Courts have further held that the proponent of an expert's opinion must not only show sources of validation by the scientific community, but that the sources cited must have a scientifically valid link to the ultimate conclusion reached. *Arias v. Dyncorp*, 928 F.Supp.2d 10 (D.D.C. 2013). In *Arias*, an expert theorized that an airborne herbicide caused acute injuries to the plaintiffs including "skin, nose and eye itchiness / irritation, skin and eye burning sensations, rashes, vomiting, respiratory problems, headaches, dizziness, stomach aches, diarrhea and burning throat." *Id.* at 14. In support of plaintiffs' causation theory, the expert submitted "studies of patients who try to commit suicide by directly ingesting large amounts of [the herbicide]". *Id*. at 22. The Court held that plaintiffs failed to show a scientifically valid link between suicide studies at large dosages and the expert's conclusion that airborne contaminants at undeterminable dosages could cause the non life-threatening [dissimilar] injuries delineated in the complaint. Therefore, the expert's methodology was deemed to be unreliable and his testimony was excluded. *Id*. at 22-23.

Courts have particularly rejected the argument that novel theories should be admissible by way of the "there is a first time for everything" argument. *Nelson v. Tenn. Gas Pipeline Co.*, No. 95-1112, 1998 WL 1297690 *8 (W.D. Tenn. Aug. 31, 1998). In *Nelson*, plaintiff's expert was offered to testify that PCB and dibenzofuran exposure caused brain disorders, epileptic seizures, cutaneous cancer and choracne. *Id*. at 3. The expert's opinions were first in kind, and only "backed up" by his own, submitted for publication but not yet peer-reviewed

studies. *Id*. at 8. In holding that the expert's novel theory was inadmissible upon grounds of unreliability, the Court cited *Daubert's* reasoning that "although juries may not learn of [some] 'authentic insights and innovations, the rules of evidence were purposed not for the exhaustive search for cosmic understanding but for the resolution of disputes.'" *Id*. The Court also weighted the *Daubert* court's observation that scientific scrutiny through the peer review process is a component of "good science" partly because it acts as a check on the accuracy of the expert's proposed methodology. *Id*. Moreover, expert testimony based upon pre-existing research unrelated to the litigation does not carry with it the same concerns as testimony that appears to be crafted for litigation purposes. *Id*. Ultimately, under a more relaxed evidentiary scheme, a back door means to admit junk science into the courtroom would undoubtedly allow the law to precede science. *Id.*

Indeed, even where the causation theories themselves are not necessarily novel, or even where they have valid support, courts have begun to require more specific evidence of the dose levels necessary to establish general causation (that a particular toxin can cause a particular injury or disease) and specific causation (that plaintiff was exposed to a sufficient dose of the toxin to cause his or her injury or disease). *See Parker v. Mobil Oil Co.*, 524 N.Y.S.2d 584 (N.Y. 2006); *Cornell v. 360 W. 51st St. Realty, LLC*, 986 N.Y.S.2d 389, 404 (N.Y. 2014) (holding that it was "not enough for a plaintiff to show that a certain ... agent sometimes causes the kind of harm that he or she is complaining of. At a minimum, ... there must be evidence from which the factfinder can conclude that the plaintiff was exposed to levels of that agent that are known to cause the kind of harm that the plaintiff claims to have suffered." (*quoting Wright v. Willamette Ind., Inc.,* 91 F.3d 1105 (8th Cir.1996)); *In Re New York City Asbestos Litigation (Juni v. A.O. Smith Water Products)* 2015 WL 1840006 (N.Y. Sup. New York Co. Apr. 13, 2015) (granting defendant's motion to set aside jury verdict on grounds that plaintiffs' experts' general and specific causation opinions lacked sufficient foundation and were insufficient to establish causation).

A particular danger for toxic tort defendants arises where an expert is offered to pose a theory of causation to avoid such requirements as establishing dose or worse yet, to avoid generally accepted general causation principles as to what dosage levels may cause certain illnesses or injuries. For example, plaintiffs have looked to the concept of "synergy" to establish causation in the absence of established scientific evidence. "Synergy" is defined as a "… phenomenon where the combined effect of two substances is greater than the sum of the effect of each substance alone." *In re: Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, No. MDL1203, 2000 WL 962545, *10 (E.D. Pa. June 28, 2000). In *In re: Diet Drugs*, defendants sought the exclusion of the testimony of two experts who opined

that a synergistic combination of Phentermine ("Phen") and Fenfluramine ("Fen") created an increased risk of Primary Pulmonary Hypertension ("PPH") and Valvular Heart Disease ("VHD"). *Id*. at 6. There, the two plaintiff experts could not present any epidemiological data to support their conclusion; nor could they produce any reliable scientific evidence to establish each element of their underlying reasoning. *Id*. at 6-9. Specifically, the experts claimed that the combination of Phen and Fen ("Phen-Fen") interferes with the clearance of serotonin from the lungs and local areas of the heart arteries and the left side of the heart, causing an increased risk for PPH and VHD. *Id.* at 6. However, there is no scientific evidence showing that Phen-Fen increases plasma serotonin, that Phen inhibits Monoamine Oxidase, the enzyme that breaks down serotonin, that Phen actually accumulates in the lungs, that increased platelet serotonin leads to PPH and VHD in humans, that Phen interferes with pulmonary clearance of serotonin in the lungs, or that Phen-Fen interferes with the pulmonary clearance of serotonin. *Id*. at 6-10. Simply stated, each of these factors, critical to the establishment of their conclusion, could not be backed up by scientific evidence. *Id*. In addition, the studies plaintiffs cited in support of their synergy claims were insufficient to show acceptance within the scientific community because they did not relate at all, let alone reasonably, to the alleged synergistic combination of Phen-Fen as a risk for PPH and VHD in humans. Rather, the studies regarded animal testing of brain serotonin levels, as opposed to serotonin in the periphery of the lungs and heart, and under testing conditions that did not use similar dosages or take into consideration the differences in "pharmacokinetics of animals and humans." *Id*. Thus, given plaintiffs' failure to establish general scientific acceptance of any aspect of their experts' synergy theory of causation, the experts were excluded on the basis of unreliability. *Id*. at 11.

In fact, allegations of synergistic effects have long been utilized by plaintiffs to make an end run around established science on causation related to their claims where the science is inconsistent with the facts of their cases. For example, in the *IBM Clean Room Litigation* and many other large chemical exposure litigations where plaintiffs alleged exposure to multiple chemical agents in their workplaces, plaintiffs have employed the "chemical soup" theory of causation with unfounded and vague allegations of synergy to support their cases. More recently, plaintiffs have used synergy theories to overcome deficiencies in scientific evidence to attempt to impose liability for cardiac deaths against the energy drink industry. In an absence of scientific evidence that the beverages' individual ingredients alone can cause adverse cardiac effects, plaintiffs have made the unsubstantiated claim that the combination of those ingredients has a synergistic effect. Unless Courts draw the line at allowing such evidence, plaintiffs would be giving juries the opportunity to decide claims, thereby creating science in

the courtroom, based on such unscientific factors as human sympathy.

In addition, overly liberal reliability standards in expert evidentiary evaluations make way for an incentive system fraught with the ethical dangers inherent in any profit-motivated venture. *Junk Science In The Courtroom, supra,* 19 Hamline L. Rev. at 396. Because experts are chosen on the basis of adversarial bias (i.e., upon their ability to make science fit a party's theory), Plaintiff lawyers who are grasping for novel theories upon which to impose frivolous product liability claims "create a limitless demand for junk science" so long as the junk science supports their position. *Id*. This can and does incentivize experts to put forth opinions they know lack scientific credibility – for the sake of making money. *Id*.

Moreover, seeking to rein in the standards for expert admissibility also has larger societal ramifications beyond each individual case and claim. As Justice Breyer commented,

> The importance of scientific accuracy in the decision of such cases reaches well beyond the case itself. A decision wrongly denying compensation in a toxic substance case, for example, can not only deprive the plaintiff of warranted compensation but also discourage other similarly situated individuals from even trying to obtain compensation and encourage the continued use of a dangerous substance. On the other hand, a decision wrongly granting compensation, although of immediate benefit to the plaintiff, can improperly force abandonment of the substance. Thus, if the decision is wrong, it will improperly deprive the public of what can be far more important benefits—those surrounding a drug that cures many while subjecting a few to less serious risk, for example.

Reference Manual on Scientific Evidence, Third Edition at 4.

The Court's gatekeeping function, requiring existing science to drive the law, is critical to ensuring that juries do not validate junk science. Future scientific validity notwithstanding, requiring all expert testimony to be supported by valid, existing science is the only way to insure that our judicial system remains balanced and fair. Thus, it remains imperative to continue to strive for science to precede the law, to have theories validated and confirmed before being permitted as evidence (and yes, this will, at times, allow for competing theories that meet the test of reliability established by *Daubert* and its progeny, to be weighed and assessed by juries), even if that means that certain novel scientific concepts that may have merit but remain unproven to date are barred from the courtroom.

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