



2.0 Is a Magic Number

By Knight S. Anderson

A look at how defense counsel and courts should treat several important concepts regarding evidence and expert testimony for purposes of admissibility.

Yes It Is. It's a Magic Number

Although as Paracelsus said, “[a]ll things are poison, and nothing is without poison; only the dose permits something not to be poisonous,” the law requires more than this contention before an expert can opine in a court of law

that an “exposure” to an agent more likely than not caused a plaintiff’s alleged injury, and it should require even more. With toxic torts, the three most important things usually are dose, dose and, well, dose. And the construct that the dose makes the poison is not limited to those agents that we commonly consider “poisons.” Rather, ubiquitous substances, such as water, common over-the-counter substances such as vitamins and aspirin, and even everyday foods such as peanut butter can become deadly when consumed in sufficient quantities. Yes, that is right, deadly. But before anyone blames an ingestion of an agent for a disease, he or she should have a scientific basis for doing so. It is truly the dose that makes a substance injurious or deadly, which may vary greatly among substances as demonstrated through scientific inquiry. In light of this, courts must require experts offering opinions on causation in litigation that has alleged a cause and effect relationship between an “exposure” to an agent and a disease or injury to base an opinion on a

sufficiently established relationship and demonstrate that the “exposure” that a particular plaintiff received to a specific agent was sufficient, as demonstrated by science, to have more likely than not caused that plaintiff’s disease or injury.

A plaintiff must establish a relationship between the specific agent and the disease or injury, identify the dose of a specific agent that a plaintiff received, demonstrate that the medical and scientific literature reliably suggests that that dose can cause that disease or injury, and exclude other causes to proceed and prevail with claims. This standard is grounded in the rules and cases law, and defense counsel must make sure that a plaintiff’s expert meets it, and a judge must act as a gatekeeper to exclude unreliable opinion evidence, particularly on causation, when science or medicine does not support an expert’s causation arguments or the evidence does not constitute “scientific evidence.” This article discusses the standards governing reliable scientific evidence and expert testimony



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reliability, whether a cause and effect relationship exists between an exposure and an alleged injury, generally accepted scientific thresholds established by epidemiological studies that can meet the preponderance of the evidence standard required to establish causation and from which an expert can reliably infer a relationship between the dose that a plaintiff experienced and an alleged injury, insufficiently alleged causal connections, and how defense counsel and courts should use these concepts for evidence and expert testimony admissibility purposes.

In Through the Out Door

Federal Rule of Evidence 702, which governs the admission of expert testimony in the federal courts, 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 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 the case.

Fed. R. Evid. 702.

A rule 702 determination is a question of law for a court. Thus, when a party seeks to admit expert testimony, a court should make an initial determination during a preliminary hearing under Federal Rule of Evidence 104(a) that the requirements of rule 702 have been met. In *Daubert*, the Supreme Court held that Federal Rule of Evidence 702 imposes a special obligation on a trial judge to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.” *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993).

In *Daubert*, the Supreme Court offered judges some guidelines regarding the admissibility of scientific evidence and then commented and expounded on that framework and those guidelines in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997). As others have mentioned elsewhere numerous times, the *Daubert* factors are not an exhaustive list of criteria that courts must

strictly apply to all evidence to determine admissibility, but rather the Court articulated a flexible standard for determining the admissibility of scientific opinions to ensure that expert scientific opinions are grounded in a reliable methodology before courts admit the opinions. This “flexible *Daubert* inquiry gives the [trial judge] the discretion needed to ensure that the courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact.” *Amorgianos v. National Railroad Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). *Daubert* and its progeny have acquired a reputation as a cure for the erroneous admission of junk science, or at least as a shield against it, and these cases impose a high standard on plaintiffs seeking to admit such opinions, one of the cornerstones of which is reliability. A judge acting as a gatekeeper should apply *Daubert* and other evidentiary standards that require indicia of reliability before admitting an opinion to ensure that a jury hears only opinion testimony that actually constitutes “scientific evidence.” And in presiding over the reliability inquiry, a judge needs “to make certain that an expert... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149–50 (1999).

Daubert held that a trial judge is required to conduct a “preliminary assessment of whether the reasoning or methodology underlying the [expert] testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” Furthermore, “[b]y holding that the admissibility of scientific testimony is governed by Rule 104(a), *Daubert* clearly holds that the party seeking admissibility must make out more than a prima facie case of reliability.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744, n.9 (3d Cir. 1994). And the party proffering the expert testimony has the burden of demonstrating “that the expert’s findings and conclusions are based on the scientific method, and, therefore, are reliable.” *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998) (en banc). *Daubert* requires a reliable expert opinion but not necessarily a correct opinion. This

reliability inquiry “requires some objective, independent validation of the expert’s methodology. The expert’s assurances that he has utilized generally accepted scientific methodology is insufficient.” *Id.* (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (on remand)). And in undertaking the reliability inquiry, it is the district court’s respon-

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sibility “to make certain that an expert... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149–50 (1999).

As the Supreme Court wrote in *Daubert*, “to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Daubert*, 509 U.S. at 590. This means that a court must make “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 592–93. *In re Paoli* noted that (1) the “proffered” witness must be a qualified expert; (2) the expert must testify about matters requiring scientific, technical, or specialized knowledge; and (3) the

expert's testimony must "fit" the facts of the case. *In re Paoli R.R.*, 35 F.3d at 741-42 (3d Cir. 1994). See also *Kannankeril v. Terminix Int'l Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). Additionally, in response to the Supreme Court decision in *Daubert*, Federal Rule of Evidence 702 was amended in 2000: "The amendment affirms the trial court's role as gatekeeper and provides

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some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony." Fed. R. Evid. 702 advisory committee's note to 2000 amend.

The rule 702 inquiry requires that a court determine that an expert has reliably based his or her testimony on scientific methods. *Daubert* explains that the rule 702 language requiring an expert to testify to scientific knowledge means that the expert opinion must have a basis in "the methods and procedures of science," as opposed to "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. An expert must have "good grounds" for his or her belief. *Id.*

The factors that courts have articulated to guide assessing the reliability of proffered scientific expert testimony include several articulated in *Daubert* and in other decisions: (1) whether the theory or technique can be tested, (2) "whether the the-

ory or technique has been subjected to peer review," (3) whether the technique has a high rate of "known or potential error," (4) whether standards "controlling the technique's operation exist," (5) whether the theory enjoys "general acceptance," (6) whether there is a sufficient relationship between the technique and methods which have been established to be reliable, (7) whether the expert witness' qualifications are sufficient, and (8) whether the method has been put to nonjudicial uses. Some courts also consider additional factors, including (1) whether the expert's proposed testimony grows naturally and directly from research that the expert has conducted independent of the litigation; (2) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (3) whether the expert has adequately accounted for alternative explanations; (4) whether the expert took as much care in forming the opinion for the litigation as he or she would in performing his or her professional work in other contexts; and (5) whether reputation indicates that the field of expertise of the expert reaches reliable results for the type of opinion proffered by the expert. The Supreme Court in *Daubert* emphasized that the rule 702 inquiry is "a flexible one" and that the individual factors are neither exclusive nor dispositive. Courts should not exclude "novel" conclusions when reliable methodology and reliable methodological application underpin the conclusions. A court's inquiry "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. And as explained in another decision, "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. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 147.

Experts often rely on epidemiological studies to support their opinions: Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations. The purpose of epidemiology is to better understand disease causation and to prevent disease

in groups of individuals. Epidemiology assumes that disease is not distributed randomly in a group of individuals and that identifiable subgroups, including those exposed to certain agents, are at increased risk of contracting particular diseases. Michael D. Green, *et al.*, Reference Guide on Epidemiology, in Fed. Judicial Ctr., Reference Manual on Scientific Evidence at 551 (3d ed. 2011).

While some courts have pointed out that *Daubert* neither requires epidemiological evidence nor epidemiology-based expert opinions, others have referred to valid, reliable, and statistically significant epidemiological studies as "critical" and "indispensable" when demonstrating causation. For example, in evaluating the reliability of opinions related to cause and effect for exposure to Agent Orange and the chemicals that Agent Orange contained, Judge Weinstein engaged in a detailed assessment and discussion of scientific evidence and concluded that "sound epidemiological studies are the only useful studies having any bearing on causation." See *In re "Agent Orange" Product Liability Litigation*, MDL No. 381, 611 F. Supp. 1223, 1240 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987). The courts have broadly recognized epidemiology as invaluable to determining that a cause and effect relationship existed and specifically caused a disease experienced by a particular plaintiff. See, e.g., R.E. Hoffman, *The Use of Epidemiologic Data in the Courts*; *Sorenson v. Shaklee Corp.*, 31 F.3d 638 (9th Cir. 1994); *DeLuca v. Merrell Dow Pharm., Inc.*, 911 F.2d 941, 954 (3d Cir. 1990), *aff'd*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 510 U.S. 1044 (1994); *Wilson v. Merrell Dow Pharmaceuticals, Inc.*, 893 F.2d 1149, 1154 (10th Cir. 1990). That said, as mentioned, the factors listed in *Daubert* are not exhaustive, and several courts have held that the legal standard does not require plaintiffs to prove causation only with statistically significant epidemiological evidence. However, courts should either exclude or at the very least subject the opinions that experts do not support with epidemiological evidence to strict scrutiny when the science widely accepts epidemiology as the reliable method for demonstrating a cause and effect relationship in humans in the scientific field involved in a case.

Defendants and defense counsel have waged a campaign against “junk science” ever since *Daubert* made that phrase infamous and common parlance among attorneys involved tort litigation. In addition to meeting other responsibilities, judges must now also assess the validity of scientific evidence. And lawyers and judges today continue to wrestle with whether expert testimony meets the criteria for admissibility.

Judges and the lawyers responsible for educating them about the scientific evidence in their cases need to know more than what makes good science; they need to understand how to identify insufficient or even bad science and explain what makes it so. Court decisions reflect judicial recognition that courts in fulfilling their gatekeeping function have an obligation to keep “junk science” out of courtrooms. While sound public policy reasons underlie the broad discretion that trial courts have to admit evidence, sound public policy also requires judges to assess expert testimony carefully to determine both its relevance and reliability before the courts admit it. Expert testimony, whether presented by plaintiffs or defendants, can strongly influence juries. As the United States Supreme Court recognized, “expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. at 595 (quoting Jack B. Weinstein, Rule 702 of the Federal Rules of Evidence Is Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)). For these reasons,

neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the “gatekeeper” duties that the Federal Rules impose.... To the contrary, when law and science intersect, those duties often must be exercised with special care. Today’s toxic tort case provides an example. To the contrary, when law and science intersect, those duties often must be exercised with special care.

Joiner, 522 U.S. at 148 (J. Breyer concurring).

Blinding Me with Science

Tort law uses the term “specific causation,” sometimes called “individual causation,” to refer to which particular events will cause or may have caused a particular injury in a specific plaintiff. Usually, for a plaintiff

to win damages in a tort case, the plaintiff must prove both general and specific causation. To win damages the law requires sufficient scientific support for any alleged claims for injury resulting from an alleged exposure to a toxic substance, and defense counsel and the courts must make sure plaintiffs meet this requirement. Plaintiffs and their experts must establish that science supports the existence of a cause and effect relationship, the plaintiff received a particular dose of the specific agent, and the medical and scientific literature has identified a link between that particular dose of that specific agent and the particular alleged disease or injury. A reliable, admissible expert opinion on the issue of causation in a toxic exposure case must demonstrate a reliable basis for the cause and effect relationship. The proponent of specific causation evidence must show that the “exposure” experienced by a plaintiff to a specific agent has been reliably shown in science and medicine to cause the particular alleged injury.

As mentioned, experts often support specific causation testimony by testifying about epidemiological studies. Epidemiological studies have conceptual roots in scientific experimentation. The “scientific method” is the established approach used by epidemiologists and other scientists to study the potential existence of a cause and effect relationship. Generally speaking, as with all science, epidemiology depends on measurements, on precision, and on validity. An epidemiological study without proper measurements does not follow accepted scientific practice, and the scientific community will not accept a study without proper measurements or that other scientists cannot verify independently because other researchers in the community cannot confirm its conclusions. Epidemiological studies help us understand disease causation and the likelihood that a population exposed to an agent may develop disease, and they help us identify and prevent disease in groups of individuals. These studies express risk or relative risk, interpreting risk on a more likely than not basis that is well-suited to the preponderance of the evidence legal standard.

An epidemiological study generally starts with an initial observation, sometimes from a “case” report that—a person with disease, referred to as a “case,”

received a particular exposure. From there, a cause and effect hypothesis is developed. The hypothesis is then tested with properly conducted research studies with appropriate referent groups. These studies must rigorously test the hypothesis and seek to establish reproducibility. When epidemiologic experiments are feasible, they are designed to reduce variation from extra-

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neous factors, meaning things not under study, compared to study factors. Most epidemiological studies are nonexperimental because of ethical and financial restrictions. Nonetheless, the goal of nonexperimental studies is to obtain valid evidence about the hypothesis under study.

A proper epidemiological study must include clear definitions of both a disease, or more generally, the outcome, and the exposures that are under study. The outcome must be defined in a manner that is accepted within the medical community, typically based on physiological and pathological criteria. The diagnostic criteria must be reliably and consistently applied to all subjects included in the study. The exposure must be defined in such a way that the determinations of which subjects have been exposed are both reliable and valid. Researchers must describe the criteria for outcomes and exposures with sufficient detail so that other qualified scientists can replicate the research methods.

There are two basic types of nonexperimental epidemiological studies: cohort studies and case-control studies. A cohort study is closely related conceptually to an experiment. Different exposure groups are compared to find out whether their outcomes differ. A case-control study compares

people who have the outcome, or the disease, to those who don't have the outcome to find out whether the groups differ in terms of their past exposures. A person without the disease is referred to as a "control." In both types of study, there is a comparison or referent group. A principal goal of incorporating a referent group is to reduce variation due to extraneous factors—things not

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under study—compared to study factors. A cohort study typically begins by identifying a group consisting of individuals who have been exposed to a particular substance—a potential cause of a disease—and a referent group consisting of individuals who have not been exposed. The epidemiologist then compares the outcomes, meaning, for instance, the disease rates, in the exposed and unexposed groups. Case-control studies are derived from a source population, which hypothetically represents a source population in which a cohort study could be conducted. The cases are then identified and their previous exposure status is ascertained. The control group is selected as a representative sample of the source population that gave rise to the cases. The epidemiologist then compares the odds of exposure among the cases to the odds of exposure among the controls.

Cohort and case-control studies seek to determine whether an association exists between an exposure and the disease being studied. An association exists when exposure and outcome—disease—occur together more frequently than would be expected by chance. For example, in a cohort study, there is an association when the disease rate in the exposed group is higher than the disease rate in the unex-

posed group. The disease rate in the unexposed group represents the disease rate due to extraneous factors that are not under study and that are randomly distributed in the population and expected by chance. In a case-control study, an association exists when the frequency of exposure, or more correctly, the odds of exposure, is higher among the cases than it is among the controls. The existence of an association in an epidemiological study does not mean that there is cause and effect relationship. Inferences about cause and effect require additional considerations.

Diseases have background rates in the general population so that in any given group of people someone would expect to find a certain number of cases of the disease in the absence of the exposure under study. Simply finding that some people who have experienced a particular exposure also have the disease does not prove any relationship between the two and cannot serve as a basis for a scientist to conclude that the exposure is associated with the disease, much less cause the disease. Insofar as the disease has a background rate in the general population, the crucial question is whether people with a particular exposure develop the disease more frequently than people without the exposure, and that can be determined only in properly conducted epidemiological studies.

A central requirement of epidemiological studies is to avoid bias. Bias is the introduction of systematic error into the risk estimate as a result of improper study design. "Selection bias" occurs when cases are chosen in a manner that is not independent of their exposures, or when the manner in which controls are chosen makes them unrepresentative of the source population from which the cases arose. In either instance, selection bias can introduce a systematic error into the estimated association between outcome and exposure. "Information bias" occurs if the data is obtained in a different manner across study groups. For example, if the diagnostic evaluation, the diagnostic criteria, or likelihood of seeking medical care differs between exposed and unexposed subjects, the exposed group may have a higher chance of being classified as cases than the unexposed group simply because they received different medical care. A second example would be if cases

and controls were determined to have been exposed using different criteria or based on differences in the investigations of past exposures. If more or different effort were expended in determining the past exposures of cases than of controls, this systematic difference would introduce error into the estimated association between outcome and exposure. Either type of bias will call the reliability of a study into question. The existence or absence of an association is measured mathematically as a "relative risk." In a cohort study, that relative risk can be expressed numerically as a standardized incidence ratio (SIR), a standardized mortality ratio (SMR), or a proportionate mortality ratio (PMR). Each is calculated by dividing the number of incident cases of disease (or deaths) by the number of incident cases of disease (or deaths) that would be expected if the study population had the same disease rate (or mortality rate) as the referent population.

In a case-control study, the potential existence of an association is measured by the calculation of an odds ratio (OR). An odds ratio is determined by comparing the odds that a case (a person with a disease) was exposed, to the odds that a control (a person without the disease) was exposed. If, for example, among 10 cases five were exposed and five were not exposed, the odds of exposure among cases would be $5/5=1.0$. If from among 12 controls, three were exposed and 9 were not exposed, the odds of exposure among controls would be $3/9 = 0.33$. The odds ratio (OR) is the ratio of the odds among cases to the odds among controls. In this example, this would mean that $OR = 1.0/0.33 = 3.0$.

"Relative risk" is an umbrella term used to describe the various measurements of association used in both cohort and case-control studies, including standardized mortality ratio (SMR), standardized incidence ratio (SIR), proportionate mortality ratio (PMR), or odds ratio (OR), among others.

A case-control or cohort study that shows a relative risk of less than 1.0 suggests that the agent is associated with a reduced risk of the disease or mortality.

A case-control or cohort study that shows a relative risk of 1.0 indicates that no association between the agent and the disease or mortality exists.

A case-control or cohort study that shows a relative risk above 1.0 suggests the existence of an association between the agent and the disease or mortality.

A case-control or cohort study that shows a relative risk of 2.0 indicates a two-fold association between the agent and the disease and that one-half, or 50 percent, of the incidence of disease or mortality is attributable to the agent and one-half is attributable to other factors, or a doubling of the risk. This suggests that the disease is just as likely to be related to the exposure to the agent as it is to be unrelated to the exposure to the agent, a 50/50 proposition of causation.

A case-control or cohort study that shows a relative risk greater than 2.0 indicates that more than one-half or 50 percent of the incidence of the disease or mortality is attributable to the agent and less than one-half is attributable to other factors. This suggests that more likely than not the disease is related to the exposure to the agent, or a > 50 percent chance of causation.

Because a plaintiff needs proof of specific causation to satisfy the plaintiff's burden of proof, specific causation proof often becomes a litigation focus. Proof of specific causation generally has two elements. A plaintiff initially must show that the level of an agent that he or she was exposed to under the circumstances of exposure, meaning the exposure frequency, dose, duration, and intensity, can cause the illness that he or she developed. This is when epidemiology becomes vitally important. And "there plainly is a hierarchy to these different indirect forms of toxic effect evidence. Epidemiology is at the top, and structural similarity, in vitro testing, and case reports are at the bottom." Federal Judicial Ctr., *Reference Manual on Scientific Evidence*, *supra*. Additionally, to use epidemiological studies properly as the basis to prove specific causation, the proponent must show that the exposure did more than simply increase the hypothetical risk of injury. Rather, as logic, science, and the law suggest, and as some courts have held, a study must show at least a doubling of the risk of the harm, a "more likely than not" chance of association. Courts, borrowing scientific terminology, often refer to the doubling of the risk as a "relative risk" of greater than two.

Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1321 (9th Cir. 1995) (finding that for epidemiological testimony to be admissible to prove specific causation, there must have been a relative risk for a plaintiff of greater than two). Many courts have "found that the requirement of a more than 50 percent probability means that epidemiological evidence must show that the risk of an injury or condition in the exposed population was more than double the risk in the unexposed or control population" to establish by a preponderance of the evidence or "more likely than not" standard that there is an association sufficient to consider causation. *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997).

Add It Up

As noted above, toxic exposure cases are, or at least they should be, about dose and science. And if the circumstances of a plaintiff's exposure cannot be demonstrated and shown by reliable science to present a sta-

tistically significant increased risk that that "exposure" more likely than not caused the disease, in the words of Robert DeNiro as Al Capone in *The Untouchables*, "You got nothing. You got nothing in court.... Nothing. NOTHING." Not only must expert opinion testimony on the issue of causation be based upon "something," a plaintiff must show that this "scientific" knowledge and the methodology used to reach an ultimate conclusion is reliable, generally accepted, or both.

In law, the preponderance of the evidence standard usually requires just enough evidence to make it more likely than not that what a party alleges is actually true. While many courts do not translate the standard statistically, it is often described as > 50 percent or 51 percent. As mentioned above, the existence or absence of an association between an exposure to an agent and a resulting injury can be measured mathematically and expressed as a "relative risk," an "odds ratio," or an "attributable

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risk.” Again, “relative risk” is an umbrella term used to describe the various measurements of association used in both cohort and case-control studies mentioned above, which can include a standardized mortality ratio (SMR), a standardized incidence ratio (SIR), a proportionate mortality ratio (PMR), an odds ratio (OR), others, or a combinations of them.

Testimony offered on these topics moves from the scientific to the hypothetical and has spawned a variety of unspecific and very unscientific “catch phrases” summarizing the bases of causation opinion theories.

As mentioned above, a scientific study (case-control or cohort study) that shows a relative risk of 2.0 indicates a two-fold association between the agent and the disease or suggests a doubling of the risk that the agent, in fact, will cause the disease. This means that the incidence of the particular disease or mortality is attributable to the agent and one-half is attributable to other factors. Thus a relative risk of 2.0 suggests that the disease is just as likely to be related to the exposure to the agent as it is to be unrelated to the exposure to the agent. Again, as mentioned above, a study that shows a relative risk of greater than 2.0 indicates that more than one-half of the incidence of the particular disease or mortality is attributable to the agent, in other words, more than 50 percent, and less than one-half is attributable to other factors. Thus a relative risk of > 2.0 suggests that more likely than not the disease is related to the exposure to the agent: a > 50 percent chance of causation. A relative risk of > 2.0 is equivalent to the “more likely than not” preponderance of the evidence legal standard. To learn more about the “more

likely than not” standard, epidemiological evidence, and a “relative risk” of 2.0, see *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 957–59 (3d Cir. 1990).

While sometimes referred to as a “talisman,” there is nothing particularly magical in science or epidemiology about a relative risk of 2.0, particularly when compared with a 1.99999999 or a 2.00000001. However, in a toxic tort case, 2.0 is the actual scientific statistic delineating the difference between more likely and less likely and the place where relative risk, indeed, becomes a magic number.

Take Another Look

Also worth reexamining, and essential if you are litigating your case in a federal court, is the Federal Judicial Center *Reference Manual on Scientific Evidence*. See *Reference Manual on Scientific Evidence* (3d ed. 2011). In 2011, the National Academy of Sciences published the third edition of the *Reference Manual on Scientific Evidence*, which was created by a panel of judges, scientists, engineers, and doctors and serves as a resource for judges to consult when dealing with scientific evidence. The topics covered in the third edition of the manual are the admissibility of expert testimony, how science works, forensic identification expertise, DNA identification evidence, statistics, multiple regression, survey research, estimation of economic damages, exposure science, epidemiology, toxicology; medical testimony, neuroscience, mental health evidence, and engineering. Many judges, both state and federal, rely on this manual as the first and perhaps even the last word on certain issues. The reference manual addresses the necessary link between exposure and disease and how that causal nexus may be established, reliable exposure assessment, and the valid and reliable scientific reasoning necessary to support the link between the exposure of a plaintiff to the specific agent at issue and the disease in that plaintiff. The manual offers questions relevant to evaluating science in a legal context, including the following:

- What are the sources of exposure?
- What are the specific agents involved in the exposure?
- What is the duration of exposure, and what is the basis for that conclusion?

- What are the pathways from the source to the exposed individuals?
- Have those pathways been established?
- What is the concentration of the agent in the media with which the exposed population came into contact?
- What is the basis for these answers? Direct measurement? Estimates? Modeling?
- If models or estimates were used, how reliable are they?
- What is the variability over time in concentrations in the media of concern?
- What is the variability over time in concentrations in the pathways of concern?
- How has the variability been determined?
- What is the variability among members of the population in their exposure to the chemical of concern and how is this known?
- What dose, over what period of time, by which routes, has the individual received?
- What cumulative dose did the individual receive?
- What calculations and evidence support this documentation?
- What is the likely error rate in the exposure estimates?
- What uncertainties are associated with the dose and duration findings?
- What has been omitted from the exposure assessment, and why?
- Has the cumulative dose of the exposure that the individual received to this specific agent been shown by reliable and statistically significant scientific evidence to cause the particular disease?

2.0 Is a Magic Number

Before an expert may offer an opinion that an “exposure” to an agent was more likely than not the cause of an alleged injury, a plaintiff must show that the plaintiff was “exposed” to a quantifiable estimated dose of a specific agent and that that dose of that specific agent has been shown by reliable scientific evidence to more likely than not cause the injury. Thus, there should be reliable epidemiological studies in the peer-reviewed published medical and scientific literature that suggest that the dose of that specific agent creates a statistically significant increased relative risk of greater than 2.0 of developing the particular alleged injury.

Magic Number, continued on page 81


Ethics, from page 79

oped competency, it is time to step over the threshold. As a professional, you will need to treat a pro bono case as you would any other representation for which you receive compensation. Just as you would handle a case for a client for which you received \$150 per hour the same as you would handle one for which you received \$350 per hour, your pro bono client would have the right

to nothing less than your focused attention and most outstanding representation. In fact, I predict that the financial, emotional, and psychological vulnerability of your pro bono client likely would spur you to work that much harder to succeed.

Lawyers should perceive pro bono representation as an entitlement of the profession rather than as an obligation. As professionals, we don't need a mandatory

rule to understand that pro bono work is integral to being lawyers. As Justice Anthony Kennedy once observed, "it is precisely because our duties go beyond what the law demands that ours remains a noble profession."


Read the rule. Turn aspiration into action. Search for training. Take on a client. Show up. 

Think Globally, from page 78

Switzerland with the German-influenced and Austrian-influenced trial systems of the other mainly German-speaking cantons. So not surprisingly, the enactment of collective redress schemes in the Swiss Civil Procedural Code (SCPC) was never discussed seriously, not only due to fears of overloading the legislative boat, but also due to profound scepticism about the perceived excesses of the U.S. class action system.

It is somewhat predictable that in the

future Switzerland will again discuss whether to amend the SCPC of 2011 to include collective redress mechanisms. Efforts to introduce collective redress systems in Switzerland might achieve momentum again in light of numerous mass cases in the banking, insurance, and fund industries during the ongoing financial crisis that started in 2007. The Swiss telecom industry with its de facto monopoly and the view that its consumers pay too much might also generate discussions about whether collec-


tive redress could lead to substantial telcom price decreases, while similar factors apply to Swiss consumers affected by a fair number of still existing horizontal monopolies. A harmful deep-heat mining project in 2007 causing an earthquake that resulted in thousands of home owners experiencing home damage in the Greater Basel Area might also fuel the discussion about whether the "access to courts" guaranteed by the Swiss Constitution must be secured through collective redress schemes. 

Magic Number, from page 72

When a plaintiff needs to tie causation to one or more particular defendants in a toxic tort case, the case will consider whether an exposure attributable to the defendants was, indeed, a "substantial factor" or a "substantial contributing factor" and a "significant" or a "significant contributing factor" in the development of the disease or injury, and perhaps even whether that disease would have developed "but for" that "exposure" or the defendant's conduct. Testimony offered on these topics moves from the scientific to the hypothetical and has spawned a variety of unscientific and very unscientific "catch phrases" summarizing the bases of causation opinion theories, including "any exposure," "any exposure above background," "all exposures," and the infamous hypothetical "one fiber" theory. Unfortunately courts have

accepted many of these theories as "scientific" without considerable analysis or scrutiny. These are offered as both an opinion and the basis for an ultimate opinion that an "exposure" was a substantial factor in the development of a plaintiff's disease or injury. They are generally offered because in many circumstances someone cannot say that a specific "exposure" was sufficient to cause the injury, or in a multiparty case, which exposure or exposures were causative or sufficient to cause disease. They allow an expert to opine on causation after as little as two minutes of scientific "inquiry" regarding the generalities about a particular case.

Though the question of whether there is evidence suggesting a causal relationship is by no means the only necessary inquiry when examining expert opinion testimony on causation and understand-

ing that epidemiology and, specifically, although a relative risk that is > 2.0 is not a "philosopher's stone" that will turn unreliable science into gold, when the medical and scientific literature presents reliable evidence of a statistically significant relative risk that is > 2.0, it may provide a scientific basis for a causation opinion on a more likely than not basis. And while all practitioners and courts do not agree that a statistically significant doubling of a risk demonstrated by reliable epidemiological evidence absolutely is required to demonstrate the admissibility of an expert opinion regarding a cause and effect relationship between an agent and a disease or injury, when assessing the legal and scientific validity of such expert opinion testimony on causation, 2.0 really is a magic number. Yes it is. It's a magic number. 

Off-Label, from page 27

tionally with the law because it restricted the availability of information that many people find very helpful) (internal citations and quote marks omitted).

The federal ban on off-label drug-use marketing is analogous to the Vermont law

that the U.S. Supreme Court found unconstitutional: at its most basic level, the FDA has prohibited commercial speech, off-label drug-use marketing, without regard for its truthfulness, out of concern that it would unduly persuade the public to make bad decisions. This concern is not a valid justi-

fication for restricting commercial speech because "[t]he choice 'between the dangers of suppressing information, and the dangers of its misuse if it is freely available' is one that 'the First Amendment makes for us.'" *Id.* at 2671 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 770). *Accord Thomp-*