

1. Judges as Lawmakers: *The Remaking of Tort Causation Rules*

Federal trial judges in products liability, toxic tort and malpractice cases have been doing far more than gatekeeping, or screening proposed expert testimony, to determine admissibility. The *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) gatekeeper power has become a tool of tort lawmaking. Under the guise of admissibility determinations, federal judges have been making significant substantive legal rules on causation by substantially raising the threshold of scientific proof plaintiffs need to get their expert causation testimony admitted, and thus survive summary judgment or a directed verdict.

In the process of developing this legal rule, judges in these cases have been making judgments about the social allocation of risk and who should bear the burden of scientific uncertainty or controversy – injured people or manufacturers of the products alleged to have caused those injuries. Few of the opinions announcing or applying this emerging standard of causation acknowledge awareness of the implications of their decisions. Accordingly, the underlying policy debate remains submerged.

Up to now, the rules of the tort system put the onus for uncertainty about the risks of a product on the manufacturer who has marketed it, perhaps without sufficient testing or warning. By doing this, our causation rules enhance the tort policies of deterring marketing of relatively untested products, and promoting expanded research on both the effectiveness and hazards of drugs and medical devices. The tort system in the past has aligned itself more with the public health protective that govern the FDA regulatory arena, where a drug is presumed not safe for marketing unless the manufacturer can prove its safety.

Now, the debate has shifted to whether the tort system instead should embrace the conservative values of the scientific discipline of epidemiology, whose internal disciplinary standards start with a hypothesis of lack of risk, and demands stringent statistical proof of a doubling or tripling of the risk of disease before entertaining the possibility of a causal connection. Federal judges have been using their evidentiary gatekeeper power to squarely align tort law with the conservative causation principles of epidemiology, thus moving the law sharply away from the more consumer protective social policies about risk embodied in the safety regulatory system.

Substantive changes in causation law have been brought about through the rubric of evidentiary admissibility decisions. Judges in this circumstance have merged admissibility decisions into sufficiency of evidence decisions. This has effected a profound but concealed change in tort law. By applying *Daubert* to subject each item of expert proof proffered by plaintiffs to substantive causation law scrutiny, to see if it, standing alone, would prove both general and specific causation. If the scientific studies underlying an expert's opinion are not alone sufficient, then the expert's testimony is deemed inadmissible. This is contrary to the traditional and proper practice, which sees the admissibility of evidence as a question quite distinct from the sufficiency of evidence to meet the plaintiff's burden of proof. The sufficiency inquiry is supposed to view the plaintiff's evidence in its entirety to see if, taken as a whole, it would support a conclusion that causation is more likely than not. By calling what is really a sufficiency of the evidence determination an admissibility decision, judges are using their evidentiary gatekeeper power to close the gate on plaintiff's opportunities to have their proof

evaluated as a cumulative whole. This substantially increases the plaintiff's burden of proving individual causation, and furthers the trend in products and toxic tort cases to shift the allocation of power away from juries to judges. Because a trial judge's decision to exclude evidence is reviewed under the lenient abuse of discretion standard of review, *General Electric Co. v. Joiner*, 522 U.S. 136, 141 (1997), this new heightened substantive standard of causation and judges' applications of it are largely insulated from meaningful appellate review.

This paper explores the history of the issue, the substantive causation law changes, the consequent social policy importance of the changes, the flaws in the approach, and a proposal for Connecticut.

It is essential for an understanding of these developments to examine the leading United States Supreme Court cases, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); and *Weisgram v. Marley Co.*, 528 U.S. 440, 120 S.Ct. 1011 (2000).

2. The Allocation of the Burden of Scientific Uncertainty: *Where Should it be Placed?*

The fundamental policy purposes of the tort compensation system are:

- (1) Compensation of innocent parties;
- (2) Shifting of the loss to responsible parties or distributing it among appropriate entities; and
- (3) Deterrence of wrongful conduct.

Mendillo v. Board of Education, 246 Conn. 456, 482 (1998).

The emerging rule of the federal cases is that plaintiffs' experts must be able to base their opinions about causation on epidemiological studies, and that these studies standing alone must show that a population-wide risk of developing the disease in question, if exposed to defendants' products, is at least double the risk without exposure.

In developing this rule, the judges are making decisions about the social allocation of risk and who should bear the burden of scientific uncertainty, or controversy – the injured plaintiff or the manufacturers.

The process of epidemiological inquiry can be characterized by the formation of a suspicion of causation, followed by slow and careful movement along a continuum from a zero level of certainty about causation towards a level of absolute certainty. The language that epidemiologists and other scientists use to describe their level of certainty is very conservative. It is one that generally understates their degree of certainty about an association between a factor and a disease and about a causal link between these factors. *See, Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1449, App. B.

Indeed, epidemiology is so inherently conservative in its reluctance to

abandon the null hypothesis that it is far more willing to tolerate false negatives - the rejection of a causal association when one may actually exist - than false positives - the attribution of an association when one does not exist. See, *Farrell, Daubert v. Merrell Dow Pharmaceuticals, Inc.: Epistemology and Legal Process*, 15 *Cardozo L. Rev.* 2183, 2210 (1994); *Thompson, Causal Inferences in Epidemiology: Implications for Toxic Tort Litigation*, 71 *N.C. L. Rev.* 247, 249-254 (1992).

This inherent conservatism about accepting the possibility of a causal association is reflected in the high relative risk threshold preferred by epidemiologists, and in the discipline's preference that an association should be replicated in several studies before embracing a causal connection. These rigorous statistical significance standards of certainty about an effect and willingness to accept false positives are the norms of epidemiology "because nothing less than the establishment or confirmation of a predictive rule of nature rests on these test results." *Farrell, supra*, 15 *Cardozo L. Rev.* at 2210.

By being reluctant to abandon the null hypothesis, and thus insisting on very strong associations before doing so, epidemiologists are quite willing to tolerate uncertainty and ambiguity. Courts, however, have to be careful not to be misled by the qualifying tenuousness and unwillingness to speak in legal cause terms that characterize epidemiologists' written or testimonial reports. As one appellate court explained, in chastising a trial judge for rejecting plaintiffs' expert causation testimony because the epidemiological studies were equivocal about causation and called for further study, epidemiology usually speaks in terms of uncertainty because it is not designed to make causal determinations, but only to identify probabilities of a risk association. *Berry v. CSX Transportation, Inc.*, 709 S.2d 552, 558

(Fla. App. 1998).

Moreover, medical science research articles qualify their conclusions and call for further study not as an expression of ignorance, but rather as an expression that all scientific fields are open-ended and can progress from their present state. Epidemiologists do not have to make decisions about who should financially bear a risk, or about how responsibility for ascertaining and reducing a risk should be allocated.

A court, on the other hand, has to make concrete decisions about what is causing a particular person's illness, a question on which statistical associational probabilities are only one form of relevant evidence, and only one relevant policy consideration. In making these individualistic causation judgments, tort law has often recognized that it is doing more than just ascertaining scientific "truth." It is making policy judgments about which party should bear the responsibility for causal uncertainty, and which party is in the best position to learn more about and absorb or spread the costs of the risks.

Our courts have routinely crafted rules of causation, including relaxing the traditional requirements for plaintiffs in order to achieve a tort goal, such as compensation of an innocent plaintiff, deterrence, risk spreading, or plain fairness. *See, Kowal v. Hofher*, 181 Conn. 355, 359-360 (1980); *Sindell v. Abbott Labs*, 607 P.2d 924 (Cal. 1980); *Summers v. Tice*, 199 P.2d 1 (Cal. 1948) (shifting the burden of proof on causation to defendants where plaintiff was unable to prove which of two negligent wrongdoers caused his single injury); *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989) (adopting market share proportionate liability approach when plaintiffs, through no fault of their own, could not prove which of several negligent

manufacturers made the drug that caused their individual injuries); *McKellips v. Saint Francis Hosp. Inc.*, 741 P.2d 467 (Okla. 1987) (allowing plaintiffs to recover proportionate damages when misdiagnosis deprived them of chance of surviving cancer, even though plaintiffs could not prove the malpractice caused their death); *Herskovits v. Group Health Coop.*, 664 P.2d 474 (Wash. 1983) (allowing plaintiff to recover percentage of damages when doctor's delayed diagnosis reduced plaintiff's chance of recovery from terminal illness).

By insisting on an attainment of a scientific certainty which is rarely likely to exist, and which cannot be supplied by epidemiology, a judge is not, like a scientist, just deferring decision until more research becomes available. Rather, a judge is selecting a specific course of action that definitively resolves important social and legal rights: this plaintiff, or this group of injured people, will receive no compensation from the manufacturer, and this product is therefore likely to continue to be marketed and labeled as "safe," even if the epidemiological studies have too quickly embraced a false negative, or when epidemiology shows some increase in risk and other scientific and individual diagnostic evidence bolsters the conclusion that the risk did in fact fall on the plaintiff.

Our courts should not follow the values of epidemiology because the purposes and social goals of our court system have always enjoyed a far broader scope than whether scientists have arrived at a conclusion, or whatever happens to be the scientific "truth" consensus at the moment. The policy considerations central to our courts and to tort law include factors such as which party is better able to bear the risk of injury and scientific uncertainty, the injured plaintiff or the manufacturer, who is able to spread the risk among all consumers.

The tort system will also take into account the consideration that if the uncertainty is due largely to the manufacturers' failure to conduct sufficiently rigorous pre-marketing testing, or post-marketing testing when reports of potential problems arise, then it may be both fair to the injured person and consistent with the goal of deterrence to make the manufacturer absorb the cost of injuries.

The tort system also can make the value judgment that it is better to withhold or withdraw a product from the market, especially a cosmetic or convenience, or non-life saving product, or a product with several equally effective and possibly safer alternatives, until it is more conclusively proven safe, than the alternative of continuing to market a product until it is conclusively proven unsafe.

This is the social value judgment that most consumers endorse. Indeed, consumers often believe that the regulatory system is far more rigorous and effective than it is, and thus assume that if a drug or medical device or food supplement is on the market, it must have been thoroughly tested by the manufacturer or the government and demonstrated to be safe. For this reason, when juries in products liability cases are presented with evidence of minimal testing by manufacturers, or conscious decisions not to follow up on trouble signs in animal tests or adverse post-marketing safety reports, they often find manufacturers liable, including for punitive damages, even in the face of inconclusive or weak individual causation evidence. While manufacturers may certainly view this tendency to determine liability despite uncertain science as alarming, it is reflective of strongly held community values that one should not market a product, especially one to be placed in the human body or ingested by people, without extensive safety testing and heightened concern about danger

signs. When the tort system does not insist on well settled conclusive epidemiology as a threshold requirement for proof of causation, it allows expression of these important community values, it avoids rewarding manufacturers who deliberately choose not to do adequate safety research, and it thus encourages more socially and scientifically beneficial safety behavior by manufacturers.

3. Setting the Stage: *Frye to Daubert*

As a general rule, experts in Connecticut are permitted to give their opinions on questions of skill and science or that relate to some art or trade. *Taylor v. Monroe*, 43 Conn. 36, 43-44 (1875). The test is not whether the subject matter is common or uncommon, or whether many persons or few have some knowledge of the matter, but whether the witness has any peculiar knowledge or experience, not common to the world, that renders his opinion any aid to the trier. *Jaffe v. State Department of Health*, 135 Conn. 339, 348 (1949). "Generally, expert testimony may be admitted if the witness has a special skill or knowledge, beyond the ken of the average juror, that, as properly applied, would be helpful to the determination of an ultimate issue." *Siladi v. McNamara*, 164 Conn. 510, 513 (1973).

Whether a witness is qualified to testify as an expert is largely a matter within the trial judge's discretion. *Oborski v. New Haven Gas Co.*, 151 Conn. 274, 280 (1964). Some facts must be shown as a foundation, but there is no rule declaring what precise facts are necessary in any given situation. *Id.* Expertise may come from practical experience or study alone. *Bryan v. Town of Branford*, 50 Conn. 246, 248 (1882). If reasonable qualifications are established, objections go only to weight, not admissibility. *Sanderson v. Bob's Coaster Corp.*, 133 Conn. 677, 682 (1947). If the witness is shown to have sufficient experience to render his opinion of value on the particular question, the admission of his opinion will not be reviewed unless clearly based on incompetent or insufficient evidence. *Oborski v. New Haven Gas Co.*, *supra*; *Sears v. Curtis*, 147 Conn. 311, 314 (1960). Similarly, the exclusion of an expert is not error unless the witness was clearly qualified. *Siladi v. McNamara*, 164 Conn. 510, 513 (1973); *Wray v. Fairfield Amusement Co.*, 126 Conn. 221, 224 (1940).

The competency of a witness to testify to technical matters is to be determined by an assessment of the nature of the technicality involved and the proposed witness's level of expertise concerning the matter. *Varley v. Varley*, 189 Conn. 490, 501 (1983).

Connecticut had expressly approved the so-called *Frye* Test for determining the admissibility of "evidence derived from innovative scientific techniques," to wit, "general acceptance by the scientific community." *Moore v. McNamara*, 201 Conn. 16, 30 (1986)(human leukocyte antigen (HLA) paternity test); see *Frye v. United States*, 293 F.2d 1013 (D.C. App. 1923).

It is clear that long before the *Daubert* decision state and federal judges were "gatekeepers." They oversaw the quality of testimony before factfinders. For example, if a physician were to testify that his patient's lung cancer was caused by radioactive emanations from a transmitter placed by aliens in his rectum, it is beyond dispute that all judges would have excluded the testimony because its lack of foundation is self-evident.

In recent years, causation testimony has dealt with more subtle questions. In many instances, those steeped in the science of the issues involved claim that causal attributions were bizarre. The nature and extent of these causal attributions in health claims were claimed to have escalated so markedly over the past twenty years, and the alleged bases so creative, that the term "junk science" was coined. This was popularized by Peter Huber in his book *Galileo's Revenge: Junk Science in the Courtroom* (1991). The term is now widely understood to mean science designed for courtroom, or misapplied in the courtroom, to prove scientifically unprovable relationships.

Against this backdrop of courtroom pressures to assign causal relationships, and the claims of big business, manufacturers, and insurers, that courts were falling prey to junk scientists, the *Daubert* decision was announced.

Until 1923, the admissibility of expert testimony focused on an inquiry into whether the expert was appropriately qualified to offer an opinion before the court. The *Frye* test of “general acceptance” arose from questions concerning evidence in a criminal case created by an early forerunner of the polygraph machine. The defendant, Mr. Frye, wanted to present blood pressure evidence in support of the expert opinion that he was telling the truth when denying that he committed a murder. The expert witness was qualified in his field of expertise, and therefore could not be excluded using the traditional qualification test. However, the court limited the expert testimony by ruling that scientific evidence must be generally accepted by others in the expert’s field. Specifically, the court stated (293 F. at 1014):

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, 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.

Critics argued that the “general acceptance” test required judges to make decisions that they were not competent to make; imposed an excessively high burden on the proponents of novel scientific evidence; excluded valuable information at the frontiers of knowledge; and produced arbitrary results depending on how a court defined “the field” in which the evidence had to attain acceptance.

The Federal Rules of Evidence were adopted in 1975, and replaced the

common law of evidence. Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.

Under Rule 702, it was up to the trial judge to ascertain whether the expert is proposing to testify to scientific knowledge that would assist the trier of fact to understand and determine a fact of issue. Many courts began rejecting the *Frye* standard.

The issue finally reached the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* Before discussing the *Daubert* decision and the three cases following *Daubert*, it is necessary to digress to Connecticut law concerning the standard of certainty of an expert's opinion before it can be admitted, and the difference between this standard and the standard of scientific certainty.

4. Fundamentals of Causation in Connecticut

Under Connecticut law, the expert opinion that seeks to establish the causal connection between the injury and the alleged negligence must rest on more than surmise or conjecture. *Shelnitz v. Greenberg*, 200 Conn. 58, 66 (1986). The expert must deal not in mere possibilities, but in reasonable medical probabilities. *Shelnitz*, 200 Conn. at 66. At the same time, it is well established that causation may be proved by circumstantial evidence, *Shelnitz*, 200 Conn. at 66, and that the causal relationship between an injury and its later physical effects may be established by the direct opinion of a physician, by his deduction by the process of eliminating causes other than the traumatic agency, or by his opinion based on a hypothetical question. *Shelnitz*, 200 Conn. at 67.

(a) Degree of certainty.

(i) Reasonable probability.

It is essential that the expert establish cause and effect by an opinion based on reasonable probability. In the case of a physician establishing an injury caused by an accident, the opinion must be based on a reasonable medical probability. The cases all set out the requirement that the cause and effect relation must rest upon more than surmise or conjecture, and that the trier of fact in a tort action is concerned with reasonable probabilities, not with possibilities. *Shelnitz v. Greenberg*, 200 Conn. 58, 66 (1986); *Bombero v. Marchionne*, 11 Conn. App. 485, 489 (1987).

(b) Greater than 50% sufficient. 51% rule.

In *Healy v. White*, 173 Conn. 438, 444 (1977),¹ the court was confronted with a case where the experts had testified as to "odds and percentages." The court held

¹ Overruled in part on different grounds: *Petriello v. Kalman*, 215 Conn. 377 (1990).

that this kind of testimony is acceptable. "Odds" as used in this context, that is a doctor assessing a greater or lesser than 50/50 chance of cause and effect, is defined as the ratio of probability that one thing is so rather than another, or that one thing will happen rather than another.

The court noted that the expert testimony in the case having to do with odds or percentages were clearly in terms of the probable permanence of the plaintiff's condition. The dispute concerned certain brain dysfunction and epilepsy. The doctors testified in terms of statistics and stated that there was a better than 50 percent chance that the plaintiff child would be left with the seizure problem throughout his life. On cross-examination, when pressed on the greater than 50 percent testimony, one doctor testified that the chance was probably 80-90 percent. Another physician stated that there was better than a 60 percent chance the child would have seizures, and that the odds were very much against the child ever being seizure-free. The court held that this testimony was sufficient to establish probable cause and effect and the probable duration or consequences of the injury.

(c) 50/50 opinion insufficient.

The court in *Healy v. White, supra*, distinguished the case from *Davis v. P. Gambardella & Son Cheese Corporation*, 147 Conn. 365, 373 (1960)² where the testimony had been that the plaintiff had a 50/50 chance that his low back condition attributable to the accident would be permanent. In condemning the 50/50 testimony, the Healy court stated (173 Conn. at 444):

In such a situation the ratio of probability is exactly even, and the witness (unlike the witnesses in the present case) is testifying as to possibilities and not probabilities. "For medical opinion testimony to

² Overruled in part on different grounds: *Petriello v. Kalman*, 215 Conn. 377 (1990).

have any probative value, it must at least advise the jury that the inference drawn by the doctor is more probably correct than incorrect. If the probabilities are in balance, the matter is left to speculation. Speculation filtered through a jury is still speculation.

5. The Difference in Legal Cause and Scientific Cause

The difference between the scientific and legal standards of proof of causation has been the subject of several law review and journal articles. *In Causation: A Medico-Legal Battlefield*, Albert Averbach, citing *Cohen, Doctors and Lawyers in Court*, Conn. State Med. J., October 1952, commented:

The methods used in medicine and in law to arrive at the truth are very different. In law it is only necessary that the doctor give an opinion on the probability not the certainty "of a medical fact." When the subject of reasonable probability is approached in court, the doctor begins to hedge. He will not state in the courtroom things about which he may have little doubt privately. He is too inclined to think of himself as a pure scientist and to think of legal proof in the same terms as he does of scientific proof. Unless a statement can be proven conclusively, he rarely admits in court that in his opinion it is so.

6 *Cleveland-Marshall Law Review* (1957), 209, 224.

In *Medical v. Legal Meanings of Causation*, Elliot Sagall, M.D., pinpointed the difference between scientific and legal proof:

Science seeks an absolute cause of a process or condition, one whose existence is demonstrated clearly and without doubt . . .

In legal considerations of cause, emphasis is primarily directed to whether something more likely than not occurred, rather than an absolute demonstration of causation. In other words, there must be "probable" causal connection.

Medical Counterpoint (March, 1970), p. 11.

In *Gaffing at a Thing Called Cause: Medico-Legal Conflicts in the Concept of Causation*, 31 *Texas Law Review* 630 (1953), Professor Ben F. Small used the following metaphor to illustrate the distinction:

A single light bulb may be subjected to a multitude of abuses and still burn for a thousand years. Yet at any time, a single flick of the switch controlling its energy may light it for the last time. The filament's life may end in a sudden last flash of blinding brilliance immediately upon switch-on. What caused it to burn out? A scientist might do an autopsy on the bulb and find cause in an inherent defect or anomaly in the

filament, one existing since its fetal and developmental stages in the factory. Another scientist might find cause in the wear and tear, the increasing vulnerability of the filament with age and use. What about the switch-on? Probably coincidence. The same light had been switched on hundreds of other times with no ill effects. The scientist might admit that a sudden impulse of energy could be a factor, along with others, in the result observed, but cause, no. Only the lawyer would be artless enough to suggest such a thing as proximate cause or occasionment in the scientist's mere factor, and with the suggestion, he would probably hear dark mutterings of "Post hoc ergo propter hoc" or worse.

31 Texas Law Review at p. 657.

Scientists, especially medical practitioners who perceive themselves as scientists, must abandon concepts grounded in scientific principles in order to conform their testimony in court to the legal approach to causation. Danner & Sagall note that a court cannot defer judgment until absolute scientific proof develops and that the legal requirement for establishing proximate cause generally is "probability," "50.1%," "more likely than not," or "reasonable medical certainty" -- all of which are requirements far less demanding than the scientific proof sought by physicians. *Danner & Sagall, Medicolegal Causation: A source of Professional Misunderstanding, American Journal of Law and Medicine, Vol. 3, No. 3 at 303-308.*

Thus, an Ohio court applied the legal standard in a case where the cause of a cancer could not be scientifically proven:

One golden thread shines ever brightly throughout all of the cited authorities. No one knows the medical cause of cancer. However, all law suits, including this one, deal not with the question of medical cause or medical proof to an absolute certainty, but rather with the question of legal causation by a preponderance of the evidence. Therefore, we deal with legal, rather than medical, questions.

Hanna v. Aetna Ins. Co., 259 N.E.2d 177, 24 Ohio Misc. 27, 52 O.2d 316 (1970).

The compelling necessity for an advocate to elicit from a scientific expert an opinion based on the legal standard of causation is apparent. Danner & Sagall pointed out the necessity of acquainting the witness with the legal approach:

When the medical expert is asked the classic question, "Doctor, do you have an opinion, with reasonable medical certainty, as to whether the conduct of the defendant proximately caused the injury and damage to the plaintiff?" his answer will be incorrect unless he fully understands the meaning of legal causation. An answer based upon the medical concept of causation will differ dramatically from an answer based upon legal concept. To respond correctly in court he must base his response on the legal concept.

American Journal of Law and Medicine, Vol. 3, at p. 308 (emphasis added).

6. The Four U.S. Supreme Court Cases: *Daubert*, *Joiner*, *Kumho* and *Weisgram*

(a) *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Daubert arises from the Bendectin litigation. When Bendectin was initially marketed to prevent or reduce morning sickness in pregnant women, the pharmaceutical company had done little research into potential adverse effects, including the potential to produce birth defects. Several women who took Bendectin and then bore children with deformed limbs filed suit on behalf of their damaged children, claiming that the drug was the cause of the birth defects. When some of these initial Bendectin cases went to trial, juries were disturbed by the paucity of safety research conducted by the manufacturer, and by the company's efforts to ignore or misrepresent warning signs in animal studies. The ensuing plaintiffs' verdicts stimulated an exponential growth in Bendectin litigation. *See, Joseph Sanders, Bendectin on Trial: A Study of Mass Tort Litigation (1998).*

The burgeoning litigation and accompanying media attention pushed the Bendectin issue onto the scientific community's research agenda. Numerous epidemiological studies, some with the financial support of the drug company, were conducted, and published results indicated that taking Bendectin during pregnancy did not appreciably increase the risk of bearing a child with birth defects. Despite this mounting scientific evidence tending to exonerate the drug, plaintiffs produced experts who conducted, for purposes of the litigation, reanalyses of the existing studies. These reanalyses were critical of some of the defense oriented studies, some of which were paid for by the drug company which disseminated the drug. Reanalyses showed that the original study excluded women deemed exposed to Bendectin but who did not take the drug until after the critical time of fetal limb

formation. Excluding these women, it showed that Bendectin more than doubled the risk of birth defect development.

When presented with plaintiffs' reanalyses of the epidemiology, and with animal study data and experts comparing the chemical structure of Bendectin to that of known teratogens, some juries still returned verdicts in favor of the plaintiffs, despite the growing body of contrary epidemiology. These verdicts were regarded as aberrational by many members of the scientific community, the defense bar, and some trial judges, and virtually all appellate courts reviewing Bendectin cases. A judicial consensus emerged to parallel the scientific consensus that Bendectin had not been proven to be a teratogen. In response to this scientific consensus, judges employed the technique of judgment notwithstanding the verdict, or ruled that plaintiffs lacked sufficient evidence to satisfy the burden of proof, and gradually adopted a legal rule that unless the plaintiffs could produce a consistent body of statistically significant epidemiological studies that showed that Bendectin at least doubled the risk of birth defects, plaintiffs did not have sufficient evidence of causation to support a verdict. *See, Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799 (D.D.C. 1986); *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307 (5th Cir. 1989).

Other courts when faced with Bendectin cases adopted similar reasoning about the essential threshold of scientific proof, but instead of supplanting a jury verdict, they deemed inadmissible the opinion of any plaintiff's expert who attempted to draw a causal inference based on anything other than statistically significant, peer reviewed, published epidemiological studies that showed a relative risk above the background risk level of two or greater. *See, Lynch v. Merrell Nat'l Labs,*

830 F.2d 1190 (1st Cir. 1987); *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir. 1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988).

In *Daubert*, the Ninth Circuit held that plaintiffs' expert testimony on causation was inadmissible because it did not meet this legal and scientific threshold. The court invoked the ruling in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). *Frye* required that in order to be admissible, a scientific opinion must be "generally accepted" within the scientific community, and that peer review and publication were inviolate requirements of general acceptance. Opinions that were contrary to the weight of a growing body of scientific studies also could not, by definition, satisfy the "general acceptance" standard. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 951 F.2d 1128 (9th Cir. 1991).

Plaintiffs petitioned the United States Supreme Court to review the Ninth Circuit decision. Review was granted on the narrow issue that the *Frye* "general acceptance" rule was outdated, had been superseded by the more liberal Federal Rules of Evidence, and unfairly operated to exclude the scientifically valid, but novel or controversial opinion. The U.S. Supreme Court reversed, holding that the ostensibly more liberal standards of Federal Rule 702 govern the admissibility of scientific expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

The *Daubert* court emphasized that under Federal Rule of Evidence 104(a), the federal trial judge had an obligation to serve as a "gatekeeper" to screen evidence and admit only scientific opinion testimony that comports with Rule 702. This aspect rejected the "just check credentials and let it all in" attitude that some judges had previously adopted towards expert testimony. *See, Ferebee v. Chevron Chemical Co.*, 736

F.2d 1529 (D.C. Cir. 1984). Rule 702 speaks of "scientific, technical, or other specialized knowledge" that will assist the trier of fact. Thus, the court held that "the subject of an expert's testimony must be "scientific knowledge" -- it must be grounded in the methods and procedures of science. 509 U.S. at 589-590.

Justice Blackmun's opinion then attempted to provide some factors to help trial judges assess scientific validity:

- 1) scientific knowledge is "falsifiable" -- it can be and has been tested to see if the results can be replicated or disproven;
- 2) scrutiny of the scientific community through peer review or publication is a factor bearing on validity, but it is not the *sine qua non* as it is under *Frye*;
- 3) the court should consider the known or potential error rates of the scientific technique or method; and
- 4) general acceptance within the relevant scientific community is a permissible, but not determinative, factor.

Daubert, 509 U.S. at 593-594.

The court stressed that this assessment of validity under Rule 702 was meant to be flexible, and cautioned that judges should focus on the principles and methodology, not the conclusions drawn from scientifically valid methodology. 509 U.S. at 594-595. The court also pointed out that under Rule 402, the scientific expert opinion must bear a valid scientific connection to the matter under inquiry. 509 U.S. at 592.

Daubert rejected the *Frye* test's required deference to scientific conventional wisdom, and stressed the liberality and flexibility of the Federal Rules of Evidence. As a result, some hailed it as a pro-plaintiff decision that would make it easier for toxic tort and products liability claimants to prove causation. *See, Roisman, Conflict*

Resolution in the Courts: The Role of Science, 15 Cardozo L. Rev. 1945 (1994); Chesebro, *Taking Daubert's "Focus" Seriously: The Methodology/Conclusion Distinction*, 15 Cardozo L. Rev. 1745 (1994). Others predicted that because the decision required trial judges closely to scrutinize the bases for scientific opinion, and to defer to the standards of the scientific community, it would lead to more widespread exclusion of plaintiffs' proposed experts, particularly where plaintiffs had new or controversial theories of causation. See, Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 Cardozo L. Rev. 2139 (1994).

Those who predicted that trial judges would flex their gatekeeper muscles to exclude vast quantities of plaintiffs' proposed expert causation opinion testimony in products liability cases have turned out to be right. The post-*Daubert* era can fairly be described as the period of "strict scrutiny" of science by non-scientifically trained judges. Judges now routinely assess the reliability of scientific studies by scrutinizing the criticisms leveled at the methodology of particular studies. What few predicted, however, is the way *Daubert* has been expanded well beyond its Bendectin context to usher in heightened substantive rules of causation. Two cases have facilitated this trend, *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

(b) *General Electric v. Joiner*, 522 U.S. 136 (1997)

Shortly after the *Daubert* decision, some judges began to question the U.S. Supreme Court's caution that admissibility determinations were to be made on the basis of the scientific validity of methodology, and not the conclusions. The United States Court of Appeals for the Third Circuit became the most forceful proponent for the view that methodology and conclusions are not so distinct as the U.S. Supreme

Court seemed to indicate in *Daubert*. In the ongoing *Paoli Railroad Yard Litigation*, the court reasoned that to exercise their role as gatekeepers, judges must not only determine if the underlying methodology on which an expert relies is scientifically valid, but must also evaluate whether the conclusion drawn from the methodology is scientifically supportable. *In Re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 745-746 (3d Cir. 1994).

This growing tendency of trial judges to throw out expert testimony because the conclusions were deemed questionable -- often because controversial or not "generally accepted" -- prompted some federal appellate courts to insist on maintaining the distinction between the admissibility of evidence and the weight to be given to it by the trier of fact. *In re Joint E.&S. Dist. Asbestos Litigation*, 52 F.3d 1124 (2d Cir. 1995); *Ambrosini v. Labarraque*, 101 F.3d 129, 141 (D.C. Cir. 1996).

The Eleventh Circuit was one of the courts that took district judges to task for scrutinizing an expert's conclusions while passing on the admissibility of the opinion. *Joiner v. General Electric Co.*, 78 F.3d 524, 529-530 (11th Cir. 1996). This prompted the next case to go to the United States Supreme Court, *General Electric v. Joiner*, 522 U.S. 136 (1997). In this case the plaintiff claimed cancer from occupational exposure to PCBs. The Eleventh Circuit reversed the trial court decision to exclude plaintiff's expert on causation. The court ruled that because the Federal Rules displayed a liberal preference for admissibility, and the judge had gone too far in evaluating conclusions and thus usurped the jury's function to weigh the competing expert conclusions, appellate courts should apply a "stringent standard of review" to decisions to exclude evidence.

Joiner was an electrician who had long experienced occupational exposure to

a PCB contaminated coolant fluid. When he contracted small cell lung cancer, he sued the manufacturer of PCBs, and the manufacturer of the transformers and coolant he had worked with, contending that his exposure to PCBs promoted his cancer. To prove causation, Joiner's experts relied on animal studies showing that PCBs injected into mice caused cancer, and on epidemiological studies of groups of workers exposed to PCBs who developed higher than expected rates of cancer. The district court picked apart these studies, despite the fact that all were concededly based on scientifically valid methodologies. The animals were infant mice, not adults; the dose they were given far exceeded the maximum PCB dose that Joiner was ever exposed to; the type of cancer the mice developed was different than the type afflicting Joiner. One epidemiologic study showing a heightened incidence of lung cancer in PCB production workers was not statistically significant; another did not rule out toxins other than PCBs to which the workers had also been exposed. For all these reasons, the district court ruled, any conclusions drawn by Joiner's experts that these studies could support a finding that PCBs could cause lung cancer in humans were not supportable.

The Supreme Court reversed the Eleventh Circuit's holding that decisions to exclude expert evidence must be reviewed under a stringent standard. Instead, the court held, like any other evidentiary decision, trial judges' decisions to exclude scientific expert testimony under *Daubert* should be assessed under the lenient "abuse of discretion" standard of review. But the court did not stop there; it went on to substantially undermine the line between methodology and conclusions it had drawn in *Daubert*. Endorsing the view propounded by the Third Circuit, and rejecting the Eleventh Circuit's determination that it is legal error to reject expert testimony

because the trial judge disagrees with the conclusions an expert draws from the data, the court stated (522 U.S. at 144):

Conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which 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. [citations omitted] That is what the District Court did here, and we hold that it did not abuse its discretion in so doing.

This aspect of the *Joiner* majority opinion prompted a partial dissent from Justice Stevens. He argued for continued adherence to *Daubert's* bright line between methodology and conclusions, and cautioned that scrutiny of an expert's conclusions at the admissibility phase usurps the traditional function of the jury to assess the validity or strength of an expert's conclusions. 522 U.S. at 154-155.

Justice Breyer, in a concurring opinion, endorsed the majority view that in exercising their gatekeeper role, judges must "make subtle and sophisticated determinations about scientific methodology and its relation to the conclusions an expert witness seeks to offer. . . ." The need for judges to make their own judgments about an expert's conclusions, Justice Breyer opined, is especially important "where the science itself is tentative or uncertain." This is an open invitation to trial judges to make normative decisions about how much scientific controversy or uncertainty the tort system should tolerate when determining whether to let plaintiffs in products liability suits have an opportunity to present their case to a jury. Indeed, Justice Breyer made his value judgment explicit (522 U.S. at 148-149):

Modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such

as chemicals. And it may, therefore, prove particularly important to see that judges fulfill their Daubert gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points towards the right substances and does not destroy the wrong ones.

The lesson of *Joiner* is that judges may scrutinize a scientists' conclusions, even when doing so requires judges to make "subtle and sophisticated" scientific evaluations and to wade into areas of scientific controversy and uncertainty. Moreover, judges should be particularly careful about admitting conclusions that are still considered tenuous or debatable, even when based on scientifically valid methodology, lest the "engine of tort liability" prematurely condemn a product that may, upon further scientific study, prove not to be harmful. In this regard, *Joiner* risks resuscitating the *Frye* "general acceptance" test supposedly repudiated in *Daubert*. And, no matter how the judge rules on a plaintiff's proffered evidence, that decision will be largely insulated from searching appellate scrutiny, because it is difficult to conclude that a trial judge has abused her discretion.

For these reasons, *Joiner* is far more than a mere lesson in the standard of review to be applied to evidentiary rulings. It expresses a judgment that judges are to be trusted more than juries (and sometimes more than scientists) in areas where law intersects with science. It also urges caution on the tort system, expressing a preference to wait for the slow attainment of scientific certainty rather than to make a decision that may be ahead of scientific consensus, which often then prompts further scientific inquiry. In Justice Breyer's view, a legal decision that a product is harmful when science is not yet certain presents greater policy problems than the alternative of allowing continued marketing and barring the courthouse door to ill people whose claims of causation may in fact later be widely

embraced by the scientific community.

Some appellate courts are still trying to perform meaningful appellate review, and to hew to the traditional line that in making admissibility decisions, district courts are not to evaluate the weight to be given to competing expert claims. Meaningful appellate review is procedurally more possible when a trial judge decides that a plaintiff's expert causation testimony is insufficient to raise a jury issue, and thus grants summary judgment to the defendant, or judgment as a matter of law setting aside a verdict. The standard of review for summary judgment and judgment as a matter of law is *de novo*, not the relatively cursory abuse of discretion standard. See, for example, *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9th Cir. 1998). In *Kennedy*, the court reversed the trial judge's grant of summary judgment in rejecting plaintiffs' expert causation testimony. The Ninth Circuit held that trial judges "should not exclude expert testimony simply because they disagree with the conclusions of the expert." 161 F.3d at 1230. See also *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124 (2d Cir. 1995), reversing a trial judge's grant of judgment notwithstanding the verdict to defendant, and finding that trial judge had rejected plaintiffs' expert causation testimony because of disagreement with expert's conclusions.

(c) *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999)

The next step in the court's expert testimony cases occurred in March, 1999, when the court decided *Kumho Tire Co. v. Carmichael*. Given the emphasis in *Daubert* and *Joiner* on scientific expert testimony, lower courts had disputed whether trial judges should also act as gatekeepers to strictly scrutinize the testimony of non-scientific or technical experts, such as engineers, forensic experts,

psychologists, economists, sociologists, or clinicians. *Kumho* was a products liability case stemming from a tire blowout which caused a fatal traffic accident. The plaintiffs sued the tire's manufacturer and distributor, claiming the blowout was caused by a defect in the tire that made its tread separate from the steel-belted tire carcass. Their defect and causation case relied extensively on the opinion testimony of an expert in tire failure analysis. When faced with the defendants' challenge to the admissibility of this expert's opinion, the district court engaged in a rather rote application of the *Daubert* factors -- peer review and publication, potential error rate of the methodology, and degree of acceptance within the relevant scientific community -- to conclude that the expert's methods and conclusions he drew from his analysis were not "reliable." The Eleventh Circuit reversed the decision to exclude the expert's testimony, holding that the *Daubert* factors were relevant only to "science," and thus should not be applied to non-scientific, experience-based observation. *Carmichael v. Samyang Tire, Inc.*, 131 F.3d 1433 (11th Cir. 1997).

The Supreme Court reversed the Eleventh Circuit's decision. First, it rejected the distinction lower courts had tried to draw between "scientific" and "nonscientific" experts, because, by its terms, Rule 702 applies to all "technical or specialized knowledge." Thus, trial judges must perform the gatekeeping task of closely scrutinizing all expert testimony. The court further concluded that while the specific *Daubert* factors may not all apply outside the scientific realm, *Daubert's* "general principles" apply. Thus, when an expert's "factual basis, data, principles, methods, or their application are called sufficiently into question . . . the trial judge must determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline." By including an expert's application of

methods and principles as among the matters to be assessed, the court again signaled its apparent approval of scrutinizing the conclusions an expert draws from data, studies, or visual inspection. Indeed, the court itself painstakingly evaluated the expert's conclusions. It did not question the methodology of visually inspecting tires, but stressed that the expert's conclusion that the particular tire in question had a defect was not reliably supported by his visual inspection, given the presence of known wear factors that could counter the defectiveness conclusion.

Although *Kumho* held that *Daubert* factors applied to the testimony of engineers and other experts who are not scientists, the court indicated that the trial judge has some discretion, and that the determination to apply *Daubert* is fact-specific, to be applied on a case-by-case basis. The decision in this respect is clear (526 U.S. at 149-150):

The petitioners ask more specifically whether a trial judge determining the "admissibility of an engineering expert's testimony" *may* consider several more specific factors that *Daubert* said might "bear on" a judge's gate-keeping determination. These factors include:

-- Whether a "theory or technique ... can be (and has been) tested";

-- Whether it "has been subjected to peer review and publication";

-- Whether, in respect to a particular technique, there is a high "known or potential rate of error" and whether there are "standards controlling the technique's operation"; and

-- Whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." 509 U.S. at 592-594.

Emphasizing the word "may" in the question, we answer that question yes.

Engineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases. See e.g., Brief for

Stephen Bobo et al as *Amici Curiae* 23 (stressing the scientific bases of engineering disciplines). In other cases, the relevant reliability concerns may focus upon personal knowledge or experience. As the Solicitor General points out, there are many different kinds of experts, and many different kinds of expertise. See Brief for United States as *Amicus Curiae* 18-19, and n. 5 (citing cases involving experts in drug terms, handwriting analysis, criminal *modus operandi*, land valuation, agricultural practices, railroad procedures, attorney's fee valuation, and others). Our emphasis on the word "may" thus reflects *Daubert's* description of the Rule 702 inquiry as a "flexible one." 509 U.S. at 594. *Daubert* makes clear that the factors it mentions do *not* constitute a "definitive checklist or test." *Id.* at 593. And *Daubert* adds that the gatekeeping inquiry must be "tied to the facts" of a particular "case." *Id.* at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (CA3 1985)). We agree with the Solicitor General that "[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." Brief for United States as *Amicus Curiae* 19. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.

(d) *Weisgram v. Marley Co.*, 528 U.S. 440, 120 S.Ct. 1011 (2000)

This case held that the Court of Appeals may enter judgment in favor of the defeated party at trial where the expert testimony has been held insufficient. The unanimous Supreme Court decision resolved a split in the circuits over whether appellate courts can enter judgment, as a matter of law, based on the existing record at the close of trial.

The case involved a woman who died of carbon monoxide poisoning during a house fire. Her son brought suit against Marley Co., the manufacturer of the baseboard heater installed in the deceased's home. As co-plaintiff in the case, the insurer of the house filed a subrogation action against Marley Co. Both plaintiffs claimed that the defendant's heater was defective and that it started the fire during

which Mrs. Weisgram perished.

The trial judge allowed the plaintiffs to present three expert witnesses to prove their claims. Although Marley Co. moved to strike the plaintiffs' expert testimony, the judge denied the motion based on *Daubert v. Merrell Dow Pharmaceuticals, Inc.* The court also denied the defense motion for judgment notwithstanding the verdict. The jury awarded damages to the plaintiffs.

Marley Co. appealed, arguing that the trial court erred in allowing the testimony of the plaintiffs' experts to stand. The Court of Appeals for the Eighth Circuit held that the defendant's motion for judgment as a matter of law should have been granted because the testimony of the plaintiffs' expert witnesses was speculative and unreliable. The Eight Circuit found the remaining evidence insufficient to support the plaintiffs' claims and directed judgment as a matter of law in favor of the defendant. The court held that the plaintiffs did not prove their case at trial after having a full and complete opportunity to do so. In effect, it held their remedy is to lose, not to try the case again.

Plaintiffs argued that if an evidentiary error occurred at the trial court level, the case should be sent back to the trial court so that the trial court can correct the error. The trial court believed that the plaintiffs' experts were reliable, and allowed the jury to hear their testimony, and allowed the case to proceed to verdict. The plaintiffs argued that they should have had the opportunity to rectify whatever problem existed. They therefore claimed a remand that would allow them to fix the discrepancies highlighted by the Eighth Circuit.

Counsel for Mrs. Weisgram argued to the U.S. Supreme Court that a remand and an opportunity for the plaintiffs to present additional evidence would be the

appropriate and fair remedies when an appellate court strikes an admissible testimony.

The Supreme Court unanimously agreed with the defense. Justice Ginsburg wrote that Rule 50 allows parties numerous opportunities to introduce evidence in support of their cases, and that the law recognizes that there are cases in which the Court of Appeals may appropriately instruct the district court to enter judgment as a matter of law against the jury verdict winner. The opinion also notes that rulings on post-trial motions for judgment as a matter of law call for the “exercise of informed discretion,” and appellate authority to make this determination is no less when the evidence is rendered insufficient by the removal of erroneously admitted testimony than it is when evidence, without any deletion, is insufficient.

See: Boat Corp. v. Brunswick Corp., 207 F.3d 1039 (8th Cir. 2000), which reversed the \$44 million anti-trust verdict (before trebling) and entered judgment for defendants because plaintiffs’ expert did not satisfy *Daubert*.

(e) The combined effect of these cases.

The combined effect of these cases is that in all areas of tort law that rest on any sort of specialized, scientific, or technical expert testimony, federal trial courts must exercise a vigorous gatekeeping function to carefully evaluate the basis and conclusions of plaintiffs' proposed expert testimony, whether going to the issue of defect, clinical diagnosis, standard of care in medical malpractice cases, or causation. In exercising this gatekeeping role, the federal trial courts may evaluate the expert's conclusion as well as his methodology, and, no matter what the district court’s ruling may be, the district judge’s decision may only be reviewed for abuse of discretion if the testimony is excluded on the trial.

7. The Role of Epidemiology, and Deciding Admissibility Issues on a Sufficiency of Evidence Standard

The author has drawn heavily on Lucinda M. Finley's article at 49 DePaul L. Rev. 335 (Winter 1999) *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*. Ms. Finley is a professor at law at the State University of New York at Buffalo.

Because of the importance of the issue, and because Professor Finley's analysis in Section III of her article, captioned *Using the Gatekeeping Role to Change the Substance of Tort Law: Elevating the Substantive Requirements for Proving Causation* presents clearly the flaws in utilizing epidemiology criteria and deciding admissibility issues on a sufficiency of evidence standard, we have reprinted that section of her article, with footnotes.

Excerpt from Finley, *Guarding the Gate to the Courthouse:*
How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules
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Section III.
Using the Gatekeeping Role to Change the Substance of Tort Law:
Elevating the Substantive Requirements for Proving Causation

The *Daubert* decision stimulated an extensive amount of commentary, including ruminations on the epistemological dilemma of how judges without scientific training could evaluate the scientific validity and reliability of evidence, and whether in trying to do so, judges would be making scientific determinations or legal rulings.³ A review of post-*Daubert* cases reveals that many judges have resolved this apparent epistemological conundrum by making what are plainly legal rulings about the type and nature of scientific evidence plaintiffs must produce to even attempt to prove causation. Some judges have used their gatekeeper power to wade into disputed scientific territory to try to resolve or choose sides in scientific controversies. Ignoring the usual legal rule that decisions about the admissibility of evidence are meant to be distinct from decisions about the weight or sufficiency of evidence, these courts have adopted the legal position that there is no difference under *Daubert-Joiner* between the sufficiency and admissibility determinations.⁴ Other judges, perhaps wishing to steer clear of the difficult task of parsing scientific evidence, have instead seized on familiar legal criteria such as "relevance" to make substantive causation law rulings with precedential effects well beyond the particular evidence at issue in the case. Several courts have also avoided the difficult implications of having to assess the reliability of scientific methodology by turning the supposedly flexible and advisory *Daubert* factors of peer review, publication, and degree of widespread

³ See, e.g., Alexander Capron, *Daubert and the Quest for Value-Free "Scientific Knowledge" in the Courtroom*, 30 U. Rich. L. Rev. 85 (1996); Farrell, *supra* note 3, at 2183.

⁴ See, e.g., *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997); *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 189, 192 (Tex. App. 1998). See also *In re Joint E. & S. Dist. Asbestos Litig.*, 827 F. Supp. 1014, 1025 (S.D.N.Y. 1993) (finding plaintiffs' evidence insufficient because the judge found their studies subject to criticism, or found the defense studies more conclusive or less plagued by criticism). The Second Circuit reversed, holding that by doing so the judge had impermissibly crossed the boundary between evaluating the sufficiency of evidence and substituting his judgment about its weight or credibility for the jury's. *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1137 (2d Cir. 1995). The appellate court also rejected defendants' argument that *Daubert* eroded the line between admissibility and sufficiency of the evidence. See *id.* at 1132-33. This tendency of judges to blur questions of the sufficiency of evidence and the admissibility of evidence started in the *Bendectin* cases. Despite growing epidemiological support for the defendants, some juries continued to return verdicts in favor of plaintiffs, and judges grew openly skeptical of juries' abilities to correctly evaluate complex science. See Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts after Daubert*, 78 Minn. L. Rev. 1387, 1431-33 (1994).

acceptance in the scientific community into simplistic legal litmus tests.⁵

The most noteworthy trend in using admissibility determinations to make substantive causation rules -- noteworthy because it is seriously scientifically and legally misguided -- is a growing number of court rulings stating that in order for an expert opinion about causation to be relevant and thus admissible, the expert must base her testimony on epidemiological studies that demonstrate the product in question at least doubles the risk of the disease from which plaintiff suffers.⁶ Courts have used two primary routes to arrive at the legal proof requirement of epidemiology with a relative risk of 2.0 or greater. One is to use the "reliability" factor from *Daubert*, which is supposed to focus on the validity and scientific soundness of the methodology, to declare any epidemiological study with a lower relative risk "unreliable" as a matter of law.⁷ The second common move is to conflate the

⁵ Examples of courts simplistically using Daubert factors such as peer review, publication, and general acceptance include *Forsyth v. Eli Lilly Co.*, 1998 U.S. Dist. Lexis 541 (D. Haw. 1998), *Minnesota Mining & Manufacturing Co. v. Atterbury*, 978 S.W.2d 183 (Tex. App. 1998). See also *Allison v. McGhan Medical Corp.*, 184 F.3d 1300 (11th Cir. 1999), where the court seemed to do little more than check off as if from a list whether an expert's theories had been published, peer reviewed, and were generally accepted. *Id.* at 1313. The court of appeals affirmed the decision to exclude the testimony, but for more searching reasons. *Id.* at 1322. Some commentators specifically warned that Daubert presented a risk that some judges would grasp at simplistic formulations as screening devices. See Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Context-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 Va. Env'tl. L.J. 1 (1996).

⁶ Epidemiological studies ascertain a "relative risk" for a certain disease if one is exposed to a product or toxin. Epidemiologists compare the number of cases of a disease in a sample group of the unexposed population, known as the "background risk," with the number of cases of the disease in a sample group of people exposed to the factor being studied. See Linda A. Bailey et al., *Reference Guide on Epidemiology*, in *Federal Judicial Center, Reference Manual on Scientific Evidence* 168 (1994). The resulting ratio is known as the relative risk. *Id.* A relative risk of 2.0 means there are twice as many cases of the disease in the exposed group than in the unexposed group. *Id.* To put it another way, it means that the increased risk above background levels faced by the group is 100%. When this group risk is translated to the individual level, it means that in the case of any person with the disease, it is 50% likely that their illness is attributable to their exposure. *Id.* For other excellent explanations of the principles and methods of epidemiology, including the relative risk concept, see Sanders, *supra* note 5, at 47-60; Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substance Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 647 (1992); Thompson, *supra* note 3, at 250.

Courts also require that the risk ratio in a study be "statistically significant," which is a statistical measurement of the likelihood that any detected association has occurred by chance, or is due to the exposure. Tests of statistical significance are intended to guard against what are called "Type I" errors, or falsely ascribing a relationship when there in fact is not one (a false positive). See Sanders, *supra* note 5, at 51. The discipline of epidemiology is inherently conservative in making causal ascriptions, and regards Type I errors as more serious than Type II errors, or falsely assuming no association when in fact there is one (false negative). Thus, epidemiology conventionally requires a 95% level of statistical significance, i.e. that in statistical terms it is 95% likely that the association is due to exposure, rather than to chance. See *id.* at 50-52; Thompson, *supra* note 3, at 256-58. Despite courts' use of statistical significance as an evidentiary screening device, this measurement has nothing to do with causation. It is most reflective of a study's sample size, the relative rarity of the disease being studied, and the variance in study populations. Thompson, *supra* note 3, at 256.

Some judges have improperly blurred the two very distinct concepts of relative risk and statistical significance by labeling the results of epidemiological studies which derived a relative risk of less than 2.0 as "statistically insignificant." See, e.g., *Maiorana v. U.S. Mineral Products Co.*, 827 F. Supp. 1014, 1041-42 (S.D.N.Y. 1993) describing epidemiological studies that yielded relative risks between 1.0 and 1.5 as "statistically insignificant").

⁷ See, e.g., *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 (11th Cir. 1999) (affirming the district court's rejection of epidemiological studies as unreliable because with a relative risk below 2.0 there cannot be a consensus in the general scientific community that an association exists). The Allison court also noted that this verged on resurrecting the Frye general acceptance test, but read Joiner as essentially permitting that resurrection.

admissibility criteria of relevance with burden of proof, to reason that since a plaintiff's burden of proof is to show that the product to which she was exposed "more likely than not" caused her disease, and an epidemiological study that shows a doubling of risk (a relative risk of 2.0 in statistical terms) means that it is 50% likely that any particular case of the disease is attributable to the exposure rather than unexplained causes, or "background risk," then only such epidemiological studies satisfy the burden of proof.⁸ Causation evidence that does not satisfy the burden of proof, these courts reason, is not "relevant" to the issue of causation, and thus can be excluded.⁹ These courts also reason that since epidemiology is the only type of science that studies causal associations in human populations, other types of scientific evidence, such as animal studies, toxicology reports, chemical structure analysis, and clinical differential diagnosis, even if "scientifically valid" evidence of the type relied on by scientists to make risk assessments or diagnostic causal attributions, are not legally relevant unless also supported by epidemiology with the requisite increase in relative risk.¹⁰

This development in causation law initially appeared in Judge Weinstein's opinion in the Agent Orange litigation,¹¹ and judges presiding over Bendectin cases picked up on it and

Id. See also *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 199- 202 (Tex. App. 1998); *Kelley v. American Heyer-Schulte Corp.*, 957 F. Supp. 873, 878 (W.D. Tex. 1997).

⁸ In the eyes of some judges, The Federal Judicial Center's Reference Guide on Epidemiology seems to endorse the approach of making admissibility determinations turn on the ultimate burden of proof, when it informs judges:

The civil burden of proof is described most often as requiring the fact finder to "believe that what is sought to be proved ... is more likely true than not true." The relative risk from an epidemiological study can be adapted to this 50% plus standard to yield a probability or likelihood that an agent caused an individual's disease. The threshold for concluding that an agent was more likely the cause of a disease than not is a relative risk greater than 2.0. Reference Guide on Epidemiology, *supra* note 49, at 168-69. See, e.g., *Merrell Dow Pharms, Inc. v. Havner*, 953 S.W.2d 706, 721-22 (Tex. 1997); *In re Hanford Nuclear Reservation Litig.*, 1998 U.S. Dist. Lexis 15028, at * 15 (E.D. Wash. 1998). The Reference Manual, however, was not making any recommendation about admissibility of evidence or the sufficiency of all plaintiffs' evidence taken as a whole. Nor was it saying that only epidemiology that reached this threshold could be relevant to the issue of causation, and neither was it instructing judges that no plaintiff with other types of scientific proof or with epidemiology with a lower relative risk but other strong evidence of individual causation could get before a jury. Rather, the Manual was attempting to educate judges about the principles of epidemiology, and illustrate those principles by equating them to legal concepts with which the judges were familiar. It was not offering prescriptive legal recommendations about how to rule on the evidence in any particular case.

⁹ See, e.g., *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 (11th Cir. 1999); *Schudel v. General Elec. Co.*, 120 F.3d 991 (9th Cir. 1997); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311 (9th Cir. 1995); *In re Hanford Nuclear Reservation Litig.*, 1998 U.S. Dist. Lexis 15028 (E.D. Wash. 1998); *Sanderson v. International Flavors & Fragrances, Inc.*, 950 F. Supp. 981 (C.D. Cal. 1996); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217 (D. Colo. 1998); *Forsyth v. Eli Lilly Co.*, 1998 U.S. Dist. Lexis 541 (D. Haw. 1998); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996); *Havner*, 953 S.W.2d at 706.

¹⁰ See, e.g., *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1217; *Hall*, 947 F. Supp. at 1387.

¹¹ *In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. 1223 (E.D.N.Y. 1985). Professor Michael Green provides an extensive discussion of how the Agent Orange litigation has influenced subsequent legal causation developments. See Green, *supra* note 49, at 671-74. For an in-depth story of this seminal toxic tort litigation and the factors that influenced Judge Weinstein to rule as he did, see Peter Schuck, *Agent Orange on Trial* (1986). Both

increasingly adopted it as a substantive rule.¹² For example, on remand from the Supreme Court, the Ninth Circuit in *Daubert* reasoned that because the burden of proof in tort is "more likely than not," only epidemiology that showed the increase in the relative risk to be 2.0 or greater could meet the "fit," or relevance prong elucidated by the Supreme Court.¹³ This principle of causation law -- that to sustain a toxic exposure claim, plaintiffs must be able to offer statistically significant epidemiology that demonstrates that the risk of disease is at least doubled upon exposure to the product in question -- has now been firmly entrenched in silicone gel breast implant litigation as well.¹⁴

The rejection of plaintiffs' expert testimony on causation may be justified in the context of Bendectin and breast implant litigation, because during the course of the litigation, the body of epidemiology grew and matured, and failed to confirm any substantial increase in risk. This cast plaintiffs' experts in the position of arguing against a developing scientific consensus and having to admit that their opinion as to a causal relationship was fraught with uncertainty. The well developed epidemiological context of these two medical products is a significant explanatory reason why courts increasingly came to reject admitting plaintiffs' expert testimony.¹⁵

Professors Green and Schuck are highly critical, both from a scientific and legal perspective, of the way in which Judge Weinstein elevated epidemiology to make it foundational to a plaintiffs' causation case. See Schuck, *supra*; Green, *supra*.

¹² See, e.g., *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311 (9th Cir. 1995); *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307 (5th Cir. 1989).

¹³ 43 F.3d at 1320-22.

¹⁴ See, e.g., *Allison*, 184 F.3d at 1300; *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1217; *Kelley v. American Hoyer-Schulte Corp.*, 957 F. Supp. 873 (W.D. Tex. 1997); *Hall*, 947 F. Supp. at 1387; *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183 (Tex. App. 1998). Contrary opinions in breast implant litigation, rejecting epidemiology with a relative risk of greater than 2.0 as a required element for a plaintiff to prove causation, include *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 917- 18 (Mass. Sup. Ct. 1998); and *Jennings v. Baxter Healthcare Corp.*, 954 P.2d 829 (Or. App. 1998). See also *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124 (9th Cir. 1994) (decided prior to publication of major epidemiological studies of breast implants and auto-immune diseases). The court in *Hopkins* held that where there is no solid body of epidemiology to review, it is appropriate to admit expert testimony that draws on other types of valid and reliable scientific data). *Id.* at 1124-1125. Cf. *Pick v. American Med. Sys., Inc.*, 958 F. Supp. 1151 (E.D. La. 1997) (silicone penile implant case where plaintiff's experts relied largely on epidemiology concerning silicone breast implants). The court rejected the proposition that epidemiology with a relative risk greater than 2.0 is required to admit general causation testimony. *Id.* at 1160.

¹⁵ See, e.g., *Ambrosini v. Labarraque*, 101 F.3d 129, 138-39 (D.C. Cir. 1996) (reasoning that Bendectin rulings were premised on the fact that there was an "overwhelming body of contradictory epidemiological evidence" aligned against plaintiffs' experts, and should be limited to that context) (quoting *Richardson v. Richardson-Merrell*, 857 F.2d 823, 830 (D.C. 1988)). See also Green, *supra* note 12, at 307; Green, *supra* note 49, at 671-72 (arguing that the courts' insistence on epidemiology for both admissibility and sufficiency of evidence rulings in Bendectin cases should be limited to situations where strong, well-developed, consistent body of epidemiology exists). Cf. *Sanders*, *supra* note 5, at 197 (warning that Bendectin litigation sets a dangerous example for other contexts because in Bendectin the well- developed epidemiological record that exonerated Bendectin "made it relatively easy to determine that substantial parts of the plaintiffs' expert testimony was 'bad' when judged by the ordinary criteria of science").

The precedential effect of these rulings have been felt well outside their scientific contexts, however. Courts facing disputes about the admissibility or sufficiency of plaintiffs' expert causation testimony in cases dealing with other products have followed the "law" of Bendectin and breast implants to rule that without some epidemiological studies that show an increase in relative risk of 2.0 or more, plaintiffs have no relevant, reliable, or admissible evidence. Underscoring the precedential, substantive law treatment accorded the Bendectin and breast implant decisions, district courts in the Ninth Circuit, which produced the *Daubert II* ruling that the only relevant causation evidence is testimony based on epidemiology that shows a doubling of the risk, have been most likely to apply this rule to other products. And, they have adopted this substantive threshold for proof of causation even where there is not yet any epidemiology studying a product, or when the epidemiology is still very tentative and preliminary.¹⁶

Because the post-*Daubert* breast implant cases have the potential for a growing influence on cases dealing with other products with quite different scientific records, it is worth parsing the reasoning of two of the most extensive breast implant discussions of the admissibility of plaintiffs' evidence. Although purporting to rest their admissibility decisions on the *Daubert* factors of scientific validity and reliability, the judges in these two cases failed to heed the advice of neutral scientific experts, and instead made substantive legal rulings based on relevancy and burdens of proof. The case of *Hall v. Baxter Healthcare Corp.*¹⁷ is illustrative of a judge's use of the legal criterion of "relevancy" to reject all scientific evidence that does not rest on epidemiology with a relative risk greater than 2.0, despite its scientific validity, and despite the fact that scientists reasonably rely on the types of rejected evidence to form judgments about causation. This case involved the consolidated claims of several plaintiffs who alleged that their leaking or ruptured silicone gel breast

¹⁶ Non-Bendectin and non-breast implant cases in which courts insist on causation testimony must be predicated on epidemiology that demonstrates at least a doubling of the risk. See, e.g., *Schudel v. General Elec.*, 120 F.3d 991 (9th Cir. 1997) (alleging that workplace exposure to industrial solvents trichloroethane (TCA) and perchloroethylene (perc) caused neurological and respiratory impairments); *Sanderson v. International Flavors & Fragrances, Inc.*, 950 F. Supp. 981, 1000 (C.D. Cal. 1996) (connecting between aldehydes in perfume products and multiple chemical sensitivity); *Forsyth v. Eli Lilly Co.*, No. 95-00185, 1998 U.S. Dist. Lexis 541 (D. Haw. 1998) (connecting the anti-depressant drug Prozac and suicide); *In re Hanford Nuclear Reservation Litig.*, 1998 U.S. Dist. Lexis 15028 (E.D. Wash. 1998) (connecting exposure to radioactive emissions from nuclear weapons plant and various cancers and thyroid diseases). See also *Bartley v. Euclid*, 158 F.3d 261 (5th Cir. 1998) (in case claiming back injuries from vibrations in coal hauling equipment, court declined to reach issue of whether epidemiology with a relative risk of greater than 2.0 is a foundational legal requirement, but then ruling plaintiffs' expert causation testimony admissible because it meets this epidemiological threshold). This list does not purport to be exhaustive; it is a sampling of cases obtained through a post-*Daubert* date restricted LEXIS search for cases containing the terms "causation and expert and epidemiolog! and relative w/5 risk."

¹⁷ 947 F. Supp. 1387 (D. Or. 1996).

implants had caused various auto-immune diseases. The defendants brought a motion in limine to exclude all testimony by plaintiffs' experts about a causal link between implants and the alleged diseases. To exercise its *Daubert* gatekeeping role, the trial judge appointed a panel of neutral scientific experts, pursuant to Federal Rule of Evidence 706, to review the parties' experts' submissions and scientific studies. The judge asked these neutral "technical advisors" from the fields of epidemiology, immunology/toxicology, rheumatology, and chemistry, to issue a report focusing on five questions drawn from *Daubert*: (1) Was a particular plaintiff's expert's opinion supported by scientific reasoning and methodology that is generally accepted in the field? (2) Is the opinion based upon scientifically reliable data? (3) If epidemiological studies are inconclusive, what other types of scientific evidence could justify a conclusion about the cause of the disease at issue? (4) Do the methodology and data support the expert's conclusions? (5) Does the data relied on by the expert apply to the disease in issue in the case, or does it speak to some other disease or syndrome?¹⁸

The neutral epidemiology expert appointed by the court, Dr. Merwyn Greenlick, reviewed the opinions and underlying studies of the two epidemiology experts, Dr. Goldsmith for the plaintiffs, and the defense expert, Dr. Ory. If the trial judge had followed the advice of his own neutral scientific expert, and that expert's interpretation of the *Daubert*-derived questions, the judge would have admitted the opinions of both experts, and left to the jury the question of which differing interpretation should be given greater weight. Dr. Greenlick concluded that both Dr. Goldsmith and Dr. Ory based their epidemiological opinions on scientifically valid data, and that their "somewhat different positions [were] a result of different, but legitimate, interpretations" of the sixteen underlying studies.¹⁹ Dr. Greenlick castigated a defense lawyer for inappropriately criticizing or diminishing Dr. Goldsmith's testimony, and advised the judge that "Dr. Goldsmith's statement is at the heart of science. Interpreted through the eyes of an epidemiologist, Dr. Goldsmith is saying that work in the area has progressed to the point . . . where he and others have begun . . . to take the possibility of an association seriously."²⁰

In response to the court's question about what types of evidence could be used to determine causation when faced with inconclusive epidemiology, Dr. Greenlick advised the court that in light of the fact that the epidemiology was not definitively negative or positive, but was sufficient to raise a serious question about the possibility of an association between

¹⁸ Id. at 1393-94.

¹⁹ Id. at 1448.

²⁰ Id. at 1448-49.

silicone implants and auto-immune diseases, it was scientifically appropriate also to consider animal studies, biophysical data, medical records, differential diagnosis and other types of scientific data. He analogized the causation issue facing the court to that of a clinician treating a patient. A clinical treating physician cannot wait for the slow evolution of epidemiological certainty about population-wide issues, but must make a judgment on all available scientifically legitimate sources about what is causing the disease in a particular patient.²¹ Dr. Greenlick then specifically concluded that "there is sufficient scientific data upon which to base the opinions both of Dr. Goldsmith and Dr. Ory, the principal epidemiology witnesses, and I believe it would be appropriate to accept both their testimonies."²²

Judge Jones did not follow this scientific expert advice. He decided to exclude the testimony of Dr. Goldsmith²³ not because he disagreed with the neutral expert's scientific analysis, but because he ruled that as a matter of law, to prove causation "plaintiffs must be able to show a relative risk of greater than 2.0."²⁴ Consequently, any epidemiological expert's opinion testimony, no matter how scientifically valid, is simply not legally relevant to the issue of causation unless it rests on studies showing the requisite doubling of risk. In arriving at this ruling, Judge Jones relied not on his scientific experts' reports or on scientific treatises, but on prior court decisions and judicial evidence manuals -- classic sources of law. Thus, this ruling, like those precedents upon which he relied, is not an example of a judge following the standards of good science to make a case specific and fact specific evidentiary admissibility determination. It is a legal policy decision, a conscious choice to reject scientific principles as legally irrelevant, which could set a precedent with potentially binding relevance far beyond the realm of breast implant litigation.

Another important feature of the new toxic causation law fashioned by the judge in *Hall* is that it conflates the plaintiffs' overall burden of proof on causation with the determination of whether to admit any particular piece of evidence. Once the court

²¹ Id.

²² Id. at 1450.

²³ The judge did not have to rule on the admissibility of Dr. Ory's testimony because once he excluded all of the plaintiffs' expert causation testimony, the plaintiffs had no case, and there was no need for the defense to put on any evidence. This demonstrates the inherent one-sidedness of the Daubert rule--it is most likely applied against plaintiffs, but defense experts rarely have to be subjected to the same scrutiny, although neutral experts and judges in fact take defense experts' criticisms of plaintiffs' experts' conclusions into account when making admissibility determinations about plaintiffs' experts.

²⁴ Hall, 947 F. Supp. at 1403.

declared the legally privileged and determinative role of statistically significant epidemiology with a relative risk of 2.0 or greater, and then excluded the plaintiffs' epidemiology experts for not meeting this legal standard, the court proceeded to exclude the remainder of the plaintiffs' scientific experts because of the lack of epidemiology experts.²⁵ What the court did, essentially, was to evaluate each proposed expert's testimony and assess whether it, standing alone, would be sufficient to satisfy the plaintiff's overall burden of proof to show that causation is more likely than not. The judge concluded that none of it was legally relevant or sufficient because it did not rest on admissible epidemiology.

In the guise of evidentiary admissibility determinations, the court made sufficiency determinations about each individual piece of evidence. Although admissibility decisions are made on individual items of evidence, this obvious fact does not logically lead to the conclusion that in order to be admissible, each individual item of evidence must be itself sufficient, standing alone, to present a jury question.²⁶ To so hold creates an admissibility and sufficiency criterion that is virtually impossible for any plaintiff to meet, because it deprives plaintiffs of the entitlement to have their evidence evaluated as a cumulative whole unless they can produce the magic bullet of the requisite strength of epidemiological studies.²⁷ Justice Stevens, writing separately in *Joiner*, warned against district judges using their gatekeeping power to erect such a legal barrier, because it is contrary both to *Daubert* and to the methodologies of sound science which *Daubert* commanded courts to

²⁵ Again, Judge Jones had to disregard the advice of one of his own appointed neutral experts. The neutral chemistry expert, Dr. Robert McClard, concluded that the testimony of plaintiffs' expert Dr. Garrido, who formed an opinion about the capability of silicone to degrade to silica, a well-known harmful agent, in the body, was supported by scientifically valid reasoning and methodology, and was clearly scientifically relevant. *Id.* at 1473 app. e. See also *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909 (Mass. 1998), where the trial judge relied on the same report from Dr. McClard to conclude that the testimony of the plaintiff's expert was admissible under the *Daubert* criteria. *Id.* at 916.

²⁶ As the Second Circuit noted in cautioning trial judges that they must keep the two inquiries distinct, "admissibility entails a threshold inquiry over whether a certain piece of evidence ought to be admitted at trial," while the sufficiency of the evidence inquiry "asks whether the collective weight of a litigant's evidence is adequate to present a jury question." *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995). The Second Circuit held that *Daubert* was not meant to erode the line between admissibility determinations and sufficiency determinations, and that in making admissibility determinations trial judges should not engage in a parsing of the weight to be given an expert's conclusions. *Id.* Accord *Berry v. CSX Transp., Inc.*, 709 So. 2d 552 (Fla. App. 1998). Florida still follows the *Frye* "general acceptance" standard, but the court has since ruled that it is inappropriate for trial judges to assess the weight to be given to a study, or whether an expert's conclusions are unassailable or subject to some criticism, in making admissibility determinations.

²⁷ In contrast to the cases discussed *supra*, courts in Texas have interpreted *Daubert* as eroding the distinction between the admissibility of evidence and the sufficiency of the evidence to prove causation. See, e.g., *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 189 (Tex. App. 1989) (interpreting the Texas Supreme Court decision in *Merrell Dow Pharmaceuticals Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997), as adopting the same criteria for the two inquiries). The *Atterbury* court explained that defendants have "two bites at the *Daubert* apple"--a motion to exclude the evidence, and then, if the trial judge does not grant that, a motion challenging the sufficiency of the evidence. *Atterbury*, *supra* at 192.

respect. Castigating the district judge for separately examining one by one each study on which plaintiffs' experts relied, rather than assessing them in their cumulative whole, Justice Stevens noted that many scientists, including the defendants' experts, used the cumulative weight of the evidence approach in making causal judgments. "It is not intrinsically 'unscientific' for experienced professionals to arrive at a conclusion by weighing all available scientific evidence -- this is not the sort of 'junk science' with which *Daubert* was concerned."²⁸ But the district judge in *Hall* in effect declared it legally invalid for scientists to look at the cumulative whole of the scientific record by, for example, adding to epidemiology with relative risk above 1.0 but below 2.0, evidence gleaned from animal studies, toxicology, chemical analyses, pathological examinations of plaintiff's tissues, and the differential diagnosis technique of ruling out other known causal agents, to arrive at an opinion about causation.

In a subsequent breast implant case that relied heavily on *Hall*, as well as Bendectin precedents, *In re Breast Implant Litigation*,²⁹ the United States District Court in Colorado refined *Hall's* principle of causation law by linking the requisite type of epidemiology to the two elements of causation lurking in every toxic tort case: general and specific causation. The general causation inquiry asks whether the product at issue is capable, in general, of causing the disease. Clearly, epidemiology, which is the study in large populations of associations between exposure and illness, is highly relevant evidence to suggest general causation. The Colorado court, however, declared it to be the only relevant evidence on general causation, and only if an epidemiological study demonstrates a doubling of risk in the general population.

This ruling is statistically, scientifically, and legally suspect. It is legally dubious because it uses a specific causation standard -- whether it is more likely than not that the product at issue caused the plaintiff's illness-- to adopt a substantive rule about the type and strength of evidence required for general causation. In other words, the court made the admissibility of general causation evidence hinge on whether it, standing alone, would also meet the specific causation burden of proof. By thus collapsing the specific and general causation inquiries, the Colorado court ruled that as a matter of law, unless plaintiffs can show that for every single member of the exposed population, it is 50% or more likely that her illness is attributable to her exposure to the product at issue, then no individual plaintiff

²⁸ *Id.* at 153.

²⁹ 11 F. Supp. 2d 1217 (D. Colo. 1998).

is entitled to try to show that she is one of the ones for whom a population-wide risk of something less than 50% risk became reality.

The plaintiffs' case proceeded on the basis that because epidemiological studies did show some increased risk of auto-immune diseases among women exposed to silicone gel implants, which did suggest that a certain percentage (although not 50%) of women with such diseases may in fact have become ill because of their implants, they should have been able to offer additional kinds of scientific evidence which tended to show that it was in fact more likely than not that the individual plaintiffs were among those whose illnesses could be linked to their implants. The plaintiffs were seeking to move to the specific causation case because the epidemiology did show some increased risk in general, and, when coupled with other scientific evidence, certainly did not rule out general causation. The court, however, refused to admit all of the scientific evidence which spoke to specific causation in the individual plaintiffs, such as clinical testimony, differential diagnosis, and examination of silicone in tissue samples of the plaintiffs, not because it lacked scientific validity or relevance to the specific causation issues, but because it did not "fit" the general causation issue because it did not rest on epidemiology with a relative risk greater than 2.0.³⁰

In addition to collapsing general causation into the standard for proving specific causation, this ruling also collapsed the plaintiff's burden of proof on the fact of individual causation into the population-wide probability of causation.³¹ As a matter of statistics, it is improper to equate a population-wide risk in an epidemiological study with the individual probability of causation. Population-wide risk estimates simply do not address, and thus cannot be translated to, the probability of causation in any one individual.³² Epidemiology, which is inherently population based, represents a range of values across the group, not a single risk probability value that can be applied to any individual.³³ The population-wide risk

³⁰ See *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1232 (discussing specific causation testimony of Dr. Kassan); 1236-37 (discussing specific causation testimony of Dr. Klapper).

³¹ See Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 *Yale L.J.* 376 (1986). As Gold explains, while traditionally only the preponderance of the evidence standard of persuasion was defined probabilistically, in toxic torts, the statistical causation evidence is also expressed probabilistically - as a factual estimate of the defendant's contribution to the plaintiff's risk. The failure to distinguish between the two kinds of probability has led to the collapse of the factual burden and preponderance standard into a single test: does the factual probability of causation exceed 50%? *Id.* at 379. As Gold then demonstrates, this subtly yet substantively alters causation law, tightening the standard plaintiffs must meet, and narrowing the evidentiary focus to probabilistic statistical evidence such as epidemiology-- precisely what the courts effectuated in *Hall* and *In re Breast Implant Litigation*. *Id.* at 392.

³² *Id.* at 390.

³³ See James Robins & Sander Greenland, *The Probability of Causation Under a Stochastic Model for Individual Risk*, 45 *Biometrics* 1125, 1126 (1989); Thompson, *supra* note 3, at 254-56.

probability cannot take into account particular susceptibilities of individuals based on factors such as genetics,³⁴ overall state of health, age, gender, race, amount and duration of exposure. Furthermore, the probability of individual causation cannot be computed solely from the population-wide relative risk, because in some individuals the exposure may accelerate the onset of disease that they might have gotten later in life as a result of age or exposure to other risk factors, and thus in fact, be a substantial contributing factor to the individual's disease. But statistically, these cases of accelerated onset tend to get accounted for as background risk cases, rather than as exposure cases, which can lead to mathematical underestimation of both the population wide relative risk, and the individual risk probability.³⁵

Statisticians, epidemiologists, and many other types of scientists understand the numerous reasons why it is invalid to equate the increase in relative risk in the population being studied with the probability of causation in any individual case. But these reasons seem to have eluded the comprehension of those judges who have made the misleadingly simple equation of legal relevance and the burden of proof on either general or specific causation with epidemiology that demonstrates a relative risk of 2.0 or greater. Dr. Greenlick, the court-appointed neutral expert in Hall, argued that from the perspective of science, and epidemiology in particular, plaintiffs should be able to try to prove a specific causation case when the epidemiology shows a relative risk of less than 2.0:

From a scientific point of view it is not appropriate to disregard relative risks of less than 2.0. First of all, relative risk is a term that applies to a population, not to an individual. While it is possible to estimate the average increased risk for members of a population, it is really not appropriate to assume that each individual in a population actually had a similar risk. It is much more appropriate to believe that the average increased risk is made up of a wide range in individual risks in the population³⁶

Even Dr. Marcia Angell, the executive editor of the New England Journal of Medicine,

³⁴ See, e.g., Cranor et al., supra note 48, at 39-40. For example, population-wide breast implant studies included in the exposed groups both women with implants which were still intact, and presumably, given the high rupture rates, women whose implants had ruptured, whether they knew of the rupture or not. Thus, the studies were not designed to take into account whether an individual's implant had ruptured, how long ago it had ruptured, how much silicone had leaked into her body, or where it had migrated to. Yet these individualistic factors of the amount and duration of exposure to silicone in the body could affect an individual's susceptibility in immune responses, i.e. they might make it more likely in an individual case that the individual was one of the people upon whom the slightly elevated population-wide relative risk in fact came to rest.

³⁵ See Sander Greenland, Relation of Probability of Causation to Relative Risk and Doubling Dose: A Methodologic Error That Has Become a Social Problem, 89 Am. J. Pub. Health 1166, 1167 (1999).

³⁶ Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1450-51 app. B (D. Or. 1996).

who has been so stridently critical of the breast implant litigation, and argues forcefully for elevating epidemiology above all other forms of scientific evidence in the courtroom,³⁷ has had to acknowledge that one of the breast implant epidemiological studies showing a relative risk of 1.24,³⁸ could mean that breast implants have in fact caused the auto-immune disease in some individual women. This relative risk could mean, she writes, that in every two out of twelve ill women with breast implants, the implants were the sole cause of their disease and in the other 10 they played no role. Or it could mean that implants played a major role in 3 or 4 women and a very small one in the others. Or it could mean that implants contributed a varying amount to the disease in all 12.³⁹

Some courts who have adopted the evidentiary requirement of epidemiology with a relative risk greater than 2.0 apparently, but erroneously think they are just adhering to the teaching of *Daubert* by following the accepted tenets of the scientific discipline of epidemiology. Other courts, displaying a far better understanding of science and the limits of epidemiology, have explicitly rejected the substantive causation rule that plaintiffs must have epidemiology with a relative risk of greater than 2.0 in order to prove causation. Adhering to the precepts of epidemiology, these courts have recognized that because studies that define risk factors do not address the cause of a disease in any particular person, it is irrational and unfair to require an individual plaintiff to produce a magic bullet level of increased population-wide risk. As a New Jersey court explained:

an epidemiologist cannot state that it is more likely than not that a particular case of colon cancer was caused by the asbestos. . . . A medical doctor, however, or even one otherwise acquainted with the physiology of a particular patient and the progress of the disease, may make a medical judgment concerning the origin of the disease, . . . factoring together epidemiological studies, other types of scientific evidence, and known individual risk factors or individual susceptibility that might enhance the risk of exposure, "even though the risk in the study fell short of the 2.0 correlation."⁴⁰ The court went on to reject the defendants' argument that experts should not be able to testify to causation unless epidemiology established a threshold relative risk of 2.0 as "proving too much." Under

³⁷ See Marcia Angell, *Science on Trial* (1996).

³⁸ Charles H. Hennekens et al., *Self-reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals*, 275 *JAMA* 616, 618 (1996).

³⁹ Angell, *supra* note 80, at 197 (quoted in *In re Breast Implant Litigation*, 11 F. Supp. 2d 1217, 1226 (D. Colo. 1998)). Judge Sparr failed to appreciate the import of this quote, however, when he rejected all of the plaintiffs' specific causation testimony because the elevated risk in the population in general was not greater than 50%.

⁴⁰ *Grassis v. Johns-Manville Corp.*, 591 A.2d 671, 675 (N.J. Super. Ct. App. Div. 1991) (decision that epidemiology of a relative risk greater than 2.0 was not required to prove causation later adopted by the New Jersey Supreme Court in *Landrigan v. Celotex Corp.*, 605 A.2d 1079 (N.J. 1992)).

the defendants' proposed rule, no plaintiff could recover if a study showed the increased risk was 1.99, but all could potentially recover if it were 2.1, a result that "makes little sense, scientifically or legally."⁴¹

Similarly, other courts rejecting the epidemiological threshold have recognized that scientists themselves factor in evidence other than epidemiology in making causal judgments, especially individual causal judgments. It is scientifically legitimate to use epidemiological evidence that falls short of the 2.0 relative risk level in combination with clinical or other experimental evidence which strengthens the inference of causation in an individual case.⁴² Other courts have allowed expert medical causation testimony when no epidemiology had even been conducted on whether there is a statistical link between exposure to the toxin in question and the plaintiff's illness, recognizing that it can be medically and scientifically acceptable to base diagnostic judgments on other types of evidence.⁴³ As the Third Circuit explained:

[i]n the actual practice of medicine, physicians do not wait for conclusive, or even published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty. However, experience with hundreds of patients, discussions with peers, attendance at conferences and seminars, detailed review of a patient's family, personal, and medical histories, and thorough physical examinations are the tools of the trade, and should suffice for the making of a differential diagnosis even in those cases in which peer-reviewed studies do not exist to confirm the diagnosis of the physician.⁴⁴

The consistency of this reasoning with accepted precepts of science and medicine is reflected in its similarity to the recommendation of Dr. Greenlick, the neutral expert epidemiologist in *Hall*. Displaying notable perceptiveness that the causation issue in a toxic tort case is more like the individual clinical medical judgment than the population-wide statistical risk estimates of the epidemiologist, he noted that courts, like clinicians, have to make concrete decisions about what is causing a particular person's illness, and often have

⁴¹ *Id.*

⁴² See, e.g., *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124 (2d Cir. 1995); *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996).

⁴³ See, e.g., *Heller v. Shaw Indus., Inc.*, 167 F.3d 146 (3d Cir. 1999); *Kennedy v. Collagen Corp.*, 161 F.3d 1226 (9th Cir. 1998); *Zuchowitz v. United States*, 140 F.3d 381 (2d Cir. 1998); *Benedi v. McNeil-PPC Inc.*, 66 F.3d 1378 (4th Cir. 1995); *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038 (2d Cir. 1995).

⁴⁴ *Heller*, 167 F.3d at 155. This case demonstrates that this does not mean abandonment of all judicial scrutiny of an expert's opinion testimony. However, the court went on to approve the exclusion of the central part of plaintiff's medical expert testimony because the experts' conclusions were not supported by the temporal relationship between exposure and onset of symptoms, and cessation of exposure and the end of symptoms. *Id.* at 164-65.

to do so in the face of less than definitive science. As Dr. Greenlick explained, clinicians making diagnoses do not have the luxury of waiting for epidemiology to arrive at more conclusive, relatively certain decisions about risk levels in general populations.

Physicians [must] do the best they can in an uncertain situation. They use all of the sources of information at their disposal, including animal studies, case reports, small or inconclusive epidemiological studies, expert opinions, conversations with colleagues, and, most importantly, their own clinical experience and judgment. . . . [P]hysicians are not dealing with the general scientific question "What causes disease in women?"; they are dealing with the particularistic clinical question "What is causing disease in this particular woman?" Those are very different questions. And the physician must draw some working causal model in the case of a single patient, even in the face of a great deal of uncertainty. The scientist has the luxury of reporting that there isn't yet sufficient data to draw a conclusion. That luxury isn't available to the clinician, because the decision to do nothing in a clinical situation is selecting a specific course of action.⁴⁵

The courts that insist on epidemiology of a certain risk probability have not explicitly rejected the view that the causation judgment is more akin to an individual clinical judgment than a probabilistic risk assessment. Instead, they acknowledge that they are not following the principles of science, but are making a legal policy determination to equate epidemiology, relative risk, general causation, and the burden of proof on individual causation. Conceding that epidemiology and other methods of science cannot directly prove causation, the Texas Supreme Court in *Merrell Dow Pharmaceuticals, Inc. v. Havner* explained its decision to nevertheless require plaintiffs to produce epidemiological studies with a relative risk of greater than 2.0 as a policy determination that "strikes a balance between the needs of our legal system and the limits of science."⁴⁶ The California Federal District Court in *Sanderson v. International Flavors and Fragrances, Inc.*,⁴⁷ was even more blunt about the policy reasons underlying its decision. When faced with the plaintiff's argument that the fact that her alleged problem had never made its way onto the research agenda of any epidemiologist created an unfair dilemma, the court said her only option was to "Wait." A question that is capable of being answered by science should await such an answer, and the courts, given their needs for certainty, efficiency, finality, and social legitimacy, should await the "laggardly pace" of the scientific research process.

⁴⁵ Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1449 (D. Or. 1996) (quoting Greenlick report).

⁴⁶ Id. at 718.

⁴⁷ 950 F. Supp. 981 (C.D. Cal. 1996).

Given the difficulties in legal resolution of scientific controversies . . . and the great benefit to society in scientific resolution of scientific controversies - meaning the progressive and continuous rejection, refinement, and confirmation of hypotheses - the court cannot avoid thinking that the framers of Rule 702 did well to make law a prisoner to science, not the other way around.⁴⁸

Thus, in the evolving post-*Daubert* case law, we have a sharp divergence of judicial opinion. One view is that judges should allow testimony if it is based on the types of evidence reasonably relied on by scientists, including clinical diagnosticians, and should not insist on epidemiology, or a certain required level of relative risk in epidemiological studies, because science itself does not always insist on such evidence. Under this view, it is fundamentally erroneous, both as a matter of law and science, to adopt the illusory equation of population based relative risk with the burden of proof on causation. Under this view, the law does not have to await scientific or epidemiological certainty before considering a casual judgment, because scientists themselves do not so insist. The contrasting legal view is that relative risk and individual burdens of proof can, as a matter of legal policy, be equated, because that is a simple device for judges to screen out scientific evidence, especially when a scientific issue is novel, or hotly debated, or highly uncertain. According to this view, the law should wait for a relative degree of scientific certainty, at least in the form of a strong epidemiological risk association. Law thus exalts epidemiology above other scientific disciplines, and makes the same highly conservative value choice on causation that epidemiology itself makes: it is worse to conclude that there is a causal relationship when in fact there turns out not to be one (a Type I false positive error), than it is to conclude that there is no causal relationship when in fact there is such a relationship (a Type II false negative error).

The growing number of courts that are adopting this position, influenced by the legal rulings adopted in Bendectin and breast implant cases, are only considering one side of the normative and policy picture. They are insisting on a strict, statistically inaccurate adherence to burdens of proof on causation, because of reluctance to move the law ahead of scientific uncertainty, out of concern for the potentially adverse consequences for defendants whose products might erroneously be judged to have caused a particular type of harm. But these courts have failed to consider many important value and policy considerations: the consequences for the tort goal of deterring risky corporate behavior, the

⁴⁸ Id. at 1004.

potential for discouraging a more adequate level of safety research, the synergistic effect that the legal system has on stimulating scientific research, the potential disparate impact on certain social groups who have traditionally been neglected by the scientific research community, and the burdens on injured people who may well have causally legitimate claims that they have been injured by an inadequately tested drug or carelessly made device or improperly disposed or dispersed toxic chemical. The final section of this article explores these important policy implications of the legal trend to require an epidemiological threshold for proof of causation.

8. Policy Problems With the Federal Cases

Those courts that have made epidemiology essential for proof of causation are making a policy judgment in three ways:

1. To tolerate or even encourage a high degree of uncertainty about the dangers of some products;
2. To reward manufacturers for ignoring risk; and
3. To require consumers to bear more of the burden of scientific uncertainty than manufacturers.

The troubling policy implications of this choice become even more apparent when one considers the synergistic effects between the tort system and scientific research.

A surprisingly large number of products, drugs, and medical devices are brought to market with disturbingly little safety testing, especially for long-term effects, or for effects on population groups, such as women or children, who were not included among the clinical trial subjects. The products liability system has played a notable role in bringing some of these serious safety problems to light, and in prompting long-overdue regulatory action and scientific research. Scientific research and publication agendas are not set in a political vacuum. A sudden onslaught of tort cases claiming a product has caused a disease can elevate an issue to the forefront of scientific interest, of the interest of research funders, including the government and manufacturers, and of the interest of the editors of scientific journals.

Tort cases, particularly when they initially result in large plaintiffs' verdicts, also stimulate media and public awareness of potential health and safety problems, with consequent demands for firmer answers, which also pushes the research and

regulatory agenda. The tort system played a highly significant, perhaps crucial role in bringing to public attention, and prompting further scientific investigation and understanding of the risks of asbestos, agent orange, thalidomide, mer/29, accutane, DES, the Dalkon shield, Bjork-Shiley heart valves, and the fenfluramine diet drugs.

Under the new heightened, epidemiology-deferential causation law, these often beneficial effects of the tort system in stimulating scientific research may be shut down. If tort law insists that plaintiffs cannot proceed to trial without already well-developed science, manufacturers will have a perverse incentive to avoid or suppress adequate safety research. There will be fewer reasons for epidemiologists to become interested in studying products when the courthouse door is prematurely closed.

Similarly, there will be little reason for funders, especially pharmaceutical companies and product manufacturers, to support epidemiological research into the health effects of products already on the market. If the consequence of no epidemiological research being performed is to largely insulate a manufacturer from liability, then why would any reasonable manufacturer want to fund post-marketing studies when they may lead to sustaining lawsuits? Manufacturers would also have an incentive to lobby regulatory agencies and government research funding entities to keep a product off their research radar screen, or to retain the leading experts and even pay them to refrain from investigating the possibility of a causal association between a product and a disease.

9. Admissibility of a Physician's Diagnosis Uncorroborated by Hard Science, and Testimony of an Auto Reconstruction Expert

(a) A Physician's Diagnosis: Must it be Corroborated by Hard Science?

The U.S. Courts of Appeals for the 3rd and 5th Circuits have confronted this question recently. They arrived at contrary results based on differing views of the extent to which *Daubert* applies to a physician's diagnosis and on the appropriateness of applying the *Daubert* factors to causation testimony based on a differential diagnosis.

The 5th Circuit cases, *Black v. Food Lion, Inc.*, 171 F.3d 308 (5th Cir. 1999) and *Moore v. Ashland Chemical*, 151 F.3d 269 (5th Cir. 1998), held that a physician's diagnosis must be supported by hard science, such as scientific studies that are often beyond the standard of practice of clinicians.

The 3rd Circuit, in *Heller v. Shaw Industries, Inc.*, 167 F.3d 146 (3rd Cir. 1999) held that the qualified physician's differential diagnosis is generally admissible under *Daubert*, even if it is not supported by scientific studies. The 4th Circuit has also held to this effect in *Westberry v. Gislaved Gummi A.B.*, 178 F.3d 257 (4th Cir. 1999).

Typically, a differential diagnosis is made after the patient's medical history has been obtained, a physical examination has been performed, and clinical and laboratory tests have been taken. Physicians then determine which of two or more diseases having similar symptoms the patient most likely has. This method is widely accepted in the medical community.

In *Heller v. Shaw Industries, Inc.*, Carol Heller and her family sued Shaw Industries, a carpet manufacturer, claiming that compounds emitted by Shaw's carpet had caused Ms. Heller to develop a respiratory illness. One of the two

experts who testified on her behalf was Dr. Joseph Papono, her treating allergist. Relying on *Daubert*, however, the district court excluded Dr. Papono's testimony and the testimony of the plaintiff's environmental expert and granted summary judgment for the defendant. Dr. Papono's opinion was that within reasonable degree of medical certainty Ms. Heller's respiratory problems were precipitated by the carpets installed in the Heller home in December 1993. The basis of his conclusion was a differential diagnosis of Ms. Heller's illness, supported by his examination of her, the results of a series of tests, her personal and family medical history, her habits and activities, environmental conditions, and the temporal relationship between her illness and the installation of the carpet.

The 3rd Circuit affirmed the exclusion of testimony and summary judgment, but found that the district court's ruling was erroneous to the extent that the exclusion of Dr. Papono's testimony was based on a lack of "grounding in scientific studies" and on a failure to rule out all of the possible causes of Ms. Heller's illness. 167 F.3d at 154-155, and 158-159.

Although the 3rd Circuit ultimately affirmed the district court's exclusion of Dr. Papono's testimony, it found that a differential diagnosis is a physician's "tool of the trade" and that, even in the absence of scientific research or supporting studies, when a doctor has "good grounds" for his or her conclusions, that testimony is admissible. The court framed the question as whether an expert's conclusion can be reliable and admissible if it is based on accepted scientifically valid methods – such as the differential diagnosis – but is not based on published studies or other data. The court concluded that "if the medical expert's opinion on causation has a

factual basis and supporting scientific theory that is reliable, it should be admitted.” 167 F.3d at 157.

The fact that a differential diagnosis is used to testify to a novel conclusion is not, alone, sufficient grounds to exclude the testimony. However, the court stated that suggested alternative causes of an illness, once addressed by the expert physician, go not to admissibility, but to the weight of the testimony.

In contrast, the 5th Circuit has held that a doctor’s diagnosis must meet the *Daubert* factors and must be supported by scientifically valid principles to be reliable. In *Moore v. Ashland Chemical* and *Black v. Food Lion*, the court concluded that under *Daubert* a medical opinion on a causal relationship between chemical exposure or injury and a plaintiff’s disease or condition, although based on sound application of a generally accepted methodology, such as differential diagnosis, is not admissible unless the causation testimony is confirmed by hard scientific studies or data. According to the 5th Circuit, an opinion that is not based on scientific studies or data is merely “theory.” *Black*, 171 F.3d at 313; *Moore*, 151 F.3d at 278-279.

In *Moore*, the district court excluded the testimony of one of the plaintiff’s medical experts. The expert was to have testified that the plaintiff developed reactive airways dysfunction syndrome (RADS) from exposure to hazardous chemicals, including toluene. The 5th Circuit affirmed the district court’s exclusion, concluding that the proposed testimony was not reliable under *Daubert*.

The plaintiff’s expert offered no scientific support for his theory that the level of toluene to which the plaintiff had been exposed would cause RADS. The expert did not even have accurate information regarding the plaintiff’s level of exposure. The 5th Circuit found that the expert’s extrapolation from other chemicals to those

to which the plaintiff had been exposed was unsupported, and that the expert did not give proper weight to the plaintiff's history of smoking and recent pneumonia.

The dissenting opinion in *Moore* argued that *Daubert* does not require all testimony that is offered to be supported by hard science. The dissent would find a differential diagnosis admissible if it is scientifically valid in the medical community, even if not supported by studies. The dissent warned the majority of the implications of "locking the gate on causation evidence derived through the principles and methodology of clinical medicine." 151 F.3d at 290.

Whether the issue of a differential diagnosis passes muster under *Daubert* in the long run remains to be seen. Petitions for certiorari were not filed in either *Heller* or *Black*, and certiorari was denied in *Moore*.

In *Black*, the district court entered judgment for the plaintiff for an injury sustained from a slip-and-fall at Food Lion grocery store and which allegedly resulted in fibromyalgia syndrome. On appeal, the 5th Circuit held that the court had abused its discretion by admitting the testimony of the plaintiff's expert physician, Dr. Mary Reyna. The 5th Circuit remanded for a recalculation of damages in light of its exclusion of Dr. Reyna's testimony. The court held that Food Lion was not liable for medical expenses, lost wages or pain and suffering attributable to the fibromyalgia.

Dr. Reyna ruled out other possible causes of the plaintiff's condition, based on the temporal relationship between the onset of the symptoms and the plaintiff's fall; the plaintiff's medical history; the lack of other possible post-fall causes; and tests performed on the plaintiff. The 5th Circuit noted that it is unknown whether

fibromyalgia is caused by muscle, nerve or hormone damage. Accordingly, the court concluded that Dr. Reyna's testimony was not reliable.

The court stated that if available medical science did not know the cause of fibromyalgia, there was no way that Dr. Reyna could know the cause of plaintiff's fibromyalgia to a reasonable degree of medical probability. The court also questioned how Dr. Reyna's opinion could be reliable under *Daubert* when her opinion was "isolated" to the plaintiff, "unsubstantiated" by medical literature and not supported by scientific studies. 171 F.3d at 312-314.

(b) Auto Reconstruction Testimony

In *Clay v. Ford Motor Company*, 215 F.3d 663 (6th Cir. 2000), the testimony of Dr. Melvin Richardson, an automobile reconstruction expert, was admitted on the trial and affirmed on appeal in a 2-1 decision.

The plaintiff Slonsky was driving a 1988 two-wheel drive Bronco II north on Interstate 77 in Ohio. The front seat passenger was Sean Lance, the vehicle's owner, and in the back seat were Clay and Strom. The four friends were headed to a club in Cleveland. Slonsky was the designated the driver. Lance had taken LSD and asked him to drive. Slonsky had never driven the Bronco II before that night, although he did drive it to a gas station to get cigarettes prior to leaving for the club.

Slonsky was driving 53-65 miles per hour in the middle lane of three lanes when he noticed a fast-moving car behind him. To avoid the faster car, he moved to the right lane. Once there, he observed that the car in front of him was slowing down, so he returned to the center lane. At that point, he felt the vehicle "jerk" or "overcorrect" to the left, and he responded by turning the steering wheel back to

the right. At some point while trying to regain control of the vehicle, he may have turned the steering wheel as much as a full revolution.

The vehicle turned sideways, its passenger side wheel rims leaving gouge marks in the pavement for approximately 15 feet. It rolled two and three-quarters or three and three-quarters times, coming to rest on the driver's side about 235 feet from the end of the gouges. Clay and Strom, who were not wearing seatbelts, were ejected during the rollover. Clay died at the scene and Strom died at the hospital soon after. Slonsky and Lance, who had been wearing seatbelts, were able to climb out of the passenger side window. At the hospital, Slonsky tested negative for drugs and alcohol.

The estates of Strom and Clay sued in federal court on a products liability theory. The jury found that the Bronco II had a design defect and that the defect proximately caused the deaths of Clay and Strom, and the injuries to Slonsky. The jury awarded \$17.5 million. Plaintiffs consented to remittiturs totaling \$7 million after the district court ruled on post-trial motions and awarded pre-judgment interest to the Clay and Strom estates.

The principal issue on appeal was the admissibility of the auto reconstruction testimony. The auto reconstructionist, Dr. Melvin Richardson, was qualified as an expert in the fields of mechanical engineering, machine design, vehicle dynamics, and accident reconstruction. Richardson had an undergraduate degree in mechanical engineering, a master's degree in both mechanical engineering, with an emphasis in machine design, and in applied mathematics, and a doctoral degree in engineering mechanics. He taught at Clemson University for 20 years in the fields of mechanical engineering, machine design, dynamics, engineering mechanics, and

stress analysis. There was also evidence that on a couple of occasions Ford had retained Richardson to consult and provide opinions.

Richardson testified that dynamics, or the analysis of the forces that produce motion in objects, can be utilized to analyze vehicles and parts of machines and that accident reconstruction is simply an application of dynamics. To reconstruct accidents, Richardson looked at the physical and factual information available, applied standard engineering principles to this information, and determined the most probable sequence of events.

Richardson had never worked in the automobile manufacturing industry, nor had he tested a two-wheel drive Bronco II. He had never published an article on vehicle handling and stability, although he made presentations on those topics.

Richardson's testimony focused on three defects in the Bronco II. He criticized the vehicle's "stability index" as too low; he testified that the rear stabilizer bar on the Bronco II would cause over-steering; and he was of the opinion that the front suspension used on the Bronco II was defective. His opinion was that these handling and stability defects caused the Bronco to roll over in this case, and that there were no other causes of the accident.

The majority upheld the admission of this testimony. The dissent would have excluded the testimony as unreliable. It argued that the record was devoid of any evidence showing that Dr. Richardson employed recognized, reliable or scientific or engineering methodology in reaching his conclusion that the Bronco II had handling and stability design defects.

10. The Connecticut Rule.

(a) *State v. Porter*

In *State v. Porter*, 241 Conn. 57 (1997), *cert. denied* 523 U.S. 1058 (1998), a 70-page en banc unanimous decision authored by Justice Borden, the Supreme Court adopted the *Daubert v. Merrill Dow Pharmaceuticals, Inc.* standard of admissibility of scientific evidence. The occasion for the ruling was the claim of the defendant that the lie detector test he took was admissible. The court, after adopting *Daubert* and explaining its reasons, held that the polygraph test did not meet the new standard for admissibility and excluded the results. Justice Berdon dissented on the lie detector issue, 241 Conn. at 137, but agreed with the majority that for admissibility of scientific evidence we should abandon the *Frye* test and adopt the general principles of *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 241 Conn. at 145.

After general review of the standards for admission of scientific evidence enunciated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and in *Daubert*, the court rejected the *Frye* test and substantially adopted the *Daubert* test for Connecticut state courts.

In explaining the “gatekeeper” function, the court emphasized that there must be a flexible approach. It noted the language in *Daubert*: “we do not presume to set out a definitive checklist or test.” 241 Conn. at 78. The court concluded (241 Conn. at 79):

[I]t is impossible to formulate a specific, clearly defined test that provides judges with a precise, complete list of factors to consider in evaluating the entire class of scientific evidence. No purely mechanical test based on a finite number of set considerations can, in and of itself, truly guide judges with regard to the admissibility of all of the varied and eclectic types of scientific evidence. Indeed, “[e]ach factor may shed some light on the scientific merits of the evidence, but none illuminates much of the total picture. Without a conceptual

framework, using [mechanical] multiple-factor tests to evaluate science is like trying to light up a ball park with a few misaimed spotlights.” (citation omitted).

The court, at some length, explained that the focus of the validity assessment of scientific evidence must be solely on principles and methodology, not on the conclusions that they generate. 241 Conn. at 81. It stated (241 Conn. at 82):

Thus, a judge should admit scientific testimony when there are good grounds for [the] expert’s conclusion, even if the judge thinks that there are better grounds for some alternative conclusion. (Quotation marks and citations omitted).

The court used as an example *Cella v. United States*, 998 F.2d 418, 420 (7th Cir. 1993). The plaintiff claimed that his polymyositis -- an inflammation of the muscles involving both the upper and lower extremities -- was caused by certain events of physical and emotional trauma he suffered while working aboard a Navy vessel. The plaintiff presented the testimony of his physician supporting his theory of liability, while the defendant presented several witnesses who testified that the cause of polymyositis is, in fact, unknown, and thus could not be attributed to the traumas with any degree of certainty. The court, in a bench trial, found in favor of the plaintiff. The defendant appealed, claiming in part that the testimony of the plaintiff’s doctor should not even have been admitted “in light of the testimony of the defendant’s medical experts and the abundance of medical literature stating that the etiology of polymyositis is unknown.” 998 F.2d at 423.

After a thorough review of the bases upon which the plaintiff’s doctor had formulated his opinion, the court upheld the admission of testimony. It noted that the plaintiff’s doctor’s conclusion differed from those of the defendant’s medical experts, nevertheless the plaintiff’s doctor had utilized an accepted methodology in reaching his conclusions. The methodology used was an analysis of the medical

literature, and a case study comparison with the individual characteristics of the patient's case to determine its cause. Even though there was little support in the literature for the doctor's specific conclusion regarding the cause of the plaintiff's injury, the court found that the doctor had employed a proper and thorough diagnostic methodology. Accordingly, it was not error to admit the testimony because as long as the expert's methodology is well founded, the nature of the expert's conclusion is irrelevant, even if it is controversial or unique.

The court stated (241 Conn. at 83):

Once the methodology underlying an expert conclusion has been sufficiently established, the mere fact that controversy, or even substantial controversy, surrounds that conclusion goes only to the weight, and not to the admissibility, of such testimony.

The issues the court considers in determining admissibility are:

1. General acceptance (241 Conn. at 84-85).
2. Whether the methodology has been tested (*Id.* at 85).
3. Whether the methodology has been subjected to peer review (*Id.* at 86).
4. The known or potential rate of error (*Id.* at 86).
5. The prestige and background of the expert witness supporting the evidence (*Id.* at 86).
6. The extent to which the scientific technique in question relies on subjective interpretations and judgments of the testifying expert, rather than on objectively verifiable criteria (*Id.* at 86).
7. Whether the testifying expert can present and explain the data and methodology underlying his or her scientific testimony in such a manner that the factfinder can reasonably and realistically draw its own conclusions (*Id.* at 86).
8. Whether the scientific technique underlying the expert testimony was developed and implemented solely to develop evidence for in-court use, or whether the technique has been developed or used for extrajudicial purposes (*Id.* at 86).

Finally, as a guide to trial judges the court stated (241 Conn. at 89-90):

A trial judge should therefore deem scientific evidence inadmissible only when the methodology underlying such evidence is sufficiently invalid to render the evidence incapable of helping the fact finder determine a fact in dispute. We adopt the *Daubert* approach, however, specifically because we conclude that a sufficient showing of validity is necessary for scientific evidence to be helpful. ... The interplay between these principles -- a general policy in favor of admission of helpful evidence, and a specific policy of requiring a showing of a certain level of validity before scientific testimony can properly be presented to a fact finder -- cannot be resolved by an absolute statement or rule. Instead, a case-by-case analysis will be necessary. (emphasis in original).

The court also held that the prejudicial impact of the scientific evidence must be weighed against its probative value, and an assessment of admissibility made on this basis. In fact, if it assumed that the polygraph evidence satisfied the admissibility threshold established by *Daubert*, it would nevertheless exclude the evidence because the prejudicial impact of polygraph evidence greatly exceeds its probative value. 241 Conn. at 93. The court analyzed at length the scientific basis of polygraph testimony and concluded that it should be excluded. Justice Berdon strenuously dissented on this point.

(b) The Code of Evidence

The relevant provisions of the Connecticut Code of Evidence is Sec. 7-2. It provides:

A witness qualified as an expert by knowledge, skill, experience, training, education or otherwise may testify in the form of an opinion or otherwise concerning scientific, technical or other specialized knowledge, if the testimony will assist the trier of fact in understanding the evidence or in determining a fact in issue.

COMMENTARY

Section 702 imposes two conditions on the admissibility of expert testimony. First, the witness must be qualified as an expert. See,

e.g., *State v. Wilson*, 188 Conn. 715, 722, 453 A.2d 765 (1982); see also, e.g., *State v. Girolamo*, 197 Conn. 201, 215, 496 A.2d 948 (1985) (bases for qualification). Whether a witness is sufficiently qualified to testify as an expert depends on whether, by virtue of the witness' knowledge, skill, experience, etc., his or her testimony will "assist" the trier of fact. See *Weinstein v. Weinstein*, 18 Conn. App. 622, 631, 561 A.2d 443 (1989); see also, e.g., *State v. Douglas*, 203 Conn. 445, 453, 525 A.2d 101 (1987) ("to be admissible, the proffered expert's knowledge must be directly applicable to the matter specifically in issue"). The sufficiency of an expert witness' qualifications is a preliminary question for the court. E.g., *Blanchard v. Bridgeport*, 190 Conn. 798, 808, 463 A.2d 553 (1983); see Section 1-3 (a).

Second, the expert witness' testimony must assist the trier of fact in understanding the evidence or determining a fact in issue. See, e.g., *State v. Hasan*, 205 Conn. 485, 488, 534 A.2d 877 (1987); *Schomer v. Shilepsky*, 169 Conn. 186, 191-92, 363 A.2d 128 (1975). Crucial to this inquiry is a determination that the scientific, technical or specialized knowledge upon which the expert's testimony is based goes beyond the common knowledge and comprehension, i.e., "beyond the ken," of the average juror. See *State v. George*, 194 Conn. 361, 373, 481 A.2d 1068 (1984), *cert. denied*, 469 U.S. 1191, 105 S. Ct. 963, 105 L. Ed. 2d 968 (1985); *State v. Grayton*, 163 Conn. 104, 111, 302 A.2d 246, *cert. denied*, 409 U.S. 1045, 93 S. Ct. 542, 34 L. Ed. 2d 495 (1972); cf. *State v. Kemp*, 199 Conn. 473, 476-77, 507 A.2d 1387 (1986).

The subject matter upon which expert witnesses may testify is not limited to the scientific or technical fields, but extends to all specialized knowledge. See, e.g., *State v. Correa*, 241 Conn. 322, 355, 696 A.2d 944 (1997) (FBI agent may testify about local cocaine distribution and its connection with violence).

In *State v. Porter*, 241 Conn. 57, 698 A.2d 739 (1997), *cert. denied*, 523 U.S. 1058, 118 S. Ct. 1384, 140 L. Ed. 2d 645 (1998), the state supreme court directed trial judges, in admitting scientific evidence, to serve a gatekeeper function in determining whether such evidence will assist the trier of fact. *Id.*, 73. In *Porter*, the court opted for an approach similar to that taken by the United States supreme court in construing the relevant federal rule of evidence in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). *State v. Porter, supra*, 61, 68.

In accordance with *Porter*, the trial judge first must determine that the proffered scientific evidence is reliable. *Id.*, 64. Scientific evidence is reliable if the reasoning or methodology underlying the evidence is scientifically valid. *Id.* In addition to reliability, the trial judge also must determine that the proffered scientific evidence is

relevant, meaning that the reasoning or methodology underlying the scientific theory or technique in question properly can be applied to the facts in issue. *Id.*

In *Porter*, the court listed several factors a trial judge should consider in deciding whether scientific evidence is reliable. *Id.*, 84-86. The list of factors is not exclusive; *Id.*, 84; and the operation of each factor varies depending on the specific context in each case. *Id.*, 86-87.

Subsequent to both *Daubert* and *Porter*, the United States Supreme Court decided that, with respect to Fed. R. Evid. 702, the trial judge's gatekeeping function applies not only to testimony based on scientific knowledge, but also to testimony based on technical and other specialized knowledge, and that the trial judge may consider one or more of the *Daubert* factors if doing so will aid in determining the reliability of the testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 119 S. Ct. 1167, 1174-75, 143 L. Ed. 2d 238 (1999). The Code takes no position on such an application of *Porter*. Thus, Section 702 should not be read either as including or precluding the *Kumho Tire* rule.

(c) Connecticut Case Law Post-Porter

In *State v. McClendon*, 248 Conn. 572 (1999), the court declined to address the issue raised in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), finding the case not to be a proper vehicle for that determination. 248 Conn. at 589, n. 5.

In *State v. Reid*, 254 Conn. 540 (9/5/00), the court again ducked the issue. In holding that microscopic hair analysis "is not the type of evidence that we contemplated in *Porter* to be subject to the *Daubert* test," it noted (254 Conn. at 549 n. 4):

We note that, in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999), the United States Supreme Court held that a trial court has discretion to apply *Daubert* to all expert testimony, not just that which constitutes "scientific evidence." We need not decide in this case whether to apply *Kumho* in our *Porter* analysis, however, because it would not alter our conclusion that the trial court properly admitted the evidence.

State v. Reid, a unanimous decision authored by Chief Justice McDonald, with Justices Borden, Palmer, Sullivan and Vertefeuille, is instructive on how our court will approach the application of *Porter* to the testimony of experts in areas outside hard science. There are four points:

1. The court looks to earlier Connecticut precedent decided under the *Frye* test. The decision states (254 Conn. at 546):

Although this court in *Porter* explicitly adopted the *Daubert* test to determine the admissibility of scientific evidence; see *State v. Porter, supra*, 241 Conn. 68; we did not explicitly overrule Connecticut precedent regarding the evidence to which a test should apply. Prior to *Porter*, this court had recognized that the *Frye* test for admissibility should not apply to all expert testimony, but only to which involves “innovative scientific techniques ...” *State v. Borelli*, 227 Conn. 153, 163, 629 A.2d 1105 (1993); *State v. Hasan*, 205 Conn. 485, 489, 534 A.2d 877 (1987). In *Porter* we recognized that *Daubert’s* vagueness as to how and when to apply the factors of the test was necessary. *State v. Porter, supra*, 78. In order to maintain flexibility in applying the test, we did not define what constitutes “scientific evidence.” *Id.*, 78-79. Accordingly, we must examine the expert testimony at issue in the present case to determine whether it is the type of evidence contemplated by *Porter*.

2. It looks to cases in other jurisdictions. It noted that several states have admitted microscopic hair analysis without applying *Daubert*, including Kentucky and Hawaii. 254 Conn. at 548.

3. It will not apply *Porter* in areas where scientific principles have become so well established that a *Porter* analysis is not necessary. The court stated (254 Conn. at 545-546):

In *Porter*, we said that “[a]s science and technology have advanced and become increasingly prevalent in our society, the number of cases, both civil and criminal, in which scientific testimony plays a role has also grown.” *State v. Porter, supra*, 241 Conn. 92. We explicitly acknowledged, however, that “some scientific principles have become so well established that an explicit *Daubert* analysis is not necessary for admission of evidence thereunder Evidence derived from such principles would clearly withstand a *Daubert*

analysis, and thus may be admitted simply on a showing of relevance." *Id.*, 85 n. 30. As an example of such a principle, this court cited a Montana court's conclusion that a *Daubert* analysis is not necessary for "ordinary finger-print identification evidence to be admissible." *Id.*, citing *State v. Cline*, 275 Mont. 46, 55, 909 P.2d 1171 (1996).

4. It will limit *Porter* to hard science cases. In reviewing its earlier cases decided under *Frye*, it observed that the testimony of a podiatrist in *State v. Hasan*, 205 Conn. 485, 490 (1987) was not based on "obscure scientific theories ... that had the potential to mislead lay jurors awed by an aura of mystic infallibility surrounding scientific techniques, experts, and the fancy devices employed."

In comparing the testimony of the hair analyst to the podiatrist in *State v. Hasan*, it reasoned that there is a distinction between scientific knowledge and technical knowledge. Technical knowledge "being something that involves the mere technical application of well established scientific principles and procedures." 254 Conn. at 548 (internal quotation marks omitted).

It seems obvious that clinical medicine, for example, involves the application of well-established scientific procedures, and would likely be excluded from the application of a *Porter* analysis.

Judge Hodgson has applied *Porter* to an engineer disclosed as an expert on the design, manufacture and assembly of an above-ground swimming pool in *Robillard v. Asahi Chemical*, Superior Court at Waterbury, Complex Litigation Docket, No. X01-CV94-0147579 (9/14/99). However, the decision notes that the "plaintiff has not claimed that the approach to expert opinion testimony adopted in *State v. Porter* does not apply to the challenged opinions."

Had the plaintiff in *Robillard* objected to a *Porter* analysis of the engineer's testimony, it is not clear how many of the proposed opinions would have been excluded.

In our practice, the presiding judge has always played a gatekeeper role, and assessed the adequacy of the evidentiary foundation for expert testimony, and the qualifications of the expert to testify in the area in question. For example, in *Dunn v. Finley*, 151 Conn. 618, 621 (1964), the court stated:

The plaintiff was unable to qualify two witnesses as experts in the design and construction of diving towers, since neither of them had previously experience in that regard. One had designed platforms on dry land, and the other sold swimming pools. The court did not abuse its discretion in excluding their testimony as experts. *Oborski v. New Haven Gas Co.*, 151 Conn. 274, 280, 197 A.2d 73; *Sears v. Curtis*, 147 Conn. 311, 314, 160 A.2d 742.

The qualification of an expert, and the adequacy of the foundation for an opinion, has always been a preliminary question of fact for the court.

11. A Proposal for Connecticut

(a) The court should limit *Porter* to hard science

The court has specifically declined to decide the *Kumho Tire Co., Ltd. v. Carmichael* issue in *State v. McClendon*, 248 Conn. 572, 589, n. 5 (1999) and *State v. Reid*, 254 Conn. 540, 549, n.4 (2000). We believe that *State v. Reid* is a strong indication, as noted, that the court will limit *Porter* to hard science. As illustrated by the federal cases set out in Section 9, even under *Kumho* there is no unanimity as to how the standards of *Daubert* are to be applied.

Rather than enter this quagmire, we believe that the court should limit *Porter* to hard science. The *Daubert* case involved an expert opinion in the field science, thereby requiring the trial court to evaluate whether the expert's opinion was reliably grounded in scientific method. By contrast, for example, a treating physician offers his opinion in a completely different discipline – clinical medicine. It is inappropriate to use the *Daubert-Porter* factors for evaluating the reliability of a doctor's opinion because the principles and methods of clinical medicine differ from those of "hard" science.

The *Daubert* decision defined "scientific knowledge" in terms of "hard science," or "Newtonian" science, i.e., knowledge obtained and tested through "the scientific method," of which Sir Isaac Newton was the leading exponent. The methodology of "hard" or "Newtonian" science is what distinguishes it from other fields of human inquiry. Scientific methodology is based on generating hypotheses and testing them to see if they can be falsified. Theoretically, therefore, hypotheses are not affirmatively proved, only falsified. Of course, if a hypothesis repeatedly withstands falsification, one may then accept it.

The *Daubert* hard scientific methods apply to hard science. These factors are empirical testing, peer review and publication, known or potential rate of error, the existence and maintenance of operational standards, and acceptance within a relevant scientific community.

(b) *Porter* should not apply to clinical medicine

These objectives, functions, subject matter and methodology vary significantly from those of the discipline of clinical medicine, as distinguished from research laboratory medicine. The hard science techniques or methods that became the "*Daubert* factors" generally are not appropriate for assessing the evidentiary reliability of an offer of expert clinical medical testimony.

There are three significant differences in the methods of hard science and clinical medicine.

1. The goals of the disciplines of clinical medicine and hard or Newtonian science are different. In hard science, the usual motive is inquiring: to gain a new understanding of some mechanism of nature. In contrast, the care and treatment of the individual patient is the ultimate, specific act that characterizes a clinical physician. In ordinary clinical treatment, the purpose is not to gain new knowledge but to repeat a success of the past.
2. The subject matter and conditions of study are different. In laboratory work the experimental material is an intact animal, a part of a person or of an animal, or an inanimate system. In clinical treatment, the material is an intact human being. The hard scientist initiates the experiment at a time of his own convenience and chooses the material usually without regard to its desire or consent for participation. In clinical medicine, the patient initiates the treatment, chooses the time, place, duration and clinician. The physician is not studying the properties of chemical compounds in a test tube. He cannot postpone dealing with cancer in a patient for fifty years because he hopes by then to have a much clearer insight into the nature of the disorder.
3. Clinical medicine and hard science have markedly different methodologies. The clinician observes at least three types of data for each patient who undergoes treatment: a disease; the host in whom the disease occurs, and the person's environmental background, including his age, race, sex, education, and external surroundings; the illness that occurs and the interaction between the disease and its environmental host. The person will

have subjective sensations, or symptoms, signs of the disease, which are findings discerned objectively during physical examination or testing.

Using this data, the clinician determines the present diagnosis, the past etiology, and a future prognosis. Some of the data the clinician relies on can be obtained by examining the patient's fluids, cells, tissues, etc.

Hard or Newtonian science has a completely different methodology. Although clinical medicine utilizes parts of some hard sciences, this does not make clinical medicine a hard science.

Based on these differences, we believe that the *Daubert* factors are simply not appropriate for use in assessing the relevance and reliability of clinical medical testimony.

Moreover, *Kumho* legitimizes what many consider to be ill-founded myths, or at least misguided assumptions, in our court system, myths and assumptions that profoundly permeate the decision-making process in the courtroom. Such myth-making includes claims that juries will be unduly persuaded by an aura of invincibility that surrounds experts. This claim is founded on the unsupported contention that juries are stupid and will be fooled, confused or misled, while judges are always better qualified than a group of our clients' peers to decide whether an expert has offered reliable testimony. Empirical studies strongly suggest that the case is otherwise, that in fact, juries are entirely capable of judging the reliability and relevancy of conflicting, often complex, expert witness testimony. Moreover, these implicit assumptions about the lower collective intelligence of jurors do great harm to our underlying beliefs in the right to trial by jury and the power of effective cross-examination to unearth the truth.

Kumho does nothing to change these assumptions. Rather, the decision serves to further institutionalize them. It also supports the view that knowledge is somehow static, instead of recognizing the reality that acquiring knowledge and determining causation are dynamic processes.

(c) Appellate review of *Porter* decisions should be de novo

General Electric v. Joiner, 522 U.S. 136 (1997) is more than a mere standard of review appellate decision. Although it rejected the “stringent standard of review” espoused by the 11th Circuit, it went further, and basically permitted judges to scrutinize scientists’ conclusions, even when doing so requires the judges to make sophisticated scientific evaluations and to wade into areas of scientific controversy and uncertainty. It garbled the distinction between methodology and conclusions. For these reasons, *Joiner* is far more than a mere lesson in the standard of review to be applied to evidentiary rulings. It expresses a strong opinion that judges are to be trusted more than juries in areas where the law intersects with science. It expresses a preference for the tort system to wait for the slow attainment of scientific certainty, rather than to make a decision that may be ahead of scientific consensus. By doing so it presents a policy decision to close the courthouse door to ill and injured plaintiffs whose claims of causation may in fact be widely embraced by the scientific community. It places on the wrong party the burden of scientific uncertainty.

The standard of review in Connecticut for evidentiary rulings is abuse of discretion. *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 264-265 (1997). There is plenary (also called de novo or full) review of a decision setting aside a verdict, rendering judgment notwithstanding the verdict, or in granting summary judgment.

See, Edwards v. Tardiff, 240 Conn. 610, 622 (1997); *Busconi v. Dighello*, 39 Conn. App. 753, 761-762 (1995), *cert. denied* 236 Conn. 903 (1996).

It would appear artificial to limit review of a ruling on the trial excluding or admitting on *Porter* grounds an expert's opinion to an abuse of discretion standard, whereas if the verdict is set aside and judgment rendered notwithstanding the verdict, or if the issue is raised on summary judgment, a de novo standard of review applies. The fact is that it is principally the expert's testimony, either admitted or excluded, that is at issue. Since the plaintiff's case may well rise or fall on the opinion of the expert or experts, coupled with other evidence, it would seem appropriate to apply a heightened or strict standard of review to those decisions admitting or excluding the offered expert testimony on *Porter* grounds. We believe that the 11th Circuit got it right in *Joiner*, and a heightened and more stringent standard of review is appropriate. In fact, the federal courts, although paying lip service to an abuse of discretion standard of review, seems to be applying a more stringent standard in its decisions. Indeed, the United States Supreme Court did this in *General Electric Co. v. Joiner*.

(d) Epidemiological evidence should not be the sole way for the plaintiff to meet the burden of proof

In those cases of scientific opinion where *Porter* applies, we believe that the court should reject epidemiological evidence as a sole way for a plaintiff to meet the burden of proof. Plaintiffs should be permitted to go forward based on the cumulative weight of all available forms of scientific evidence and medical opinion, so long as they all involve methodologies reasonably relied upon by experts in the medical or scientific disciplines. We believe the court must remain open to the scientific reality that epidemiology, with a relative risk of less than 2.0, does not

rule out individual causation, and is not the only relevant piece of evidence for admitting an opinion.

In short, in order to alleviate the many pitfalls and health research disincentives of the emerging causation law as reflected in the federal decisions, courts faced with making an admissibility determination about a plaintiff's offered causation evidence must not place the burden of scientific uncertainty on the plaintiff, especially when the uncertainty is largely due to manufacturers' derelictions in adequately testing their products. While courts do not need to go so far as overtly shifting the burden of proof on causation to manufacturers, as some have proposed, they can avoid the scientifically and statistically unsound step of elevating epidemiology into the sole way to meet the burden of proof.