"Weight of the Evidence" Approach

# A Backdoor Attempt to Undermine the Court's *Daubert* Gatekeeping Obligation

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**Plaintiffs have more and more frequently started to rely on a "weight of the evidence" approach as a purported "scientific methodology" for offering opinions in courts on causation.**

Proof of causation is at the core of drug and device litigation battles. Causation battles are fought on two fronts: general causation (is a particular drug or device capable of causing injury?) and specific causation (is the individual plaintiff's claimed injury caused by the drug or device?). Both are critical.

*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), or a particular state's equivalent standard, has posed significant challenges to the plaintiffs' bar's attempts to prove both general and specific causation. Many times, perhaps most times, litigation centered on whether a product causes injury attempts to lead the science, rather than following the science. This is particularly true when the medical and scientific evidence does not prove that a particular agent causes disease generally, or that for whatever reason, an individual plaintiff's condition is not due to that agent.

Always inventive, the plaintiffs' bar continues to work diligently to limit the effect of *Daubert*. A variety of different tactics have been used in an effort to undermine or to dilute the courts' gatekeeping function of properly assessing whether experts are permitted to make claims of general and specific causation. In some cases, plaintiffs cobble together the scientific or the medical literature, retaining an expert to offer purported causation opinions based on less than the acceptable proof upon which



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the scientific or the medical community generally draws such conclusions. In other cases, attempts are actually made to create the science solely for purposes of perpetuating the litigation. In still other cases, plaintiffs try to convince courts to lower the standard under which experts are permitted to form and offer causation opinions for legal purposes.

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When the defense is able to prevail with a *Daubert* challenge to a plaintiff's general causation experts, the case is over. Given the nature of the injuries often alleged, and in particular the aggregate values of mass tort cases, the financial incentive to prove causation—despite the science—is enormous. Thus, the stakes are arguably never higher during litigation than they are during challenges to the reliability of the methods used by plaintiffs' experts to render their opinions.

When the defense takes the position that good science has not concluded that the agent in a case causes disease, our colleagues in the plaintiffs' bar will use every tool in their arsenal to try to raise a question of fact to get the causation issue, and thus the case, before a jury. To counter the defense argument that reliable science has not proved that an agent causes injury, plaintiffs have more and more frequently started to rely on a "weight of the evidence" approach as a purported "scientific methodology" for offering opinions in courts on causation.

This article will discuss this renewed and concerted effort to convince the courts to accept this thinly veiled *ipse dixit*—I am right because I say I am right—of plaintiffs' experts. The "weight of the evidence" concept is no more than an *ipse dixit* opinion that is offered under a new and different name. Of course, the courts have traditionally roundly rejected *ipse dixit*. Proof beyond the say-so of an expert is always required. In essence, the proffered expert says the following:

- I am an expert.
- I follow the scientific method, which involves applying expertise to the literature.
- There is literature.
- I have read the literature.
- Having read the literature, and using my expertise, I think that the weight of the evidence demonstrates that the agent causes injury.

The advocates of such evidence believe that there should be little or no analysis of the validity of the underlying literature relied upon by the expert offering this line of reasoning. Of course, good science—and good law—must evaluate the validity of the materials relied upon in coming to scientific conclusions, as well as legal conclusions about the sufficiency of those opinions. The "weight of the evidence" approach attempts to give a rigorous sounding methodological name to a purely subjective approach. Such a "methodology" would allow a dozen experts to say that they followed the process, but come to a dozen different conclusions, but that each conclusion nonetheless is admissible. This is the very definition of an inability to replicate the methodology and the conclusions, and why the "weight of the evidence" approach is not a scientific method.

This so-called methodology is used by plaintiffs and their experts to convince courts to defer blindly to the subjective judgment of a scientist or an expert without scrutinizing the underlying evidence upon which the scientist or expert may rely. They try to induce a court to shrink from its *Daubert* responsibility to scrutinize the body of evidence being relied upon by an expert and focus on magic words that say in substance "I reviewed everything, and the weight of the evidence supports my opinions." To appreciate fully the radical change that this *ipse dixit* "weight of the evidence" theory portends, we will first examine a court's traditional role in assessing expert evidence, after which we can put this latest attempt to gut the courts' gatekeeping responsibility into proper context.

## The Establishment of the Gatekeeping Function of Courts Under *Daubert*

Federal Rule of Evidence 702 establishes the standard under which an expert may testify:

> 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: (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; (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.

The *Daubert* opinion lays out additional factors for the trial and the circuit courts to apply that bear on admissibility, including whether a theory has been tested, whether it has been subjected to peer review and publication, the potential rate of error, and whether it has gained general acceptance in the relevant scientific community. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See, e.g.*, Tamara Goorevitz, *Can Expert Opinions Be Successfully Challenged?*, For The Defense, Jan, 2009, at 30, available at http://dritoday.org/articles/2009/01_January/FTD-0901-Goorevitz.pdf (discussing *Daubert* factors further); Michael Yarbrough, Daniel Long, & Carla De La Barra Helstrom, *Ruling in/Ruling out Differential Diagnosis*, For The Defense, Jan. 2009, at 43, available at http://dritoday.org/articles/2010/01_January/FTD-1001-YarbroughLongHelstrom.pdf (same).

As the Supreme Court stated,

> The subject of an expert's testimony must be 'scientific… knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation. The

term 'applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.

509 U.S. at 480–81. Further, "under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 481. To discharge this responsibility requires a trial court to undertake "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 482.

Other important considerations required for a critical assessment of an expert's opinions under *Daubert* include that the expert must bring the "same level of intellectual rigor" to the methodology used in reaching his or her opinions as used by experts in that field in other areas of professional life beyond the courtroom. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Moreover, in *Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997), the Supreme Court stated that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert," and that expert testimony may be excluded if there is "too great an analytical gap between the data and the opinion proffered." *Id.*

## Traditional Assessment of Scientific and Medical Literature

For the past 20-plus years under *Daubert*, federal courts around the country have grappled with whether the scientific and the medical literature in a particular context rises to a level that will permit experts to testify before a jury on general and specific causation claims. The question answered in this context is whether a plaintiff offered sufficient evidence to raise a question of fact on general or specific causation or both. To raise a question of fact, a plaintiff must present admissible evidence sufficient to raise that question of fact. So, we will turn to the type and the quality of evidence that experts use in attempting to refute or to prove causation.

Regardless of the theories that plaintiffs try to espouse to establish causation, epidemiology remains the science that studies whether causation exists. Different types of evidence are weighed very differently by scientists in the field of epidemiology. The types range from case reports and case series, which are the weakest form of evidence because they are in essence anecdotal reports without comparators, to randomized, well-controlled trials, the most rigorous type of evidence. In exposure cases, clinical trials that study the ultimate endpoint (harm) may not be possible because it is unethical to conduct a trial that would randomly assign people to receive or not to receive a potentially harmful substance. So, often analytic studies such as case control or cohort studies are conducted, sometimes retrospectively. Epidemiologists first assess whether there is an association between an exposure and disease, completing a statistical assessment. If an association is established, then epidemiologists will assess the evidence—or obtain it if it does not already exist—to determine whether or not the association is causally related.

Plaintiffs' attorneys and experts like to try to use case reports and case series and adverse drug reaction reports and medical device reports in various combinations as evidence of causation. Case reports and case series are reports of individual patients who were exposed to a particular drug or device and who have reported a subsequent condition that the peer-reviewed literature will publish, or that sometimes even appear in literature that has not undergone peer review. The authors may even hypothesize about the cause of a reported condition. While these reports by their very nature are hypothesis-generating—and appropriately so—even plaintiffs' experts will concede that they do not prove a causal connection. Experts and courts will readily concede that case reports alone cannot establish general causation. However, plaintiffs' experts frequently will try to aggregate these case reports and drug and medical device adverse event reporting and create the impression of causation. And, if the numbers of the articles and the reports increase, the authors of articles or reporters of events (and counsel for claimants as well) will *assume* causation. Later authors and reporters will then take those assumptions and report that they are proven assumptions. Many times, these assumptions and presumptions are based on nothing other than a cited case report, which almost everyone agrees does not prove causation.

At the other end of the spectrum are well-designed and controlled epidemiological studies. Epidemiologists will say that well-controlled studies comparing exposed and non-exposed groups that show a statistically significant increase in disease in the exposed group may show an association with an agent involved in the study. Epidemiologists will also say that assessments of causation cannot be done unless an association has been shown. There are rigorous, controlled epidemiological studies that test whether or not there are sufficient scientifically valid statistical bases to conclude causation. Properly conducted and powered studies will study a sufficiently well-sized group of people exposed to a particular agent with the goal of assessing whether there is an association *and* a causal connection between the identified substance and the disease in question, which itself needs to be well defined.

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In assessing whether an expert can offer opinions on general causation to a jury, courts have engaged in a two-step analysis to assess a particular body of evidence. A court first separately scrutinizes each piece of evidence relied upon to determine its reliability and relevance, rejecting those pieces of evidence that are not scientifically reliable or relevant to the issue on which the expert opines. After segregating those portions of the evidence that are reliable and relevant, a court ultimately decides whether that remaining body of evidence is sufficient to allow an expert to express the opinions offered. Doing that should require

courts to apply the same scientific methodology that would allow a scientist to draw a causal connection.

## The Emergence of the "Weight of the Evidence" Nomenclature

The term "weight of the evidence" is ill-defined and historically used to describe different things, both in the scientific and legal communities. As such, it is important to look beyond the phrase and attempt to understand precisely what it means.

In *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584 (D. N.J. 2002), the plaintiff was allegedly exposed to dry cleaning fluid, perchloroethylene (PCE), after which the plaintiff was diagnosed with myelogenic leukemia. The court held a *Daubert* hearing with respect to the reliability and relevance of the medical causation experts in the case. The plaintiff's expert Dr. Ozonoff described the methodology that he used in rendering his opinions as "the weight-of-the-evidence methodology." According to Dr. Ozonoff, "[a]lthough there is no accepted definition [of the] methodology, the essence of the 'weight-of-the-evidence' approach requires that different types of data be evaluated together." The court criticized the plaintiff's expert's use of this methodology: "Dr. Ozonoff still did not offer any scientific method to guide what weight he had accorded each piece of evidence nor did he explain why he weighted the evidence as he did nor how, given the body of evidence before him, he arrived at his ultimate conclusions."

Moreover, the court recognized that because this approach involves the subjective judgment of the expert, it is paramount that the expert details how he or she weighed the scientific evidence:

> Importantly, because the weight-of-the-evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert supply his method for weighting the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion. How else can one expert's choice of "weight" be helpful to a jury which may be called on to assess a "battle of weighers"? The particular combination of evidence considered and weighed here has not been subjected to peer review.

The court also emphasized ultimately that a plaintiff's expert's methodology must be based on the scientific method and not based on subjective belief and speculation:

> In order for Dr. Ozonoff's expert opinion to be admitted, his weighing process must be based on methods and procedures of science, rather than on subjective belief or unsupported speculation. The question here is not the reasonableness, in general, of undertaking a "weight-of-the-evidence" analysis. "Rather, it [is] the reasonableness of using such approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant. [citations omitted]."

The *Magistrini* court did not reject "weight of the evidence" as a methodology outright. But, critically, the court engaged in a traditional *Daubert* analysis. This is precisely what ought to happen. The court scrutinized the plaintiff's expert's analysis, and using traditional *Daubert* factors, rejected how he weighed the evidence:

> In order to ensure that the "weight-of-the-evidence" methodology is truly a methodology, rather than a mere conclusion-oriented selection process that weighs more heavily those studies that supported an outcome, there must be a scientific method of weighting that is used and explained. In this case it appears that Dr. Ozonoff relied most heavily on his own study, which itself looked at only seven (7) cases of leukemia and had a huge confidence interval, indicating that the results of the study are unstable and imprecise. He neither explained why the confidence interval in that study was not of concern to him, nor did he sufficiently discredit other studies that found no association or a negative association with much more precise confidence intervals, nor sufficiently explain why he did not accord weight to those studies.
>
> In the final analysis, there was no deference to the scientist's subjective judgment. Rather, the court properly fulfilled its gatekeeping role and scrutinized the bases of the opinions proffered by the expert.

Even in the specific causation context, courts have rejected deferring to a scientist's or an expert's judgment regarding a subjective interpretation of the literature. For example, in *Scaife v. Astrazeneca LP*, 2009 Del. Super. Lexis 216 (Sup. Ct. Del. 2009), the court engaged in a thorough *Daubert* analysis, scrutinizing the plaintiff's expert's specific causation opinions and her reliance on the literature. In refusing to defer to the expert's approach, the court rejected the "weight of the evidence" concept:

> [T]he expert cannot simply "look back" subjectively to selected features of the plaintiff's history so that she can randomly plug them into selected findings from the medical literature in order to cobble together a specific causation opinion; again, the methodology must be grounded in a "definitive scientific process." Subjectively selecting items from the medical literature without explanation of the process for selection or the methods by which the literature is evaluated is by no means a "definitive scientific process."

*Id*. at *72–73. *See* Yarbrough, Long, & De La Barra Helstrom, *supra* (discussing the "differential diagnosis" and *Daubert* factors in detail).

## The "Weight of the Evidence" Approach Can Lead Courts to Defer Blindly to the Subjective Judgment of a Proffered Expert

In absence of a true and rigorous scientific methodology for engaging in and undertaking a "weight of the evidence" approach, plaintiffs' counsel have attempted to contrive a scientific methodology in an effort to satisfy *Daubert*. This effort is highlighted by a recent decision from the First Circuit involving a "weight of the evidence" claim asserting general causation. The First Circuit agreed that the plaintiff's expert would be permitted to offer his "weight of the evidence" causation theories to the jury. The expert was permitted to extrapolate from one set of epidemiological studies involving a different but related disease and to render causation opinions about the disease at issue.

In *Milward v. Acuity Specialty Products Group, Inc.,* 639 F.3d 11 (1st Cir. 2011), the plaintiff alleged developing leukemia as a

result of exposure to benzene-containing products. On the general causation issue, the plaintiff offered the opinions of Dr. Martyn Smith, a toxicologist, bolstered by the opinion of a philosopher, yes, a philosopher, Dr. Carl Cranor, who offered an opinion about the scientific method, even though Dr. Cranor was not a scientist. Dr. Smith offered a general causation opinion that exposure to benzene-containing products was capable of causing the plaintiff's particular type of leukemia. There was undisputed evidence of a causative relationship between the exposure at issue and a type of leukemia that differed from the plaintiff's leukemia. There was also "a small set" of epidemiological studies that showed a nonstatistically significant increased risk for the type of leukemia at issue. Without further epidemiological evidence but with some other studies that the expert extrapolated from, and based on this "weight of the evidence" argument, the court opined that a jury should be able to hear that Dr. Smith drew an inference that if exposure causes one type of leukemia, then it causes another even without epidemiological evidence of a statistically significant increased risk.

Through a combination of these two witnesses, the plaintiff introduced a slightly different spin on the "weight of the evidence" approach in an effort to fill the holes identified previously by courts when other experts attempted to use this so-called methodology. Essentially, the court uncritically accepted the philosopher expert, not a scientist, permitting this expert to offer a purported scientific methodology about how scientists reach conclusions on causation. The court described this methodology as follows:

> As explained by plaintiffs' expert on methodology Dr. Cranor, Distinguished Professor of Philosophy at the University of California, Riverside, inference to the best explanation can be thought of as involving six general steps, some of which may be implicit. The scientist must (1) identify an association between an exposure and a disease, (2) consider a range of plausible explanations for the association, (3) rank the rival explanations according to their plausibility, (4) seek additional evidence to separate the more plausible from the less plausible explanations, (5) consider all of the relevant available evidence, and (6) integrate the evidence using professional judgment to come to a conclusion about the best explanation.

*Id*. at 15. According to this philosophy expert, as long as a scientist follows this methodology, including claims that the expert considered all available evidence and integrated that evidence using subjective judgment, the court should permit the conclusions to be heard by a jury.

As a threshold matter, there is no empirical support for the claim that this "weight of the evidence" concept has actually been used in the scientific community. To the contrary, there is no discussion in the scientific literature that such a method is generally accepted. This proffered methodology appears to be an evolving creation, rather than a recognized, existing methodology that some plaintiffs' experts use to fill in gaps to meet court requirements to present causation conclusions to juries.

Somewhat misleading about the *Milward* court's discussion about this methodology is that it is inserted in a discussion of a true scientific methodology, the Bradford Hill criteria, which epidemiologists sometimes use in assessing causation. Under the Bradford Hill criteria, there are nine factors to evaluate the probability of a causal connection once the available data establishes statistical significance. (The authors respectfully refer you to Sir Bradford Hill's paper in which he articulated the Bradford Hill criteria that is used in litigation and in medical and scientific discussions of causation. It is very instructive to read what he wrote as opposed to what others say that he wrote: A. Bradford Hill, *The Environment and Disease: Association or Causation*, 58 Proc. Royal Soc'y Med. 295 (1965)). In this limited context, mentioning the nine factors, the court acknowledged that different scientists are entitled to disagree about scientific frameworks and scientific judgment does play a role in evaluating statistical probability.

However, this "weight of the evidence" approach is not simply about disagreement within the framework of an accepted scientific methodology. Rather, the approach suggests, especially given Bradford Hill's criteria that as long as a scientist states that he or she engaged in this exercise, opinions that an expert offers *ipso facto* are scientifically reliable. If faced with arguments that *Milward* allows scientific experts to offer opinions during trials based on the weight of the evidence in a particular case, it is important to remember that it was not disputed that there were decades of studies showing an increased risk of developing one type of leukemia after exposure to the substance at issue, although such evidence did not exist for the type of leukemia that the plaintiff in the case actually had. This will likely be a critical distinction for a case that your client may face.

**Experts and courts** will readily concede that case reports alone cannot establish general causation.

The court decision in *Milward*, with its limited acceptance of this "weight of the evidence" approach as placed in the context of an otherwise accepted scientific methodology, as well as the reference to the *Milward* decision in *The Reference Manual on Scientific Evidence* (3d ed. 2011), likely has emboldened the plaintiffs' bar to go further. For example, in a Pennsylvania state court litigation, the same duo of Dr. Martyn Smith and Dr. Carl Cranor teamed up to advocate applying a "weight of the evidence" approach. In that case there was not any reliable epidemiological evidence from the scientific community at large other than case reports. Nonetheless the plaintiffs and their experts argued that the court should totally defer to experts who claimed to have used this amorphous "weight of the evidence" methodology.

In *In Re Denture Adhesive Cream Litigation*, 2014 Phila. Ct. Com. Pl. Lexis 135 (Common Pleas Court, Philadelphia Cty. 2014), the plaintiffs attempted to establish a causal connection between a medical device and a particular neurological condition. In those cases, Dr. Smith misapplied the Bradford Hill criteria when he attempted to use the criteria for considering causation without first establishing

a statistically significant association—a threshold requirement before using the Bradford Hill methodology. Nevertheless, the plaintiffs argued that Dr. Smith's causation conclusions were scientifically reliable because he said he used the "weight of the evidence" approach by claiming that he integrated all available evidence. In applying the *Frye* standard, the court flatly rejected Dr. Smith's opinions for that reason:

> Importantly, the Bradford-Hill criteria are to be applied only after an epidemiological association has been established. See id. As is noted above, Dr. Lautenbach's expert report does not provide a sound epidemiological basis from which to conclude there is an association between Fixodent and copper deficiency myeloneuropathy. Similarly, Dr. Smith's report does not contain any other source from which to conclude such an association exists. Thus, the Court is left to conclude Dr. Smith applied the Bradford-Hill criteria without first having an epidemiological association. Plaintiffs have not provided any evidence to suggest the application of the Bradford-Hill criteria in the absence of an epidemiological association has been generally accepted by the scientific community. Since it is based on a scientific methodology that has not been generally accepted by the scientific community, Dr. Smith's testimony must be precluded.

*Id*. at *40–41.

**Put into context,** under currently existing *Daubert* standards, a court is permitted to scrutinize each piece of scientific or medical evidence to determine sufficiency and reliability, to reject junk science and ultimately to make sure that experts introduce opinions in litigation based only on literature that is scientifically or medically reliable.

Moreover, in a return to the reasoning of the courts in *Magistrini* and *Scaife*, the court recognized that simply stating that an expert followed something called a "weight of evidence" approach could not serve as a substitute for a scientifically acceptable methodology:

> Dr. Smith's "weight of the evidence" test fails to conform to even the most basic definition of scientific methodology since there is no way for other scientists to test or replicate Dr. Smith's "weight of the evidence" analysis. As the Superior Court has noted, a key component of any scientific methodology is the ability to test a hypothesis through replicated experimentation. [*39] *Trach v. Fellin,* 817 A.2d at 1113 (stating "Key aspects of the scientific method include the ability to test or verify a scientific experiment by a parallel experiment… and to replicate the experiment to expose or reduce error"). Here, Dr. Smith's "weight of the evidence" methodology does not have any predetermined standard for weighing the evidence. Dr. Smith Deposition, Moving Defendants' Motion at Ex. 51, 81:4-12 (September 25, 2012). It is axiomatic that if there is not a predetermined standard for weighing evidence, then another scientist will not be able to replicate Dr. Smith's analysis because the other scientist will not know how to weigh certain evidence. Dr. Smith admitted the same in his deposition. Id. at 83:9-11. Accordingly, Dr. Smith's methodology cannot be replicated to expose or reduce error. For this reason, Dr. Smith's "weight of the evidence" methodology must be rejected because Plaintiffs have not produced any evidence to show general acceptance of a methodology that cannot be tested or replicated.

*Id*. at *39–40.

## The "Weight of the Evidence" Approach in the Scientific Community

There is yet one other reason why the "weight of evidence" approach as presented and rejected in the Pennsylvania case discussed previously is misplaced. It simply does not exist as a recognized published scientific methodology.

In 2005, Dr. Douglas Weed, an epidemiologist, undertook a systematic review of the phrase "weight of the evidence" as used in the scientific community. Douglas Weed, *Weight of Evidence: A Review of Concepts and Method,* Risk Analysis, Vol. 25, No. 6, 2005. In this review, the author identified three different uses of the term. The first use of the term is "methaphorical" without any identifiable methodology, but instead merely descriptive of a body of evidence without any objective quantification. The second use of the term is methodological in nature "with a fairly simple premise: that *all* available evidence should be examined and interpreted." The third way that the term is used is "to refer to well-known methods for summarizing and interpreting scientific evidence." It is the third use that would include the traditional types of scientific methods generally considered by the courts, such as "systematic narrative reviews, … criteria-based methods of causal inference, … the statistical technique of meta-analysis, or… some combination of these well-known (and oft-debated) techniques, some more qualitative than others." In this respect, the term "weight of evidence" is entirely consistent with a court's traditional gatekeeping role.

## The Dilution of Credible Scientific Research

For those who question whether a court should defer to an expert's "integration" of all available evidence, there is an even bigger concern related to the reliability of the literature itself. This point is accentuated in a recent article "Blinded by Scientific Gobbledygook." *See* Tom Speers, Blinded by Scientific Gobbledygook, Ottawa Citizen, Apr. 14, 2014, http://www.ottawacitizen.com/technology/Blinded+scientific+gobbledygook/9757736/story.html (last visited July 30, 2014). The author of this article intentionally put together what he describes as the "world's worst science research paper."

The research paper was entitled "Acidity and aridity: Soil inorganic carbon storage exhibits complex relationship with low-pH soils and myeloablation followed by autologous PBSC infusion." The author intentionally combined unrelated concepts of soil science and stem cell cancer treatment to create a nonsensical topic for his paper. He then included graphs from a paper about Mars and footnotes from a paper on wine chemistry. Portions of the paper were blatantly plagiarized. He purported to be from the nonexistent University of Ottawa-Carleton, referenced the fictitious Nepean Desert, and listed an imaginary co-author.

This paper was submitted to 18 journals for publication. Within 24 hours, the author received a response from one claiming that a "peer reviewer" read the paper and gave it a glowing review, offering to post it online for $500. In total, seven journals accepted the paper for publication, including one that discovered that the author had plagiarized from other works. In fact, one of the journals offered the author a position on the editorial board, which would have put him in a position to judge others' work.

The point is that these predatory "journals" offer opportunities for publication of nonsense under the guise of "scientific research." The pressure on researchers young, old, and in-between to publish, coupled with these avenues for publication, have substantially diluted the legitimacy and reliability of some published scientific research.

Put into context, under currently existing *Daubert* standards, a court is permitted to scrutinize each piece of scientific or medical evidence to determine sufficiency and reliability, to reject junk science and ultimately to make sure that experts introduce opinions in litigation based only on literature that is scientifically or medically reliable. Simply stating that an expert reviewed "peer-reviewed" literature does not preclude analysis of the legitimacy of the conclusions reached in that literature. In particular, the U.S. Supreme Court has identified peer review as one of the critical factors. In contrast, under the purported "weight of evidence" approach, if "all available evidence" is considered and rises to a certain undefined level, scientists or paid experts acting as advocates would be permitted to offer opinions on general and specific causation without a court taking the necessary steps to evaluate the sufficiency of the underlying evidence. This would result in a backdoor gutting of *Daubert* and everything that it stands for in our legal system.

## Practice Tips

We have six critical practice tips designed to handle the "weight of the evidence" approach when you encounter it in litigation.

The first may seem obvious, but is worth mentioning. At the outset, ascertain what the epidemiological literature says. Look behind the literature. Read the references. Do they support the propositions for which the literature cites them? Read the references of the references. Engage an epidemiologist or biostatistician or both to help you understand the literature and to develop strategies to use the literature to your client's advantage.

Second, when you develop a strategy to deal with *Milward* and the "weight of the evidence" approach, it will be important to do two things. Understand the law in your circuit or your state, which may well be different. Carefully analyze the science and methodology used by the expert in *Milward* so that you understand the two distinctions to be drawn: the distinction between the methodology used by the expert in your case and the methodologies that courts in your jurisdiction have found acceptable.

Third, if a plaintiff's expert states that he or she has "extrapolated," which has happened more and more with experts in drug and medical device litigation involving chronic or latent or rare situations, carefully analyze that from which the expert has inferred or extrapolated to undermine the extrapolation or inference for *Daubert* purposes.

Fourth, carefully scrutinize previous work and published materials by the proffered expert to find examples of methodologies used by that expert in studies or work done outside of a courtroom that are of a higher quality of scientific rigor than that used by the expert when living in the litigation world.

Fifth, identify situations in which reliance on descriptive evidence alone or unreplicated studies or both led to conclusions that were later disproved, as has happened with silicone breast implants, vaccines and autism, and analogize that situation to your own as proof of the unreliability of the proffered expert evidence.

Finally, if an association is described in the literature, identify whether it is an epidemiologic association or the literature simply uses the word association more generally. Remember, an epidemiologic association must exist before a causation assessment can be conducted. FD