CURRENT PERSPECTIVES IN MEDICAL CAUSATION ROBERT E. KLEINPETER JANUARY, 2008

I. INTRODUCTION

An essential element of plaintiff's case is causation. There must be some reasonable connection between the defendant's act or omission and the harm suffered by the plaintiff. As simple as that sounds "[t]here is perhaps nothing in the entire field of law which has called forth more disagreement, or upon which the opinions are in such a welter of confusion." Analysis of the casual relationship between defendant's conduct and plaintiff's harm involves two different elements: cause-in-fact and proximate or legal cause. Most of us recall the headache - inducing experience of trying to separate these concepts while learning first year torts.

This paper and presentation address medical cause-in-fact issues. Medical causation is a critical issue in any tort case, and it is becoming more expensive and time consuming. Hopefully, these thoughts about substantive law, procedure, scientific evidence and presentation to the trier of fact will help you in handling medical causation issues in your tort cases.

II. VALUABLE PLAINTIFF CAUSATION TOOLS

The most contested issue in a tort case frequently involves causation. Did defendant's action, product, process or chemical "cause" or "contribute" to the plaintiff's injury? Defense tactics used to dispute a plaintiff's medical causation case are predictable and consistent. Typically they involve blaming a plaintiff's injury on a lifestyle choice, such as smoking, drinking or eating spicy foods; claiming plaintiff's predisposition to injury comes from pre-existing, developmental, psychological, or genetic factors; or pointing a finger at another entity or event which could have caused injury.

Another technique frequently used by defendants is to define the medical specialty pertinent to a plaintiff's case as rarefied--only their hired gun experts possess such unique expertise. Sometimes defendants insist that only a certain methodology can be used to properly analyze a victim's medical history. This methodology is supposedly used by a defendant's expert but not the plaintiff's. And defendants often claim normal clinical methodologies are insufficient to prove medical causation in a court of law. These defense tactics can be squarely refuted by plaintiff.

A. Take the Victim as You Find Him

A plaintiff's psychological tendencies, previous trauma and genetic predisposition have long been discovery areas where defendants sought information about confounders to mitigate or redirect their liability for hurting the plaintiff.

The Louisiana Supreme Court has affirmed many timesⁱⁱⁱ the common law rule, found in Restatement (Second) of Torts, §461, which reads: "The negligent actor is subject to liability for harm to another although a physical condition of the other which is neither known nor should be known to the actor makes the injury greater than that which the actor as a reasonable man should have foreseen as a probable result of his conduct." Thus, the tortfeasor is responsible in damages for the consequences of his tort although the damages so caused are greater because of a prior condition of the victim which is aggravated by the tort. For example, in *Reck v. Stevens*^{iv} the supreme court reversed the court of appeal's reduction of the trial court's award for damages, finding the plaintiff's dormant (but until then controlled) psychiatric condition was activated by the tortfeasor's conduct. Likewise, in *Walton v. William Wolf Baking Co., Inc.* medical testimony indicated the victim was predisposed toward neurosis. Although the victim functioned well before the accident, his reaction to the injury was more severe than that of most people. The court still found this did not lessen the tortfeasor's responsibility to compensate the plaintiff for all the consequences of the accident.

The Louisiana Supreme Court in *Lasha v. Olin Corp.* vi held both lower courts committed reversible error in overlooking or misapplying the rules of law that require the defendant to take the victim as he finds him and to be responsible for aggravation during treatment of plaintiff's injuries, so long as plaintiff exercised reasonable care in placing himself for treatment. The plaintiff in *Lasha*, a truck driver exposed to chlorine gas while unloading a truck at defendant's chemical plant, was a heavy smoker and had experienced ordinary problems of bronchitis and sinusitis. He had never been diagnosed with chronic respiratory problems nor diagnosed with depression. After he suffered chemical exposure, he had permanently disabling respiratory and psychological problems.

The defendant plant acknowledged Lasha's exposure to chlorine gas but argued successfully in the trial and appellate courts that heavy smoking caused his health problems along with a tendency toward hypochondria and depression caused by negligent overmedication by his physicians. The lower courts found plaintiff failed to prove the cause-infact element of his case since over-medication by his own doctors had exacerbated a tendency to depression and hypochondria which disabled him. And since the chlorine gas did not cause compensable injury to a co-worker located near Lasha at the time of the exposure who neither missed work nor suffered health problems, the lower courts found Lasha especially predisposed or vulnerable to respiratory illness since a "normal" person would not suffer harm.

But the supreme court found liability against the defendant plant. Even though the plaintiff's problems may have also been attributable to heavy smoking and a tendency toward hypochondria, and although a co-worker suffered no injury, the defendant's liability was not mitigated by the fact plaintiff's pre-existing infirmities or conditions were responsible in part for the consequences of his injury. The defendant plant had to take Lasha as it found him and was responsible for all natural and probable consequences of its tortious conduct. Thus, this long-standing rule applies to any predisposition of the plaintiff and can be used offensively by counsel to aid in successfully prosecuting the case. The Louisiana Supreme Court has affirmed that the finding of the trier of fact as to whether the defendant's negligent action aggravated a pre-existing injury or condition is subject to the manifest error or clearly wrong standard of review.^{vii} A jury instruction on aggravation of pre-existing injuries may read as

follows.

The defendant "takes its victim as it finds him," and is responsible for all natural and probable consequences of its conduct, including aggravations of pre-existing injuries. This means that even if the plaintiff had medical problems before the accident, the defendant is responsible if it made those problems worse. *Lasha v. Olin Corp.*, 625 So.2d 1002 (La. 1993); *Thibodeaux v. Wal-Mart Stores, Inc.*, (1998-0556 (La.App. 1 Cir. 4/1/99), 729 So.2d 769, writ denied,, 1999-1244 (La. 6/18/99), 745 So.2d 28; *Price v. Exxon Corporation*, 95-0392 (La.App. 1 Cir. 11/9/95), 664 So.2d 1273.

B. Reasonable Possibility

A potent trial weapon for the acute, if not chronic, trauma or exposure case is a conclusion of law for the trial judge or instruction for the jury on "reasonable possibility" as it relates to medical causation. Louisiana has long recognized medical causation is sufficiently proved if two conditions are met: (1) good health prior to the accident, and (2) medical testimony showing a reasonable possibility that the accident caused the injury. The plaintiff has been found in good health even when he or she had a pre-existing injury or illness that was dormant before the accident. Although some courts have held the showing of reasonable possibility is alone sufficient to prove causation of other courts have considered plaintiff's showing of reasonable possibility as to medical causation created a rebuttable presumption in his or her favor. A jury instruction as to reasonable possibility might read as follows.

The plaintiff's injuries are **presumed** to be caused by an accident, if before the accident the plaintiff was in good health, but beginning with the accident the symptoms of the injuries appear and continuously manifest themselves afterwards, providing there is a reasonable possibility of a causal connection between the accident and the injuries and no other event occurs to explain the symptoms. This presumption also applies if the plaintiff had some symptoms before the accident, but the symptoms became more severe, or new symptoms appeared, and continuously manifested themselves after the accident, providing there is a reasonable possibility of a casual connection between the accident and the more severe or newly appearing symptoms and no other event occurs to explain the symptoms. This means that, if you find the plaintiff was not experiencing symptoms during the period before the accident, and you find that beginning with the accident the symptoms of the injuries appeared and continuously manifested themselves afterwards, and there is a reasonable possibility of a causal connection between the accident and the injuries and no other event occurred to explain the symptoms, then you must find the accident caused the symptoms unless there is evidence to the contrary. This also means that, if you find the plaintiff had some symptoms before the accident, and you find the symptoms became more severe, or new symptoms appeared, and continuously manifested themselves after the accident, and there is a reasonable possibility of a causal connection between the accident and the injuries and no other event occurred to explain the symptoms, then you must find the accident caused the symptoms unless there is evidence to the contrary. La. Code Evid. arts. 302-307; *Housley v. Cerise*, 579 So.2d 973 (La. 1991); *Lapleine v. Morgan's Louisiana & Texas R. & S.S. Co.*, 40 La.Ann. 661, 4 So. 875 (1888); *Thibodeaux v. Wal-Mart Stores, Inc.*, 1998-0556 (La.App. 1 Cir. 4/1/99), 729 So.2d 769, *writ denied*, 1999-1244 (La. 6/18/99), 745 So.2d 28; *Price v. Exxon Corporation*, 95-0392 (La.App. 1 Cir. 11/9/95), 664 So.2d 1273); *Arceneaux v. Howard*, 633 So.2d 207 (La.App. (La. 1st Cir. 1993), *writ denied*, 93-3128 (La. 2/11/94), 634 So.2d 833; and *Peppers v. Toye Bros. Yellow Cab Co.*, 198 So. 177 (La.App. Orleans 1940).

C. Substantial Factor

There must be some connection between the act or omission of the defendant and the damage suffered by plaintiff for a tort to be actionable. The vast majority of typical torts allow this cause-in-fact query to be satisfied by the "but-for" rule which has been stated as follows: The defendant's conduct is a cause of the event if the event would not have occurred but for that conduct; conversely, the defendant's conduct is not a cause of the event if the event would have occurred without it.^{xi}

There is a class of tort cases-for example, those involving toxic insults or multiple actors- where the but-for rule fails. If two causes contribute to bring about an event, and either one of them, operating alone, would have been sufficient to cause the same result, some test other than but-for is required. Over time common law courts developed an alternative causation rule which has become known as the "substantial factor" test or formula. Thus, the defendant's conduct is a cause of the event if it was a material element and a substantial factor in bringing it about. There has been considerable discussion among commentators as to whether "substantial factor" is a phrase sufficiently helpful to furnish an adequate guide for the jury, and whether it is possible or desirable to reduce it to any lower terms.^{xii}

Louisiana law has long held that negligence is a cause in fact of the harm to another if it was more likely than not a substantial factor in bringing about the harm. And a long-recognized principle of Louisiana law is there can be more than one cause in fact making both wrongdoers liable. Causation is not defeated by the possibility that the injury would have happened without the defendant's involvement. XiV A jury instruction on the issue of substantial factor may read as follows.

In Louisiana, the test for cause-in-fact is whether defendant's fault was a substantial contributing factor in injuring plaintiff. To be considered a substantial factor, defendant's fault need only increase the risk of harm. To be considered a "contributing" factor, defendant's fault need not be the sole cause but merely a contributing cause. To the extent that defendant's fault had something to do with the injury, the test of a factual, causal relationship is met. You can find causation if [plaintiff's chemical exposure at defendant's plant] or [plaintiff's harm from the wreck] is only one cause of injury even though several other causes unrelated to [his chemical exposure at defendant's plant] or [his harm from the wreck] also exist. Fontenot v. Fontenot, 635 So.2d 219 (La. 1994); Faucheaux v. Terrebonne Consolidated Government, 615 So.2d

289, 292 (La. 1993); Hill v. Lundin & Associates, Inc., 260 La. 542, 256 So.2d 620, 622 (1972); Dixie Drive It Yourself System New Orleans Co. v. American Beverage Co., 242 La. 471, 137 So.2d 298, 302 (La. 1962); Simpson v. State Through DOTD, 636 So.2d 608 (La. App. 1st Cir. 1993); and A. Johnson, Louisiana Civil Law Treatise, Civil Jury Instructions, Sec. 3.03 (2001).

D. Burden of Proof

The defense will almost always employ experts who testify the applicable science does not support the plaintiff's medical causation. The initial method for dealing with such testimony is getting the defense expert to agree that the burden of proof in the case is "more likely than not", not "scientific certainty". Any trial court analysis of your expert's theory (which is what you're now asking the defense expert to evaluate) must give due consideration to the simple fact that the standard of proof in a civil trial is still, and always has been, more likely than not. The defense expert may not only resist, but be unwilling to consider the civil justice system's standard of proof. As Professor Sheila Jasanoff, Chair of Cornell University's Department of Science and Technology Studies (who was cited by the court in Daubert), has written, "It is often said that standards of proof are fundamentally different in science and the law. Thus, proof for scientists generally amounts to something like a 95 percent certainty that a presumed cause-effect correlation is not due to mere chance. Proof in civil litigation, by contrast, requires only a showing that the harm alleged was more probably than not caused by the defendant's conduct. Overly stringent restrictions on admissibility could imperceptibly ratchet up the standard of proof in civil litigation. It should be noted that the Daubert majority viewed the older 'general acceptance' test from Frey as too restrictive."xv

In *Lasha v. Olin Corp.*, xvi the Louisiana Supreme Court reversed the lower courts who had erred in requiring the plaintiff to prove "to a reasonable medical certainty" his exposure to chlorine gas caused his injuries. A plaintiff's burden of proof is by a preponderance of the evidence or more likely than not, not by some artificially created greater standard. The court explained the lower courts' error as follows:

When the term "reasonable medical certainty" is used to describe the measure of persuasion in a tort case, it produces harmful error in two respects. First, it places upon the plaintiff a higher degree of proof than is required in the ordinary civil case. To require plaintiff to prove defendant's negligence, for example, to "a reasonable certainty" is to require him to prove it to such degree as to leave no reasonable doubt, which is equivalent to saying that he must prove it beyond a reasonable doubt. Second, because the word "medical" is susceptible of being construed as referring only to expert medical testimony, the use of the phrase "reasonable medical certainty" tends to preclude the trier of the facts from considering evidence other than that of expert medical witnesses. While expert medical evidence is sometimes essential, it is self-evident that, as a general rule, whether the defendant's fault was a cause in fact of a plaintiff's personal injury or damage may be proved by other direct or circumstantial evidence. (citations omitted).**

A jury instruction on the proper burden of proof to apply to the issue of medical

causation may read as follows.

The plaintiff must prove by a "preponderance of the evidence" that the accident in question caused his injuries. A preponderance of the evidence means "more likely than not." In other words you do not have to find that it is scientifically certain that the accident in question caused the plaintiff's injuries, or that nothing else could possibly have contributed to the plaintiff's injuries; you need only find it is more likely than not that the accident was a substantial factor in causing the plaintiff's injuries. The evidence may, but does not necessarily have to, include expert medical testimony. *Lasha v. Olin Corp.*, 625 So.2d 1002 (La. 1993); *Faucheaux v. Terrebone Consolidated Government*, 615 So.2d 289, 292 (La. 1993); *Campbell v. DOTD*, 94-1052 (La. 1/17/95), 648 So.2d 898, 905.

E. Reversing *Daubert* on Defense Experts

Getting the defense expert to validate your expert's methodology or exposing flaws in the defense expert's analysis is attainable and worth the effort. If the defense expert refuses to analyze the medical causation issue through the proper "more likely than not" burden of proof, then reverse his scientific requirements against him. For example, the expert may state the cause of your client's condition is most consistent with some predisposing physical, environmental or unknowable factor - its anything but the actions of the defendant. Have the scientific expert explain his analysis. Then make the defense expert critique your causation theory in great detail, which may include his imposition of additional methodologies he considers necessary to comprise "good science". Then have him apply that same analysis to his alternative causation theory. Almost always, the defense expert will be unable to meet his unnecessarily stringent requirements of proof for alternative causation.

Another way to illustrate the same point is to have the scientific expert explain his opinion of medical causation and how he arrived at it. Then ask him to assume his opinion is wrong. Ask what process would the expert go through to analyze and assess the opinion to find the error? Usually the expert will not respond the same way to this question as to the initial explanation of how he arrived at his medical causation opinion.

The court can readily infer the defense expert is not applying the same intellectual rigor to his alternative causation theory as he claims is required by "good science"; or, he is not as critical of his own opinion as he should be. Either way, a foundation is laid for validation of the plaintiff's methodology on medical causation since it is similar to or more analytical than defendant's methodology. If the defense expert is unable to meet his requirements for alleged "good science" he may be subject to a *Daubert* motion to exclude his alternative medical causation theory.

III. DAUBERT AND PROCEDURAL CONSIDERATIONS

A. DAUBERT AS APPLIED IN LOUISIANA

The Louisiana Supreme Court requires inferior courts examine three issues regarding

the admission of expert testimony. *Cheairs v. DOTD*, 2003-0680 (La. 12/3/03), 861 So.2d 536. The inquiry involves whether:

- (1) the expert is qualified to testify competently regarding the matters he intends to address;
- (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and
- (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. *Id* at 542 (quoting *City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 562 (11 Cir. 1998), *cert. den.* 528 U.S. 812, 120 S.Ct. 309; 145 L.Ed.2d 42 (1999)).

Louisiana law excludes experts who arrive at their conclusions without use of reliable methods. LSA-C.E. art. 702 governs the admissibility of expert testimony. LSA-C.E. art. 104 allows the court to conduct a preliminary hearing to determine whether the qualifications and/or opinions of an expert are reliable enough to allow them to be heard by the jury. The standard for the admission of expert testimony was set forth by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579; 113 S.Ct. 2786 (1993). The Louisiana Supreme Court adopted the principles set forth in *Daubert* in *State v. Foret*, 628 So.2d 1116 (La. 1993). In applying these principles, the trial court is vested with vast discretion. *Merlin v. Fuselier Construction, Inc.*, 00-1862 (La. App. 5th Cir. 5/30/01), 789 So.2d 710 and *State v. Stokes*, 99-1287 (La. App. 5th Cir. 4/13/00), 759 So.2d 980.

Foret establishes that LSA–C.E. article 702, which is based upon former federal Rule 702, controls the admissibility of expert scientific evidence in Louisiana. To qualify as an expert witness, the court must first determine whether the expert's reasoning or methodology embodies "actual scientific knowledge." In making this determination, the following factors should be considered by the court:

- (1) whether the expert's methodology can be (or has been) tested;
- (2) whether the expert's methodology has been subjected to peer review and publication;
 - (3) the known or potential rate of error relating to the expert's methodology;
 - (4) whether any standards controlling the methodology exist; and
- (5) whether the expert's opinion is "generally accepted" in the scientific community.xviii

An essential objective of *Daubert's* gatekeeping function is to "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." That is to say, an expert's methodology should be the same, whether he is in his laboratory or testifying in court.

Note that the court must proceed under Article 702 (identical to former federal Rule 702) as opposed to present federal Rule 702. The governing rules provide:

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.

A 2000 amendment to the federal rule added the additional following qualifier:

"... if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

Despite an attempt in the 2001 Regular Session, the Louisiana Legislature has refused to follow the new federal approach.^{xx}

While former federal Rule 702 and current state Article 702 focus on the methodology of the expert, amended federal Rule 702 allows further gatekeeper inquiry into the experts' conclusions as well by testing whether the expert had sufficient facts (step 1) and whether the expert reliably applied the methodology to those facts (step 3). *Daubert*, 509 U.S. at 595, clearly limited the relevant inquiry to methodology only - "the focus, of course, must be solely on principles and methodology, not on the conclusions they generate."

The Louisiana appellate courts have repeatedly emphasized that the sole focus is the expert's methodology, not the expert's conclusions. Two cases from the Fourth Circuit clearly articulate the narrower Louisiana rule.

Recently, this Court decided in *Dinett v. Lakeside Hospital*, 2000-2682 (La.App. 4 Cir. 2/20/02), 811 So.2d 116, that Daubert comes into play only when the methodology used by the expert is being questioned. This court found it improper to use Daubert analysis when questioning the conclusions reached by applying the methodology to the facts. *Doe v. Archdiocese of New Orleans*, Nos. 2001-CA-0739, 2001-C-1748 (La. App. 4 Cir. 5/8/02) 2002 WL 1038751 at p. 2.

The Fifth Circuit agreed in *Keener v. Mid-Continent Casualty*, No. 01-CA-1357 (La. 5 Cir. 4/20/02), 817 So.2d 347, 355.

We find that the trial court did not err in admitting Dr. Adams' testimony.

The focus of the gatekeeper under C.E. art. 702 "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, supra at 595, n. 6, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. (emphasis supplied)

Thus, in Louisiana, as long as the expert's methodology is acceptable, cross-examination at trial is the means by which the facts and application are tested whereas federal courts now test facts and application at the gatekeeper hearing before allowing the expert to testify at all. While one can argue whether the new federal approach is helpful or impermissibly invades the province of the court and jury, it is inarguable that the new federal approach goes beyond Louisiana Article 702. Focusing on methodology only, the experts should be excluded if they violate fundamental principles of their disciplines' methodologies.

A trial court record containing a ruling on a *Daubert* challenge is recommended for practitioners who wish to defend the ruling on appeal.^{xxi}

B. Medical Causation and Reliability - A *Daubert* Case Study

Cases concerning Parlodel, a lactation suppressant, demonstrate the *Daubert* issues associated with admission of scientifically reliable medical evidence necessary to prove causation. Some courts have allowed expert opinions into evidence to establish a causal link between Parlodel and acute myocardial infarction (AMI);^{xxii} others have refused admission of expert medical evidence claiming a link between Parlodel and seizures or strokes^{xxiii} Analysis of one of the Parlodel cases, *Globetti v. Sandoz Pharmaceutical Corporation*,^{xxiv} is helpful in evaluating a court's determination of how it approached compliance with its *Daubert* "gatekeeping" requirements.

Mrs. Globetti suffered an AMI about six days after delivering her sixth child, having taken Parlodel twice daily after the child's birth to suppress lactation. Her overall health was good, she was not a smoker or overweight, and had "protective" (very low) cholesterol levels. She had no history of high blood pressure and had never experienced hypertension during pregnancy nor delivery. Angiography of her heart wall failed to reveal any thrombus, dissection, or occlusion of the coronary artery that could account for the AMI. Her initial treating cardiologist concluded her heart event had been caused by a spasm of the coronary artery. This cardiologist knew of the possible association between Parlodel and AMI but opined Mrs. Globetti's heart spasm was spontaneous. Other treating cardiologists and retained experts expressed medical opinions the Parlodel contributed to the arterial spasm that caused the AMI. The defendant pharmaceutical company (Sandoz) challenged these causation opinions by summary judgment motion.

Sandoz contended the medical expert opinion of the plaintiff's treating and retained doctors was nothing more than unscientific speculation, excludable under *Daubert*. According to Sandoz, plaintiffs needed an epidemiological study showing an increased risk of AMI associated with Parlodel use for a sufficiently reliable scientific opinion to be admissible. Plaintiffs opposed the motion, arguing that epidemiological evidence was not needed since there was plenty of scientifically reliable data from which a medical expert could conclude Parlodel can cause vasoconstriction sufficiently severe to cause AMI: animal studies, case reports, Food and Drug Administration Adverse Drug Reaction Reports (ADRs) and the generally accepted opinion of the medical community that Parlodel is a risk factor for AMI since it causes vasoconstriction.

The Globetti opinion began its analysis by noting the four Daubert factors**xv were

neither exclusive nor exhaustive, that it remains for the trial court to determine what procedures are necessary for it to analyze the admissibility of an expert's opinion^{xxvi} and *Daubert* supplemented the old *Frye*^{xxvii} standard with a more "flexible" approach. Thus, the "gatekeeping" role of the trial court requires a practical recognition of what can be known and how it is known. The gatekeeping role is to separate opinions supported by appropriate validation based on "good grounds" from simple subjective speculation masquerading as scientific knowledge. The court wrote:

It is not part of the trial judge's gatekeeping role to determine whether the proffered opinion is scientifically *correct* or *certain* in the way one might think of the law of gravity. The gatekeeping role is addressed to mere evidentiary admissibility; it is the fact-finder's role (usually a jury) to determine whether the opinion is correct or worthy of credence. For the trial court to overreach in the gatekeeping function and determine whether the opinion evidence is correct or worthy of credence is to usurp the jury's right to decide the facts of the case. All the trial judge is asked to decide is whether the proffered evidence is based on "good grounds" tied to the scientific method.xxviii

Three of plaintiffs' experts used the differential diagnostic technique, wherein the physician lists the known possible causes of a condition or disease, usually from most likely to least likely, then utilizes diagnostic tests eliminating causes from the list until left with the most likely cause. Diagnostic tests typically include physical examination, medical history, testing of blood and other body fluids, MRIs, CAT scans, X-rays and other techniques for "falsifying" a hypothesis the disease came from a particular listed cause. The court recognized tests such as these performed on Mrs. Globetti are scientifically accepted techniques for confirming or eliminating specific causes for her AMI. Thus, the court considered the doctors' conclusion the AMI was caused by an arterial spasm to be well-supported.

The court then considered the quality of the next part in the causation opinion that the spasm was caused by plaintiff's ingestion of Parlodel. Experts for plaintiffs reasoned Parlodel has vasoconstrictive characteristics and is capable of causing a coronary artery spasm and was the most likely cause of AMI in the absence of any other reasonable explanation. Sandoz attacked this reasoning by claiming there was no reliable evidence Parlodel can cause vasconstriction and plaintiffs' experts were incorrect in concluding there were no other causes for Mrs. Globetti's AMI.

The court concluded plaintiffs' experts based their opinion Parlodel can cause vasoconstriction sufficiently severe to cause an AMI on sound scientific evidence and methodologies. As foundation for their opinions plaintiffs' experts cited animal studies of ergot alkaloids similar to Parlodel to have a vasoconstrictive effect; Sandoz acknowledged and relied upon these studies in internal documents. Case reports and ADRs reported to the FDA were consistent with literature reviews that identified Parlodel as a risk factor for AMI in the postpartum period. Also, several medical textbooks state that bromocriptine (the chemical compound from which comes Parlodel) is a risk factor for AMI in the postpartum period. These sources and others were more than adequate evidence from which a reliable conclusion could be drawn about the association between Parlodel use, arterial spasm and AMI. Sandoz

pointed out there is no epidemiological study showing an increased risk of AMI associated with bromocriptine. This lack of study, according to defendant, was fatal to plaintiffs. The court disagreed. Plaintiffs argued and the court agreed that an epidemiological study of the association between Parlodel and AMI is not practical because of the relative rarity of AMIs among postpartum women. The court wrote:

To gather a population of postpartum women with a sufficient sub-population of those who have suffered an AMI to be statistically significant would require hundreds of thousands, if not millions, of women. The evidence suggests that AMI occurs in postpartum women at the rare rate of 1 to 1.5 per 100,000 live births. Thus, even in a study of one million women, the sub-population of those suffering an AMI would be only ten to fifteen women, far from enough to allow drawing any statistically significant conclusions. In short, the best scientific evidence available *as a practical matter* is that presented by plaintiffs' experts. *xxix*

The court also commented on the ethical problems associated with experimenting on human beings just to satisfy an evidentiary standard. A control-group study would require administering Parlodel to women and exposing them to the possibility of strokes and heart attacks. Thus, for the association between Parlodel and AMI or stroke to be scientifically established, a scientist must expect a number of deaths to occur among the test subjects.

The court further noted although one can question the adequacy of the scientific evidence relied upon by plaintiffs' experts, the validity of the methodologies is adequate. Thus, the court denied the defendant's motion for summary judgment on medical causation since there is reliable scientific information from which a reasonable scientific inference can be drawn that Parlodel can cause vasoconstriction under circumstances of low vascular resistance and that such vasoconstriction can cause arterial spasm to occlude a coronary artery leading to a myocardial infarction.

Other courts have recently upheld the admissibility of expert medical testimony that strokes were caused by Parlodel, xxx finding it sufficiently reliable. These cases represent excellent analyses of the admissibility issues stemming from *Daubert*.

C. Summary Judgment and Expert Testimony in Louisiana State Court

In *Independent Fire Insurance Company v. Sunbeam Corporation*, xxxi the Louisiana Supreme Court clarified the role of expert testimony in supporting and opposing a motion for summary judgment. The Court also reiterated several traditional principles of summary judgment law which endure even after the 1996 and 1997 amendments to La. Code Civ. P. art. 966.

Before *Sunbeam*, supporting or opposing a motion for summary judgment using expert testimony was an uncertain practice. Courts of appeal inconsistently applied La. Code Civ. P. art. 967, describing the type of documentation a party may submit. The First Circuit held that expert opinions do not meet article 967's requirement of "personal knowledge", though it tempered that stance to allow expert opinions submitted by way of deposition. The Third and

Fifth Circuits disallowed expert opinions not based on first-hand observation or knowledge, whether by affidavit or deposition. The Fourth Circuit allowed expert opinion to support a motion for summary judgment. The Second Circuit has held both ways. In *Sunbeam*, the Supreme Court resolved the conflict among the circuits by deciding that expert opinion testimony, whether by affidavit or deposition, may be considered in support of or in opposition to a motion for summary judgment. Assuming the testimony would be admissible at trial, it must be considered at the summary judgment stage.

The case began after homeowners and their insurer filed suit against the manufacturer of a propane gas barbecue grill, contending a fire in the home was caused by a defective grill or by a defective safety valve on the propane tank attached to the grill. The grill manufacturer third-partied a service station, who the plaintiff then added as a direct defendant, claiming the service station negligently overfilled a spare propane tank, causing vented vapors to ignite during grill use while cooking hamburgers. The third-party defendant service station filed a motion for summary judgment, asserting there was no evidence it had overfilled the spare propane tank nor any evidence it had contributed causally to the fire. Along with the deposition of the homeowner and a service station employee (who testified he didn't remember filling the spare tank, described the customary procedure for filling a propane tank like the one at issue, and testified that the service station had state inspected equipment and proper training to fill propane tanks), the service station also produced three expert witnesses by deposition. The first expert, a mechanical engineer, testified the spare tank was not overfilled, based on the eyewitness testimony of the homeowner and his own examination of the service station facility, which met applicable safety standards for filling propane gas tanks. Another engineer opined the fire started from a gas discharge from the safety valve of the operating grill tank where it was subjected to excessive heat. The third expert said the most likely cause was the malfunction of the hose line connected to the operating grill tank.

In opposition to the service station's motion for summary judgment, the plaintiffs and third-party plaintiffs produced the report and deposition of the grill manufacturer's own expert employee. That expert performed tests using equipment similar to the homeowner's grill but with a properly filled spare propane tank and a non-defective operating tank and grill. After testing the grill by replicating the facts as described by the homeowner, he concluded it was not possible that the flames came from the operating tank. This expert opined that, counter to the homeowner's eyewitness testimony and recollection of the fire, the only possible scenario was that the fire occurred from the accidental venting of the safety relief valve of an overfilled spare tank. The expert's conclusion was that the fire was the service station's fault. This was not based on any first-hand knowledge.

The Supreme Court found a genuine issue of material fact existed, reversing the court of appeal which had affirmed the trial court's granting of summary judgment for the service station. The Court commented that "it would be inequitable and illogical to allow a party who has eyewitness testimony to be granted summary judgment over a party who has no eyewitness testimony, but who does have expert opinion evidence, which if believed, would contradict the eyewitness testimony."xxxiii The Court thus adopted the *Daubert* standardsxxxiii for admissibility of expert opinion evidence at the summary judgment stage, as have the federal courts. The Court pointed out that although no affidavits were submitted in connection with the motion at issue, they may properly be used in support of or in opposition

to a motion for summary judgment and are subject to challenge by way of a *Daubert* hearing, a motion to strike, or counter affidavits.

The Court emphasized four principles in its decision. The first is that the trial judge cannot make credibility determinations on a motion for summary judgment. Second, the court must not attempt to evaluate the persuasiveness of competing scientific studies. In performing its gatekeeping analysis at the summary judgment stage, the court must "focus solely on the principles and methodology, not on the conclusions they generate." Third, the court "must draw those inferences from the undisputed facts which are most favorable to the party opposing the motion." Fourth, and most importantly, summary judgments deprive the litigants of the opportunity to present their evidence to a jury and should be granted only when the evidence presented at the motion for summary judgment establishes that there is no genuine issue of material fact in dispute. If a party submits expert opinion evidence in opposition to a motion for summary judgment that would be admissible under *Daubert* and the other applicable evidentiary rules, and is sufficient to allow a reasonable juror to conclude that the expert's opinion on a material fact more likely than not is true, the trial judge should deny the motion and let the issue be decided at trial.

The Court's decision in reversing a grant of summary judgment allowed the opinion of one expert to successfully counter eyewitness testimony and three other experts. *Sunbeam* lays down a uniform approach to the role of expert testimony in supporting and opposing summary judgment. Equally important, it restates the overall law of summary judgment in a manner which restores some of the imbalances created by overly expansive interpretations of the 1996 and 1997 amendments.

IV. ESTABLISHING THE FOUNDATION FOR A MEDICAL OPINION

A. Use the Reference Manual on Scientific Evidence

A helpful source of information for understanding scientific concepts, including medicine, is the *Reference Manual on Scientific Evidence*, now in its second edition. The manual is published by the Federal Judicial Center as part of its mission to develop and conduct education programs for judicial branch employees. According to the preface, the manual "furthers the goal of assisting federal judges in recognizing the characteristics and reasoning of 'science' as it is relevant in litigation."

About 100,000 copies of the reference manual have been distributed since its initial publication. Its use is widespread in educational programs for federal and state judges, attorneys, and law students. According to the *Reference Manual's* preface, the reference guides "are not intended to instruct judges concerning what evidence should be admissible or to establish minimum standards for acceptable scientific testimony." But some courts ignore that directive and quote the reference guide as an authority for admissibility of scientific evidence. Regardless, counsel handling toxic tort cases should become familiar with, and regularly use, the *Reference Manual*.

B. Expert Qualifications of a Physician

Both lay testimony and physician testimony can be used to prove a plaintiff's damages. Expert testimony is required when the conclusion regarding medical causation is not one within common knowledge. This expert testimony is usually provided by a physician. To render an opinion a doctor, of course, must be qualified.

In the United States, a physician is someone who has met the rigorous requirements of a four year program and graduated from a credentialed medical or osteopathic school.** The expected next stage of medical training is a formal medical residency program. For example, the American Board of Internal Medicine (established in 1936) is one of twenty-four primary medical specialty boards recognized by the American Board of Medical Specialties (ABMS), which is the pre-eminent professional organization in the United States responsible for setting standards for certifying all physicians. The credential of ABMS board certification is a marker of substantial proficiency within a particular area of medicine.**

C. Special Physician Qualifications Relevant to Toxic Torts

There is relatively little structured (organized) study of public health, occupational medicine, and toxicology in a traditional US medical school curriculum; an MPH degree offers enhanced training in epidemiology, toxicology, and other related aspects of public health. The American Board of Preventive Medicine (the board for occupational medicine was established in 1948) is also one of the twenty-four primary medical specialty boards recognized by the American Board of Medical Specialties (ABMS). A significant issue in most toxic tort cases is the proper diagnosis of a spectrum of medical conditions in an adult, and whether they are causally related to chronic or acute exposure to toxic chemicals.

Appropriate research experience and training in analysis of epidemiological methods and study results can also be a relevant criterion. Hospital appointments are a further positive indicator of a doctor's qualifications and experience in clinical medicine. The study of the stud

D. Information Relied on to Reach a Diagnosis

In submitting an opinion, the doctor should review readily available information. Of course, this changes from patient to patient. The patient history is one of the primary and most useful tools in the practice of clinical medicine, and should be obtained directly by the examining physician. A thorough patient history includes not only the present illness and past medical history, but aspects of medical, occupational, personal, and family background relevant to the present problems. The possible, a doctor should personally examine the client and take a thorough history during a clinical visit. A written medical report may contain separate sections on occupational (work) history, present illness (medical history), social history, family history, and past medical history, and a review of systems.

Although there is no established standard patient history questionnaire form, there is agreement that a useful adult patient history should include the following six categories of information 1) patient identification; 2) chief complaint and history of present illness; 3) medical history of injuries, past medical diagnoses, and surgical procedures; 4) lifestyle characteristics including smoking, drug and alcohol use, and environmental exposures; 5) family history; and 6) occupational history. However, gathering a thorough history is

improved by use of a formal written questionnaire to ensure that relevant topics are not slighted or missed entirely. A registered nurse may interview the client face-to-face and complete a very detailed personal and medical history questionnaire in advance of the client's examination by the doctor.

Although time consuming and cumbersome, an examination of patient records from treating physicians, clinics, and hospitals can sometimes be crucial for accurate diagnosis. The doctor may review pages of personal medical records of the client, including those from multiple treating physicians, medical and surgical hospitalizations, laboratory tests, radiology studies, and neuropsychological testing results before arriving at his medical opinion. The client's individual employment and medical surveillance examinations from the employer may be available. The doctor's review of a complete set of personal and occupational patient medical records before he arrives at his medical opinion in the case is desirable, if the case permits.

The physical examination is a routine procedure for evaluating a patient and determining a proper diagnosis. The physical examination has standard components which include determination of vital signs, a description of the patient's general appearance, and examination of specific regions and organ systems of interest. The doctor's performance of the physical examination should comport with the recommendations of the FJC Reference Guide on Medical Testimony for medical experts. This may include specific findings for the Head and Neck (HEENT), Chest, Heart, Abdomen, Extremities, and Neurological Examination, as well as the other recommended components.

In addition to the specific content of the physical examination, there are accepted methods of performing the physical examination properly as well. A reliable causation determination of the client's medical condition is usually aided by a competent general physical examination. Further, it is the consensus of responsible medical authorities that a patient must be disrobed in order for any physician to perform a thorough physical examination. The doctor should perform a competent general physical examination using acceptable methods, and a proper recording of his medical findings.

In modern medical practice, appropriate diagnostic tests are helpful to confirming most diagnoses. These may include laboratory tests, pathology tests, and clinical tests. All such tests have strengths and limitations for their use in reaching a diagnosis or making a causal inference. The physician's decision to order a specific test from among those available should take into account expense, risk, accuracy, and predictive value, if known, as well as the patient's individual circumstances, and institutional capabilities. Based on the doctor's personal history taking and physical examination of the client, his review of previous medical records, and his knowledge of adverse health effects reported in the professional medical literature, he may recommend that certain additional pertinent diagnostic studies be performed by the client's local treating physicians. These additional studies can be representative of those relevant and appropriate studies that can be ordered based on a careful consideration of factors including cost, institutional capabilities, diagnostic sensitivity, and the patient's exposure and risk circumstances, and are not to be an exhaustive and uncritical catalogue of all those which are possibly relevant.

In a case where the medical work-up indicates a potential occupational or environmental disease, special attention must to be paid to documenting the patient's potential chemical exposures. For example, in a toxic tort case, the physician will almost never have direct quantitative exposure levels. However, exposures can be properly inferred by an experienced physician from other types of information, such as workplace layout, work process descriptions, exposure duration, correlates such as acute irritative symptoms, and nearby work activities, among others. Each of these alternate information sources should be available and reviewed by the doctor in formulating his opinion. The doctor in a toxic tort case may review a detailed industrial hygiene report from a certified industrial hygienist. The doctor may obtain chemical process or exposure information directly relevant to these issues during his face to face patient interview with the client. From that interview, he can describe in his written report pertinent exposure information such as the plant layout and work processes, work shifts, job activities, personal protective equipment (or lack thereof), specific chemical identification, and recurrent acute irritative symptoms and the circumstances of their appearance.

Other useful records sources for exposure information in toxic cases include industrial hygiene records, private consultant reports, and government reports. Examples of each of these types of records if available can be reviewed by the doctor in determining his medical causation opinion. The responsibility and duty to conduct adequate industrial hygiene monitoring rests solely with the employer (assuming it's a work-related exposure) under federal law; the workers bear no burden in this regard. The lack of useful quantitative data is strictly and directly the employer's fault.

In the virtual absence of any useful industrial hygiene quantitative exposure information, there is still a wealth of useful exposure data in this case from multiple sources, amounting to much relevant confirming information. The doctor can potentially review a large amount of relevant exposure information which allows him to make a careful medical causation determination. This can include, when available, specific workplace chemical identification, detailed work process descriptions, quantitative environmental release data from government reports, expert reports from company private consultants, medical surveillance program summaries, and individual irritative symptom correlates, and expert industrial hygiene reports.

In summary, the medical causation doctor may have credible information from a number of sources in each category of information; direct patient history, detailed questionnaire data, an extensive collection of personal and occupational medical records, multiple detailed sources of external exposure information, a properly conducted physical examination, and appropriate medical diagnostic studies, that a physician may consider in reaching a final medical causation opinion as recommended by the FJC Reference Guide on Medical Testimony under Part III.

E. Placing the Clinical Treating Physician in Context

It's apparent that a qualified clinical treating physician's credentials, qualifications, and methodology must be evaluated in terms of the physician's acknowledged expertise. There are three relevant chapters in the Reference Manual on Scientific Evidence with respect

to different kinds of experts who may hold a medical or medical field-related degree. They are the Reference Guide on Medical Testimony, the Reference Guide on Epidemiology, and the Reference Guide on Toxicology. There is no mention in the current Reference Manual that any one of these three chapters holds sway over another, nor that one specific methodology is superior to another in determining medical causation. There are three separate chapters to recognize three sometimes similar, but distinct, disciplines and methods for doctors with differing qualifications, training, and clinical experience to use in arriving at valid determinations of medical causation.

Defendants sometime labor under the impression that the only valid method is that outlined in the Reference Guide on Toxicology. That is not so. The primary methodology for physicians is that outlined in the Reference Guide on Medical Testimony. A clinical doctor should be judged only upon his performance within the appropriate clinical boundaries of the relevant Reference Guide on Medical Testimony. To expect him to meet the requirements specified for a physician epidemiologist or physician toxicologist in addition to those of a clinical physician specialist in his specialty, is akin to saying that an architect must also be a iron worker and a commercial banker in order for him to be allowed to design an office building.

V. THE METHODOLOGY OF DIFFERENTIAL DIAGNOSIS

The Federal Judicial Center's Reference Guide on Medical Testimony explains the process of differential diagnosis: liii

In the process of performing a differential diagnosis, the physician determines which of two or more diseases with similar clinical findings is the one that the patient is suffering from. The physician does this by developing a list of all the possible diseases that could produce the observed signs and symptoms, and then comparing the expected clinical findings for each with those exhibited by the patient. (citations omitted)

For the most part, courts are reaching a consensus that the basic methodology used by physicians to diagnose disease is sufficient for courtroom purposes.

A. Differential Diagnosis in Louisiana State Courts

For example, recent Louisiana state court cases allow the opinion testimony of treating doctors who follow their routine and established practices in making diagnoses.

Keener v. Mid-Continent Casualty^{liv} discussed the methodology of a differential diagnosis in a case involving a stroke.

We find that the trial court did not err in admitting Dr. Adams's testimony. The requirements of *Daubert* and *Foret* were satisfied. *Daubert* requires that to qualify as scientific evidence, an opinion must be derived by an accepted scientific method; the four-part test is illustrative, but is not an exclusive guide to determine the reliability of scientific testimony. We find that

Dr. Adams's use of differential diagnosis, which is clearly an accepted methodology in the medical community, was proper. Dr. Adams moved to rule out every possible explanation of Mr. Keener's stroke before concluding that it was probably related to the surgery. Dr. Adams was honest in his acknowledgment that medical science cannot, at this point in time, clearly explain the cause of Mr. Keener's stroke, but that there was some suggestion, in current medical literature, that the temporal association between the surgery and the stroke was a factor. The fact that his opinion was not admittedly 100% certain goes to its weight, not its admissibility. The focus of the gatekeeper under C.E. art. 702 "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, supra at 595, n. 6, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. (emphasis supplied)

The Louisiana Fifth Circuit addressed a similar argument in *Younce v. Pacific Gulf Marine, Inc.*, when the defendant argued that *Daubert* somehow eliminated the equally traditional medical method of relying in part on the patient's history in favor of exclusive reliance on objective tests. The Fifth Circuit quickly dispatched the defense notion.

Dr. LaBorde, PGM's medical expert, testified that of the two factors used to determine causation, the "objective" evidence--records from physical examinations--is more reliable than the "subjective" evidence--the history given by the patient. Dr. LaBorde testified that while "medical causation," causation within the realm of treatment, may be based solely on the patient's history, "objective" evidence takes precedence in a determination of "forensic causation."

We agree with the trial judge's determination on this issue--we cannot agree that a treating physician's opinion on causation is so unreliable as to be inadmissible at trial. We note first that Daubert's concern is the reliability of expert's opinions based on less than "firsthand knowledge or observation." Daubert, 509 U.S. at 591, 113 S.Ct. at 2796, 125 L.Ed.2d at 482. It has also been stated that Daubert is "concerned with determining the admissibility of new techniques." State v. Foret, 628 So.2d at 1121 (emphasis supplied). We can't see how either of these concerns implicates an opinion on the causation of injuries given by a patient's treating physician. Dr. Watermeier's testimony, that "all" doctors rely on the patient's own statements in determining causation, was not contradicted by PGM's expert. Further, the risks inherent in relying exclusively on records are revealed by Dr. LaBorde's own testimony. Dr. LaBorde's assertions that "objective" records are more reliable are called into question by Dr. LaBorde's admission that his initial opinion, rendered without all of Younce's medical records, might "change" on review of additional information.

In *Dinett v. Lakeside Hospital*, lvi the trial court's exclusion of the treating physicians' opinions was reversed. The case involved whether plaintiff contracted hepatitis C from a blood transfusion. The treating doctors properly relied upon what the appellate court called "the standard medical methodology of relying upon patient history." The court pointed out

that defendant's motion sought to exclude physician opinions when their **methodology** was sound, thus making *Daubert* inapplicable.

. . .It is a routine and well established practice for a physician to give opinion testimony as to the cause of a patient's condition based upon the history provided by the patient. In the instant case, however, the trial court excluded the testimony on the sole basis of the testimony of another physician, Dr. Sandler, that because it is scientifically impossible to determine with any certainty that the transfusion was the source of Mrs. Dinett's infection, any opinion to that effect is merely a "guess."

We find the trial court erred in excluding the testimony on this basis. *Daubert* is inapplicable to the instant situation because it is not the experts' methodology that is being questioned; rather, it is the conclusions they reached in applying that methodology to the instant facts. Given that a pre-1990 blood transfusion is a known risk factor for acquiring Hepatitis C and Mrs. Dinett's history of having received such a transfusion (as well as having undergone other surgical procedures which also could have exposed her to Hepatitis C), there is nothing inherently unreliable about a physician testifying as to the probability that the transfusion caused her infection.

The plaintiff's burden in a civil case such as the instant one is to prove that defendant's conduct "more probably than not" caused plaintiff's condition. If the burden were to prove each element of the case beyond a reasonable doubt, as in a criminal matter, the testimony of Dr. Sandler that such proof of causation is scientifically impossible arguably would merit the granting of summary judgment in favor of defendants. In the instant case, however, the exclusion of the plaintiffs' experts at the summary judgment state improperly usurps the function of the jury at trial, which is to weigh the opinions of those experts against that of Dr. Sandler in determining whether the plaintiffs have met their burden of proving causation.

Other state court decisions have been receptive to the notion of separating physicians' methodology from their conclusions. And a recent appellate decision correctly noted that "it appears from the depositions that the requisite scientific level is higher than the indicia of reliability required for expert testimony and opinion at trial."

B. Differential Diagnosis in Most United States Courts of Appeal

The vast majority of federal appellate courts have held that a medical opinion on causation founded on differential diagnosis satisfies Rule 702 of the Federal Rules of Evidence. For example, the Second Circuit in *McCullock v. H B. Fuller Co.* lviii accepted as reliable a doctor's opinion that glue fumes caused the plaintiff's respiratory symptoms and throat polyps, although the doctor could not specify any medical literature stating that glue fumes cause throat polyps. According to the court, the doctor's opinion was reliable.

Dr. Fagelson based his opinion on a range of factors, including his care and

treatment of McCullock; her medical history (as she related it to him and as derived from a review of her medical and surgical reports); pathological studies; review of Fuller's MSDS; his training and experience; use of a scientific analysis known as differential etiology (which requires listing possible causes, then eliminating all causes but one); and reference to various scientific and medical treatises. **Disputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.** (emphasis added)

In *Zuchowicz v. United States*, lx the Second Circuit reaffirmed a clinical medical expert opinion in pulmonary medicine as sufficiently reliable for a causation opinion. The court approved the causation opinion of a pulmonary medical doctor who testified that overdose of the endometriosis drug Danocrine caused plaintiff's primary pulmonary hypertension. The doctor's conclusion was based on the temporal relationship between the overdose and the start of the disease and the differential etiology method of excluding other possible causes. The Third Circuit has also held that a clinical physician's methodology of differential diagnosis was sufficiently reliable to support the admissibility of that expert's opinion that polychlorinated biphenyls caused specific plaintiffs' illnesses. lxi

The Fourth Circuit affirmed a district court's admission of doctors' testimony that a plaintiff's severe liver damage was caused by mixing extra-strength Tylenol and alcohol.

Benedi's treating physicians based their conclusions on the microscopic appearance of his liver, the Tylenol found in his blood upon his admission to the hospital, the history of several days of Tylenol use after regular alcohol consumption, the liver enzyme blood level, and the lack of evidence of a viral or any other cause of the liver failure. Benedi's other experts relied upon a similar methodology: history, examination, lab and pathology data, and study of the peer-reviewed literature. We conclude that the district court did not abuse its discretion when it determined that the methodology employed by Benedi's experts is reliable under *Daubert*. We will not declare such methodologies invalid and unreliable in light of the medical community's daily use of the same methodologies in diagnosing patients. [kiii] (emphasis added)

Another Fourth Circuit court stated in *Westbury v. Gislavi Gummi AB*, lxiii "differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely. lxv, lxvi

C. A View of the U. S. Fifth Circuit Court of Appeal

In *Curtis v. M & S Petroleum, Inc.*, lxvii the U. S. Fifth Circuit vacated a district court's dismissal of numerous refinery workers' suits and remanded them for trial, finding an abuse of the trial court's discretion in excluding plaintiffs' expert industrial hygienist on the issue of medical causation. The case is significant in that the same court only nine months earlier found no abuse of a trial court's discretion in excluding the opinion of a highly qualified pulmonary physician on the causal relationship between a plaintiff's exposure to industrial chemicals and his pulmonary illness. Analysis of the cases is therefore helpful in evaluating when a federal trial court's exclusion of an expert's medical opinion may abuse its considerable discretion. Lxix

The plaintiffs in *Curtis* were refinery workers and their wives who alleged they were exposed to excessive amounts of heavy aromatic distillate ("HAD"), a dangerous component more than 25 percent of which is benzene. A defendant, M & S Petroleum, Inc. ("M&S"), planned to process the HAD, a DuPont product, at a leased refinery which was not designed to handle highly toxic chemicals such as benzene. Immediately after M&S began processing HAD at the refinery serious problems erupted; workers became soaked in HAD daily while fixing clogged equipment and were continuously exposed to HAD fumes that possessed a very strong distinctive odor. These exposures contemporaneously caused the refinery workers to experience headaches, nausea, dizziness, diarrhea, and a lack of energy.

After conducting a hearing *in limine* shortly before trial, the district court excluded the proffered testimony of Dr. Frank Stevens, plaintiffs' expert industrial hygienist, on the issue of medical causation. The expert's opinion was that the plaintiffs' exposure to benzene caused their symptoms and that this exposure subjected them to known long-term health problems. Although the trial court found that plaintiffs' industrial hygienist had adequate support for his general causation opinion that exposure to benzene at levels of 200-300 ppm would cause the injuries suffered by plaintiffs, it excluded his testimony as unreliable since plaintiffs had not demonstrated the amount of benzene to which they were exposed. But the appellate court found ample evidence supporting the expert's finding that the refinery workers were exposed to benzene at levels several hundred times the permissible OSHA standard of 1 ppm. This was important since if his causation opinion was not based on sufficient information of the level of benzene to which plaintiffs were exposed, his methodology would not be reliable, rendering his causation opinion inadmissible.^{lxx} However, the law does not require plaintiffs to show the precise level of benzene to which they were exposed.

The industrial hygienist's medical opinion was reliable since the facts adequately supported the expert's findings of the level of benzene to which the refinery workers were exposed. The court found sufficient support for Dr. Stevens's causation opinion for multiple reasons:

First, Dr. Stevens found the symptoms experienced by the refinery workers to be extremely important. He testified that the cluster of symptoms that the refinery workers began experiencing shortly after HAD was introduced into the refinery - headache, nausea, disorientation, and fatigue - are well-known symptoms of overexposure to benzene. He concluded that these symptoms were all indications of exposure to benzene at levels of at least 200-300 ppm.

Dr. Stevens also relied upon the results of the Draeger tube tests performed by the refinery workers. The particular Draeger tubes used were designed to measure a maximum of 10 ppm based on twenty pumps. Because these tubes were only pumped twice before becoming saturated, measuring the maximum of 10 ppm, Dr. Stevens calculated that the refinery workers were exposed to at least 100 ppm. Additionally, Dr. Stevens relied upon the work practices at the refinery. The refinery workers were required to clean the strainers and the oily water separator, and gauge the tanks on a daily basis. All of these functions made exposure to high levels of benzene likely. Dr. Stevens was particularly impressed with the testimony of the refinery workers that they often became soaked in HAD when required to perform this work.

Finally, Dr. Stevens relied on the design of the refinery. Dr. Stevens testified during the *in limine* hearing and stated in his report that the refinery was not designed to process highly toxic chemicals such as benzene. Dr. Stevens testified that refineries that process benzene and other toxic chemicals are completely enclosed to eliminate the possibility that these toxic chemicals can escape into the environment. Exxii

Since the court viewed his causation opinion as based on scientific knowledge that would assist the trier of fact pursuant to Fed. R. Evid. 702, it should have been admitted by the trial court.

Nine months previously, in *Moore v. Ashland Chemical, Inc.,* lxxiii the Fifth Circuit held that the district court did not abuse its discretion in excluding the opinion of a physician that the plaintiff's exposure to toluene and other chemicals caused his reactive airways dysfunction syndrome ("RADS"). Interestingly, a concurring opinion pointed out that it would not have been an abuse of the district court's discretion had it admitted the proffered testimony. Mr. Moore became exposed to toluene and other chemicals manufactured by Dow Corning, Corp. ("Dow") while cleaning up the spilled material in an enclosed 28-foot trailer for about an hour. He immediately sought emergency room treatment after the onset of respiratory distress which occurred less than an hour after his exposure. The Fifth Circuit found the exclusion of the plaintiff's highly qualified expert pulmonologist, Dr. Jenkins, acceptable since he did not know what tests Dow had conducted in generating the MSDS and "perhaps more importantly, Dr. Jenkins had no information on the level of exposure necessary for a person to sustain the injuries about which the MSDS warned. The MSDS made it clear that the effects of exposure to Toluene depended on the concentration and length of exposure." The court in *Curtis* explained its exclusion of Dr. Jenkins in *Moore*.

In *Moore*, this Court discussed the admissibility of the proffered testimony of the plaintiff's expert on causation. After finding that the expert offered no scientific support for his general theory that exposure to Toluene solution at any level could cause Reactive Airways Dysfunction Syndrome, the Court stated:

Given the paucity of facts Dr. Jenkins had available about the level of Moore's

exposure to the Toluene solution, his causation opinion would have been suspect even if he had scientific support for the position that the Toluene solution could cause RADS in a worker exposed to some minor level of the solution. Under *Daubert*, 'any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology. In re Paoli R.R. Yard PCB Litigation, 35 F.3d 717, (3d Cir. 1994) (emphasis in original). lxxvi

Since the "analytical gap" between Dr. Jenkins' causation opinion and the scientific knowledge and available data advanced to support that opinion was too wide, it was within the trial court's discretion to exclude his opinion.

At first blush, it's perplexing that the Fifth Circuit would require an industrial hygienist's causation opinion to be admitted in Curtis, yet allow the exclusion of a highly qualified pulmonologist's opinion as to the cause of a lung problem in *Moore*. A careful reading of both opinions leads one to the conclusion that the appellate court feels comfortable requiring admissibility when there is ample factual information about the exposure to a widely studied chemical, like benzene, as in Curtis. In Curtis, perhaps serendipitously, the safety manager, himself a later plaintiff, took Draeger tube readings for benzene when he became sick and personally convinced that his and other workers' symptoms were caused by chemical exposure. The employer, M & S, should have been regularly monitoring for benzene exposure pursuant to its agreement with Dupont and for compliance with OSHA standards. Since the employer did not perform monitoring, but an employee on his own did, there was additional information upon which the industrial hygienist could reliably estimate the benzene level. While the court did not specifically say so, the other factors relied upon by Dr. Stevens - well known symptoms of overexposure to benzene, work practices at the refinery, and design of the refinery - probably were sufficiently reliable on their own to require admittance of his opinion.

Judge Eugene Davis, author of *Moore* and *Curtis*, again ventured into the arena of medical causation in *Pipitone v. Biomatrix Inc.*^{lxxvii} Thomas Pipitone had severe osteoarthritis in his knees. Because of pre-existing medical conditions, he chose to have his knees injected with a synovial fluid product, Syvnisc, manufactured by defendant, Biomatrix. Soon after injection, Pipitone suffered significant knee pain and a fever. A few days later, tests confirmed he had a salmonella infection, which is highly unusual in joints.

After Pipitone and his wife filed suit, Biomatrix moved to exclude the testimony of the plaintiffs' experts pursuant to *Daubert*. The district court granted Biomatrix's motion for summary judgment after finding the testimony of plaintiffs' experts unreliable. The Fifth Circuit reversed.

The appeals court found the testimony of the orthopedist who injected the joint properly excluded. The orthopedist deferred to the other treating physician, Dr. Coco, an infectious disease expert. Also, the orthopedist was equivocal as to how the infection occurred. The court noted that a perfectly equivocal opinion is not a relevant one. Since the orthopedist testified it was as likely as not (not more likely than not) that the Synvisc syringe

contained the salmonella bacteria that infected Pipitone's knee, the district court did not abuse its discretion in excluding his testimony.

But the appellate court disagreed with the trial court's exclusion of Dr. Coco, the infectious disease expert. The district court based its decision to exclude Dr. Coco's testimony on three factors. First, the district court pointed out Dr. Coco performed no epidemiological studies. Next, the district court noted that Dr. Coco's hypothesis that Synvisc caused the joint infection was undermined by his literature search, which revealed no reports of salmonella infection from contaminated injectable knee products. Last, the district court found Dr. Coco had failed to eliminate "many viable alternative sources" for the salmonella infection.

The Fifth Circuit analyzed Dr. Coco's reasoning that led to his conclusion that the Synvisc injection caused infection. While it was true Dr. Coco did not perform an epidemiological study, no such study was necessary or appropriate in a case involving one infected person. And Dr. Coco's literature search showing no other reports of infection from knee injections did not contradict his opinion. Failure to uncover other reports actually supported his conclusion by eliminating the possibility that "unsterile injection technique or some other cause unrelated to Synvisc" had caused the infection. As the Supreme Court pointed out in *Kumho Tire Co. Ltd. v. Carmichael*, had a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist." No one should reasonably expect a published report on a phenomenon that had not occurred before.

Having analyzed Dr. Coco's opinion through *Daubert's* "testing" and "peer review" factors, the court noted that the "error rate" factor "is not particularly relevant, where, as here, the expert derives his testimony mainly from firsthand observations and professional experience in translating these observations into medical diagnoses." The court observed "this circuit has upheld the admission of expert testimony where it was based on the expert's specialized knowledge, training, experience, and first-hand observation while supported by solid evidence in the scientific community." As to the *Daubert* factor of "general acceptance," the court noted "Dr. Coco based his opinion on how Pipitone contracted salmonella in large part on accepted medical knowledge of the ways in which salmonella functions as an organism and how it infects humans."

The appellate court disagreed with the district court's finding that Dr. Coco had identified "many viable alternative sources" of the salmonella infection in Pipitone's knee. Instead, Dr. Coco eliminated almost all alternative sources of the infection through analysis and investigation. The disputed factual record allowed a fact-finder to choose the Pipitone's contentions over those of defendant. Thus, the district court's grant of summary judgment was reversed.

- i Prosser and Keeton, *Torts*, 5th ed. (St.Paul, Minn.: West Publishing Co., 1984), 263.
- ii See Maraist and Galligan, Louisiana Tort Law, (Charlottesville: Michie, 1996), Chapter 4.

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- Thames v. Zerangue, 411 So. 2d 17 (La. 1982); Aisole v. Dean, 574 So. 2d 1248 (La. 1991); Walton v. William Wolf Baking Co., Inc., 406 So. 2d 168 (La 1981); Reck v. Stevens, 373 So. 2d 498 (La. 1979).
- iv Supra.
- v Supra.
- vi 625 So. 2d 1002 (La. 1993).
- vii Touchard v. Slemco Electric Foundation, et al., 99-3577 (La. 10/17/00), 769 So. 2d 1200).
- viii *Marcantel v. Allen Parish School Board*, 490 So. 2d 1162 (La.App. 3d Cir.) *writ denied*, 496 So. 2d 328 (La. 1986); *Davis v. Galilee Baptist Church*, 486 So. 2d 1021 (La.App. 2d Cir. 1986).
- ix Housley v. Cerise, 579 So. 2d 973 (La. 1991); Wisner v. Illinois Central Gulf Railroad, 537 So. 2d 740 (La.App. 1 Cir. 12/20/88), writ denied, 540 So. 2d 342 (1989).
- x Davis v. Galilee Baptist Church, 486 So. 2d 1021 (La.App. 2 Cir. 1986); Miller v. Allstate Insurance Company, 221 So. 2d 908 (La.App. 1st Cir. 1969).
- xi Smith, Legal Cause in Actions of Tort, 1911, 25 Harv.L.Rev. 103, 106, 109, McLaughlin, Proximate Cause, 1925, 39 Harv.L.Rev. 149, 155.
- xii Green, *Rationale of Proximate Cause*, 1927, 132-141; Green, *The Causal Relation Issue*, 1962, 60, Mich.L.Rev. 543, 554. Hart and Honore, *Causation In The Law*, 1959, 216-218, 263-266.
- xiii Dixie Drive It Yourself Systems v. American Beverage Co., 242 La. 471, 137 So. 2d 298 (1962).
- xiv See *In Re Ralph C. Manguno*, and cases therein citing Louisiana law, 961 F. 2d 533 (5th Cir. 1992).
- xv Sheila Jasanoff, *Judging Science: Issues, Assumptions, Models*, 1997 Forum For State Court Judges 9 (The Roscoe Pound Foundation) July 19, 1997.
- xvi 625 So. 2d 1002 (La. 1993).
- xvii *Id.* at 1005 (citations omitted).
- xviii Daubert 113 S.C. at 2786 and Exxon Pipeline Co. v. Hill, 763 So.2d 144, 151 (La.App.1st Cir. 6/23/00).

xix

- Kumho Tire Company v. Carmichael, 526 U.S. 137,152; 119 S.Ct. 1167, 1176. See also, Exxon Pipeline Co. v. Hill, 763 So.2d 144, 151 (La.App.1st Cir. 6/23/00); Seatrax v. Sonbeck Intern'l, Inc., 200 F.3d 358, 372 (5th Cir. 2000).
- Sen. Dardenne (R- EBR Parish) filed Senate Bill 446, it was referred to the Judiciary A Committee, but it never passed even that initial stage.
- xxi State v. Chauvin, 2002-1188 (La. 5/20/03), 846 So.2d 697.
- xxii Globetti v. Sandoz Pharmaceutical Corporation, 111 F.Supp. 2d 1174 (N.D. Ala. 2000); Anderson v. Sandoz Pharmaceutical Corporation, 77 F.Supp. 2d 804 (S.D. Tx. 1999).
- xxiii Hollander v. Sandoz Pharmaceutical Corporation, 95 F.Supp. 2d 1230 (W.D.Okla. 2000); Glastetter v. Novartis Pharmaceutical Corporation, 107 F.Supp. 2d 1015 (E.D.Mo. 2000); Brumbaugh v. Sandoz Pharmaceutical Corporation, 77 F.Supp. 2d 1153 (D.Mont. 1999).
- xxiv 101 F.Supp. 2d 1174 (N.D. Ala. 2000).
- These factors were testability, peer review and publication, assessing the known or potential rate of error of the proposition, and whether it has found general acceptance in the scientific community.
- xxvi See *Kumho Tire Company, Ltd. v. Carmichael, 526* U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).
- xxvii Frye v. United States, 293 F. 1013 (1923).
- xxviii Globetti, 101 F.Supp. 2d at 1177.

xxix *Id.* at 1179.

xxx Brasher, et al., v. Sandoz Pharmaceutical Corp., et al., 160 F.Supp. 2d1291 (N.D. Ala. 2001).

xxxi 99-2257 (La. 2/29/00), 755 So. 2d 226.

xxxii *Id.* at 235.

xxxiii Daubert v. Merrell Dow Chemicals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.ED.2d 469 (1993).

xxxiv Citing Daubert, at 595.

xxxv Citing Frank L. Maraist and Harry T. Lemmon, 1 Louisiana Civil Law Treatise, Civil Procedure, § 6,8, p. 145 (1999).

XXXV

An electronic version of the reference manual can be found at http://air.fjc.gov/public/fjcweb.nsf/pages/16.

xxxvii Lasha v. Olin Corp., 625 So.2d 1002 (La. 1993).

xxxviii *Hutchinson v. Shah*, 94-0264, (La.App. 1Cir. 12/22/94), 648 So.2d 451, *writ denied*, 95-0541, 653 So.2d 570, (La. 4/21/95) and *Schexnayder v. Exxon Pipeline*, 815 So.2d 156, 01-1236 (La.App. 5 Cir. 3/13/02).

xxxix Federal Judicial Center (FJC) Reference Guide on Medical Testimony, Part II A, p. 447.

xl FJC Reference Guide on Medical Testimony, Part II A, p. 448.

xli FJC Reference Guide on Medical Testimony, Part II A, p. 447.

xlii There is no ABMS Board of Medical Toxicology; Medical Toxicology is not a recognized primary medical specialty in the United States; and the ABMS Subspecialty Certificate has only been available since 1995.

xliii. FJC Reference Guide on Medical Testimony, Part II C, p. 450.

xliv FJC Reference Guide on Medical Testimony, Part II A p. 448-449.

xlv FJC Reference Guide on Medical Testimony, Part III A, p. 452-453.

xlvi FJC Reference Guide on Medical Testimony, Part III A, p. 453.

xlvii FJC Reference Guide on Medical Testimony, Part III B, p. 455.

xlviii FJC Reference Guide on Medical Testimony, Part III C, p. 455-456.

xlix See standard medical textbooks by DeJong, Harrison, or Bates.

FJC Reference Guide on Medical Testimony, Part III D, p. 457-461.

li FJC Reference Guide on Medical Testimony, Part III A2, p. 454-455.

lii FJC Reference Guide on Medical Testimony, Part III A2, p. 455.

liii FJC Reference Guide on Medical Testimony, Part IV, p. 463.

liv No. 01-CA-1357 (La. 5 Cir. 4/20/02), 817 So.2d 347, 355, writ den. 2002-1498 (La. 9/20/02) 2002 WL 31175447.

lv 01-0546 (La. App. 5 Cir. 4/10/02), 817 So.2d 255, rev'd on other grounds, 827 So.2d 1144, 2002-4343 (La. 10/4/02).

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811 So.2d 116, 2000-2682 (La.App. 4 Cir. 2/20/02).

lvii Wingfield v. State of Louisiana, 2001-2668 (La.App. 1 Cir. 11/8/02), 835 So.2d 785, writ denied, 2003-0313 (La. 5/30/03), 845 So.2d 1059, 1060.

lviii61 F.3d 1038 (2nd Cir. 1995).

lix61 F.3d 1044 (2nd Cir. 1995).

lx140 F.3d 381 (2nd Cir. 1998).

lxi*In Re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3rd Cir. 1994).

lxii*Benedi v. McNeil-P.P.C., Inc.*, 94-2596, 66 F.3d 1378, (4th Cir. 1995).

lxiii 178 F.3d 257, 51 Fed. R. Evid. Serv. 682 (4th Cir. 1999).

lxiv *Id.*, 178 F.3d at 262. See also *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252-253, 50 fed. R. Evid. Serv. 115 (1st Cir. 1998).

Ixv Kannankeril v. Terminix Intern., Inc., 128 F.3d 802, 807, 47 Fed. R. Evid. Serv. 1376 (3d Cir. 1997), as amended, (Dec. 12, 1997) (explaining that "differential diagnosis is defined for physicians as 'the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting the clinical findings'" (quoting Stedman's Medical Dictionary 428 (25th ed. 1990)). See also McCullock v. H. B. Fuller Co., 61 F.3d 1038, 1044, 42 Fed. R. Evid. Serv. 1047 (2d Cir. 1995) (describing differential etiology as an analysis "which requires listing possible causes, then eliminating all causes but one"); Glaser v. Thompson Medical Co., Inc., 32 F.3d 969, 978, 40 Fed. R. Evid. Serv. 47, 1994 FED App. 0287P (6th Cir. 1994), reh'g and reh'g en banc denied, (Nov. 9, 1994) (recognizing that differential diagnosis is "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury and disease").

lxvi For a more extensive discussion see Branch, Turner W. and Branch, Margaret Moses, Environmental Tort Litigation, ATLA's Litigating Tort Cases, §67:35, pp. 88-91 (Roxanne Barton Conlin and Gregory S. Cusimano, eds.) (West & ATLA 2003).

lxvii 174 F.3d 661 (5th Cir. 1999).

lxviii *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269 (5th Cir. 1998), also authored by Judge W. Eugene Davis.

lxix Abuse of discretion is the federal standard of review to be applied to admissibility of an evidentiary opinion. *General Electric Co. v. Joiner*, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). The seminal case for admissibility of expert testimony is *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

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The Supreme Court set out four non-exclusive factors to aid in the determination of whether the methodology is reliable. They are: (1) whether the theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error of the method used and maintenance of standards controlling the technique's operation; and (4) whether the theory or method has been generally accepted by the scientific community. *Daubert*, 509 U.S. at 593-94, 113 S.Ct. at 2796-97.

lxxi Curtis, 174 F.3d at 670, citing Lakie v. Smithkline Beecham, 965 F.Supp. 49, 58 (D.D.C. 1997).

lxxii *Curtis*, 174 F.3d at 671-672.

lxxiii 151 F.3d 269 (5th Cir. 1998).

lxxiv *Id.* at 279 (Benavides, J., concurring).

lxxv *Id.* at 278.

lxxvi *Curtis v. M & S Petroleum, Inc.*, 174 F.3d 661 (5th Cir. 1999).

lxxvii 288 F.3d 239, 58 Fed. R. Evid. Serv. 1123, Prod.Liab.Rep.

lxxviii 526 U.S. 137 (1999).

lxxix See Skidmore v. Percision Printing and Packaging, Inc., 188 F.3d 618 (5th Cir. 1999) (holding that the district court properly admitted testimony of a psychiatrist who diagnosed plaintiff because the psychiatrist "testified to his experience, to the criteria by which he diagnosed [the plaintiff], and to the standard methods of diagnosis in his field"); St. Martin v. Mobil Exploration & Producing U.S., Inc., 224 F.3d 402, 406-07 (5th Cir. 2000) (holding that ecologist's first-hand observation of flooded marsh at issue combined with his expertise in marshland ecology were sufficiently reliable bases of his opinion on causation under Daubert to admit the testimony).