Admitting and Excluding Medical Causation Testimony in Pharmaceutical and Toxic Tort Substance Litigation

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I.
ADMISSIBILITY REQUIREMENTS FOR EXPERT TESTIMONY

Texas Rule of Evidence 702 imposes specific limitations on the admissibility of expert testimony. 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, 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.

For an expert's testimony to be admissible under Rule 702 of the Texas Rules of Civil Procedure, the proponent of an expert bears the burden of proving that the expert witness is qualified, and that his testimony is relevant to issues in the case, reliable, and helpful to the trier of fact. *Guadalupe-Blanco River Auth. v. Kraft*, 77 S.W.3d 805, 807 (Tex. 2002); *Gammill v. Jack Williams Chevrolet, Inc.,* 972 S.W.2d 713, 720 (Tex.1998); *Robinson*, 923 S.W.2d at 556-557 ("Once the party opposing the evidence objects, the proponent bears the burden of demonstrating its admissibility.").

A. EXPERT OPINION TESTIMONY MUST CONCERN SCIENTIFIC, TECHNICAL OR OTHER SPECIALIZED KNOWLEDGE, AND MUST NOT USURP THE ROLE OF THE JUDGE OR JURY:

Rule 702 does not afford the expert unlimited license to testify without first relating that testimony to some "specialized knowledge" on the expert's part. In other words, the opinion must be an "expert" opinion (that is, an opinion informed by the witness' expertise) rather than simply an opinion broached by a purported expert. "Testimony consisting merely of personal opinion is not "scientific, technical, or other specialized knowledge," because "the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589, 590 (1993); *GTE Southwest, Inc. v. Bruce*, 998 S.W.2d 605, 620 (Tex. 1999) ("Where . . . the issue involves only general knowledge and experience rather than expertise, it is within the province of the jury to decide, and admission of expert testimony on the issue is error."); *accord*, *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (expert evidence must be "genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist");

B. EXPERT TESTIMONY MUST ASSIST THE TRIER OF FACT TO UNDERSTAND THE EVIDENCE OR TO DETERMINE A FACT IN ISSUE

Rule 702's requirement "that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue' . . . goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."

Daubert, 509 U.S. at 591 (citation omitted) . Thus, the court must ensure that the proposed expert testimony is "relevant to the task at hand." *Daubert*, at 597.

An expert's testimony assists the trier-of-fact when the expert's knowledge and experience on a relevant issue are beyond that of the average juror and the testimony helps the trier-of-fact understand the evidence or determine a fact issue. *K-Mart Corp. v. Honeycutt,* 24 S.W.3d 357, 360 (Tex. 2000). The trial court should exclude the expert's testimony (a) when the jury is equally competent to form an opinion about the ultimate fact issue or (b) when the expert's testimony is within the common knowledge of the jury. *Id.*

C. EXPERT WITNESS MUST BE QUALIFIED BY KNOWLEDGE, SKILL, EXPERIENCE, TRAINING OR EDUCATION TO RENDER AN OPINION

A witness may be qualified to testify as an expert on a particular subject through "knowledge, skill, experience, training, or education." The party offering the testimony bears the burden to prove that the witness is qualified under Rule 702. *Broders v. Heise*, 924 S.W.2d 148, 151 (Tex. 1996). The decision of whether an expert witness is qualified to testify is within the trial court's discretion, and will be reviewed on appeal only if the ruling is an abuse of discretion, meaning that the trial court acted without reference to any guiding rules or principles. Broders v. Heise, 924 S.W.2d at 151.

In *Broders v. Heise*, the Texas Supreme Court confirmed the exclusion of an emergency room physician's testimony as to the cause in fact of a head injury in a medical malpractice action against a neurosurgeon holding that "what is required is that the offering party establish that the expert has 'knowledge, skill, experience, training or education' regarding the specific issue before the court which would qualify the expert to give an opinion on that particular subject." 924 S.W.2d at 152-53. The Supreme Court emphasized that the focus must be "on whether the expert's expertise goes to the very matter on which he or she is to give an opinion." *Id.*

Likewise, in *Gammill v. Jack Williams Chevrolet, Inc.*, the Texas Supreme Court held that the trial court did not abuse its discretion in excluding the testimony of one of plaintiffs' experts who, despite his experience in designing and testing fighter planes and missiles, was not shown to have any training or experience in the design or manufacture of automobiles or their relevant components and only had experience with automobiles as a part-time mechanic doing general repairs. 972 S.W.2d 713, 719 (Tex. 1998).

In *United Blood Services v. Longoria,* the Texas Supreme Court excluded the testimony of the plaintiffs' putative expert on the standard of care in the blood bank industry because he:

> is not a doctor of medicine or osteopathy, has previously conceded that he did not consider himself as an expert in blood banking, hematology or immunology, never worked for a blood bank, never took any courses in blood banking, never published any articles related to blood banks, and obtained his Ph.D. by correspondence

> course from Pacific Western University, which is not accredited by any nationally recognized accrediting agency.

938 S.W. 2d 29, 30 (Tex. 1997).

Recently, in *Pioneer Natural Resources USA, Inc. v. W.L. Ranch, Inc.,* the Corpus Christi Court of Appeals held that a petroleum engineer was not qualified as an expert on drilling horizontal wells and to testify about the standard of care for drilling a horizontal well where he had experience drilling vertical wells and admitted he did not have any experience in drilling horizontal wells. 127 S.W.3d 900, 906 (Tex. App.-- Corpus Christi 2004, pet. denied).

Courts have been reluctant to accept blindly 'curb side' causation testimony from clinical physicians." *Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *30 (Tex. Dist. Ct. June 7, 1999). Self-study in preparation for litigation will not qualify an expert. *Robinson v. Warner*, 998 S.W.2d 407, 411 (Tex. App. – Waco 1999, no pet.).

Likewise, courts exclude testimony by witnesses whose "expertise is gained exclusively from reading real experts' work." *Burton v. Danek Med., Inc.*, 1999 U.S. Dist. LEXIS 2619, 1999 WL 118020, *3-4 (E.D. Pa. Mar. 1, 1999) (board certified neurologist not qualified to testify as an expert regarding spinal fusion surgery, with which he had no experience); *Mancuso v. Consolidated Edison Co.*, 967 F. Supp. 1437, 1442-45 (S.D.N.Y. 1997) (rejecting the qualifications of a proffered "expert" concerning PCB exposure, although he was a medical doctor, because he had no experience with toxic torts and his "self-education" in the effects of PCBs was insufficient); *Diaz v. Johnson Matthey, Inc.*, 893 F. Supp. 358, 372-73 (D.N.J. 1995) (disqualifying pulmonologist from testifying that plaintiff had a platinum allergy because he had no qualifications "other than his medical education and his years practicing as a pulmonologist," had only casually studied the literature on platinum allergy, and had never previously treated a patient who had that condition); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1476 (D.V.I.), *aff'd*, 46 F.3d 1120 (3d Cir. 1994) (witness educated as a pediatrician, pharmacologist, and toxicologist was not qualified to testify on the cause of birth defects because he had only reviewed selected literature on the subject for the purposes of litigation).

D. RELIABILITY REQUIREMENTS

1. FEDERAL:

In the case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993), the U.S. Supreme Court held that FED. R. EVID. 702 overturned earlier case law requiring that expert scientific testimony must be based upon principles which have "general acceptance" in the field to which they belong. *See Frye v. US.*, 293 F. 1013 (D.C. Cir. 1923) (establishing the "general acceptance" test for scientific expert testimony). Under Rule 702, the expert's opinion must be based on "scientific knowledge," which requires that it be derived by the scientific method, meaning the formulation of hypotheses which are verified by experimentation or observation. The Court used the word "reliability" to describe this necessary quality.

In *Kumho Tire Co. v. Carmichael*, 526 U.S.137, 11 S. Ct. 1167, 143 L.Ed.2d 238 (1999) (ruling below: 131 F.3d 1433 (11th Cir. 1997)), the Supreme Court said that the reliability and relevancy principles of *Daubert* apply to all experts, not just scientists, and where objection is made the court must determine whether the evidence has "a reliable basis in the knowledge and experience of [relevant] discipline." The trial court has broad discretion in determining how to test the expert's reliability. *Id.*

2. TEXAS CIVIL PROCEEDINGS:

The Texas Supreme Court adopted the *Daubert* analysis for TEX. R. EVID. 702, requiring that the expert's underlying scientific technique or principle be reliable and relevant. *E.I. du Pont de Nemours v. Robinson*, 923 S.W.2d 549 (Tex. 1995). The Texas Supreme Court listed factors for the trial court to consider regarding reliability: (1) the extent to which the theory has been or can be tested; (2) the extent to which the technique relies upon the subjective interpretation of the expert; (3) whether the theory has been subjected to peer review and/or publication; (4) the technique's potential rate of error; (5) whether the underlying theory or technique has been generally accepted as valid by the relevant scientific community; and (6) the non-judicial uses which have been made of the theory or technique. *Robinson*, 923 S.W.2d at 557. *See America West Airline Inc. v. Tope*, 935 S.W.2d 908 (Tex. App.--El Paso 1996, no writ) (somewhat unorthodox methods of mental health worker in arriving at DSM-1II-R diagnosis did not meet the admissibility requirements of *Robinson*). The burden is on the party offering the evidence to establish the reliability underlying such scientific evidence. *Robinson,* 923 S.W.2d at 557.

In *Gammill v. Jack Williams Chevrolet, Inc.*, 972 S.W.2d 713 (Tex. 1998), the Texas Supreme Court announced that the reliability and relevance (discussed below) requirements of *Robinson* apply to all types of expert testimony, whether or not it is based on science. In *Gammill,* a unanimous Supreme Court said:

> We conclude that whether an expert's testimony is based on "scientific, technical or other specialized knowledge," *Daubert* and Rule 702 demand that the district court evaluate the methods, analysis, and principles relied upon in reaching the opinion. The court should ensure that the opinion comports with applicable professional standards outside the courtroom and that it "will have a reliable basis in the knowledge and experience of [the] discipline." [FN 47]
>
> We agree with the Fifth, Sixth, Ninth, and Eleventh Circuits that Rule 702's fundamental requirements of reliability and relevance are applicable to all expert testimony offered under that rule. Nothing in the language of the rule suggests that opinions based on scientific knowledge should be treated any differently than opinions based on technical or other specialized knowledge. It would be an odd rule of evidence that insisted that some expert opinions be reliable but not others. All expert testimony should be shown to be reliable before it is admitted. [FN 48]

Gammill, 972 S.W.2d at 725-26.

After noting that the reliability and relevancy criteria listed in *Daubert* may not apply to experts in particular fields, the Texas Supreme Court noted that nonetheless there are reliability criteria of some kind that must be applied. The Court said:

> if the specific factors set out in *Daubert* for assessing the reliability and relevance of scientific testimony do not fit other expert testimony, the court is not relieved of its responsibility to evaluate the reliability of the testimony in determining its admissibility.

Gammill, 972 S.W.2d at 724.

3. TEXAS CRIMINAL PROCEEDINGS:

The Texas Court of Criminal Appeals, which established a reliability requirement even before the U.S. Supreme Court decided *Daubert* (*see Kelly v. State*, 824 S.W.2d 568 (Tex. Crim. App. 1992)), has extended reliability requirements to all scientific testimony, not just novel science. *See Hartman v. State*, 946 S.W.2d 60 (Tex. Crim. App. 1997) (applying *Kelly*-reliability standards to DWI intoxilyzer). In the case of *Nenno v. State,* 970 S.W.2d 549 (Tex. Crim. App. 1998), the Court extended the *Kelly*- reliability standards to mental health experts, but indicated that the *Daubert* list of factors did not apply. Instead, the Court of Criminal Appeals suggested the following factors be applied to fields of study outside of the hard sciences (such as social science or fields relying on experience and training as opposed to the scientific method): (1) whether the field of expertise is a legitimate one; (2) whether the subject matter of the expert's testimony is within the scope of that field; (3) whether the expert's testimony properly relies upon and/or utilizes the principles involved in the field. *Nenno*, 970 S.W.2d at 561.

4. RELIABILITY OF EXPERT'S IPSE DIXIT:

In summary, the offering party also has the burden of proving that their expert's opinions are reliable. Reliability includes three components:

- **Foundational reliability:** *Merrell Dow Pharmaceuticals, Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997)("If the foundational data underlying opinion testimony are unreliable, an expert will not be permitted to base an opinion on that data because any opinion drawn from that data is likewise unreliable.").

- **Methodological reliability:** *id.* at 714 ("Further, an expert's testimony is unreliable even when the underlying data are sound if the expert draws conclusions from that data based on flawed methodology. A flaw in the expert's reasoning from the data may render reliance on a study unreasonable and render the inferences drawn there from dubious.").

- **Connective reliability:** *Gammill v. Jack Williams Chevrolet, Inc.*, 972 S.W.2d 713, 727 (Tex. 1998) (The Court adopted the "analytical gap" analysis for assessing reliability by which the trial court may determine that there is too great

> of an analytical gap between the data the expert relies upon and the opinion offered. Such an analytical gap exists if an expert fails to demonstrate how his or her observations support his or her conclusions. There must be a "nexus" between the expert's opinion and the facts of the particular case--*i.e.*, the opinion must not be admitted where it is connected to the data in the case only by the *ipse dixit* of the expert. *Id.* at 727 (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 519, 139 L.Ed.2d 508 (1997)).

JUDGE HARVEY BROWN, EIGHT GATES FOR EXPERT WITNESSES, 36 HOUS. L. REV. 743, 747-79 (1999).

Foundational, methodological and connective reliability cannot be established by the bare opinion ("*ipse dixit")* of a credentialed expert. *Havner*, 953 S.W.2d at 712-13 ("The view that courts should not look beyond an averment by the expert that the data underlying his or her opinion are the type of data on which experts reasonably rely has likewise been rejected by other courts. The underlying data should be independently evaluated in determining if the opinion itself is reliable."); *Guadalupe-Blanco River Auth. v. Kraft*, 77 S.W.3d 805, 808 (Tex. 2002) ("[the expert's]'bald assurance' that he was using the widely accepted approach was not sufficient to demonstrate that his opinion was reliable."); *Robinson*, 923 S.W.2d at 559 (an expert's "self-serving statements that his methodology was generally accepted and reasonably relied upon by other experts in the field are not sufficient to establish the reliability of the technique"); *Gammill*, 972 S.W.2d at 727 ("The district court was not required, in *Joiner's* words, to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert" quoting from *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 519, 139 L.Ed.2d 508, 519 (1997)).

"In *Robinson*, the Supreme Court set forth some of the factors that courts should consider in looking beyond the *ipse dixit* of the expert." *Havner*, 953 S.W.2d at 714. Those factors include:

1) the extent to which the theory has been or can be tested;

2) the extent to which the technique relies upon the subjective interpretation of the expert;

3) whether the theory has been subjected to peer review and publication;

4) the technique's potential rate of error;

5) whether the underlying theory or technique has been generally accepted as valid by the relevant scientific community; and

6) the non-judicial uses that have been made of the theory or technique.

Robinson, 923 S.W.2d at 557.

E. RELEVANCY REQUIREMENT

TEX. R. EVID. 401. Definition of 'Relevant Evidence'

> 'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.

TEX. R. EVID. 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

> All relevant evidence is admissible, except as otherwise provided by Constitution, by statute, by these rules, or by other rules prescribed pursuant to statutory authority. Evidence which is not relevant is inadmissible.

Daubert and *Robinson* contain a relevancy requirement, to be applied to expert evidence. As explained in *Gammill v. Jack Williams*, 972 S.W.2d 713, 720 (Tex.1998):

> The requirement that the proposed testimony be relevant incorporates traditional relevancy analysis under Rules 401 and 402 of the Texas Rules of Civil Evidence. To be relevant, the proposed testimony must be "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Evidence that has no relationship to any of the issues in the case is irrelevant and does not satisfy Rule 702's requirement that the testimony be of assistance to the jury. It is thus inadmissible under Rule 702 as well as under Rules 401 and 402.

II.
PRESERVING ERROR ON *DAUBERT/ROBINSON/HAVNER* OBJECTIONS

It is a fundamental rule of evidence law that a party wishing to exclude evidence offered by another party must make a timely objection. Otherwise the evidence is admitted and no right to complain on appeal has been preserved. TEX. R. EVID. 103; TEX. R. APP. P. 33.

A. PRELIMINARY QUESTIONS OF ADMISSIBILITY

TEX. R. EVID. 104. Preliminary Questions

> (a) Questions of Admissibility Generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination the court is not bound by the rules of evidence except those with respect to privileges.

> (b) Relevancy Conditioned on Fact. When the relevancy of evidence depends upon the fulfillment of a condition of fact, the court shall admit it upon, or subject to the introduction of evidence sufficient to support a finding of the fulfillment of the condition.
>
> (c) Hearing of Jury. In a criminal case, a hearing on the admissibility of a confession shall be conducted out of the hearing of the jury. All other civil or criminal hearings on preliminary matters shall be conducted out of the hearing of the jury when the interests of justice so require or in a criminal case when an accused is a witness and so requests.
>
> (d) Testimony by Accused Out of the Hearing of the Jury. The accused in a criminal case does not, by testifying upon a preliminary matter out of the hearing of the jury, become subject to cross-examination as to other issues in the case.
>
> (e) Weight and Credibility. This rule does not limit the right of a party to introduce before the jury evidence relevant to weight or credibility.

Generally, FED. R. EVID. 104 and TEX. R. EVID.104 provide that the court shall determine preliminary questions concerning the qualification of a person to be a witness, or the admissibility of evidence. In making its determination, the trial court is not bound by the rules of evidence other than with respect to privileges. FED. R. EVID. 104(a); TEX. R. EVID. 104(a). Such a preliminary proceeding must be conducted out of the hearing of the jury, "when the interests of justice so require." FED. R. EVID. 104(c); TEX. R. EVID.104(c). The *Daubert* case itself invokes FED. R. EVID. 104(a). *Daubert*, 509 U.S. at 592 ("trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

B. MOTION IN LIMINE

A motion *in limine* alone is not an adequate vehicle to pursue a *Daubert* challenge. Texas appellate cases have made it clear that a ruling on a motion *in limine* cannot itself be reversible error. *Hartford Accident & Indemnity Co. v. McCardell*, 369 S.W.2d 331, 335 (Tex. 1963) (overruling of motion *in limine* doesn't preserve error; must make objection at time evidence is offered in trial); *Keene Corp. v. Kirk*, 870 S.W.2d 573, 581 (Tex. App.--Dallas 1993, no writ) (where motion *in limine* is granted, counsel still must offer the excluded evidence); *Waldon v. City of Longview*, 855 S.W.2d 875, 880 (Tex. App.--Tyler 1993, no writ) (where motion *in limine* is granted, proponent must tender the evidence offered in a bill of exceptions and secure a ruling on its admission).

C. OBJECTION DURING TRIAL

TEX. R. EVID. 705. Disclosure of Facts or Data Underlying Expert Opinion

> (a) Disclosure of Facts or Data. The expert may testify in terms of opinion or inference and give the expert's reasons therefor without prior disclosure of the underlying facts or data, unless the court requires otherwise. The expert may in any event disclose on direct examination, or be required to disclose on cross-examination, the underlying facts or data.
>
> (b) Voir dire. Prior to the expert giving the expert's opinion or disclosing the underlying facts or data, a party against whom the opinion is offered upon request in a criminal case shall, or in a civil case may, be permitted to conduct a voir dire examination directed to the underlying facts or data upon which the opinion is based. This examination shall be conducted out of the hearing of the jury.
>
> (c) Admissibility of opinion. If the court determines that the underlying facts or data do not provide a sufficient basis for the expert's opinion under Rule 702 or 703, the opinion is inadmissible.
>
> (d) Balancing test; limiting instructions. When the underlying facts or data would be inadmissible in evidence, the court shall exclude the underlying facts or data if the danger that they will be used for a purpose other than as explanation or support for the expert's opinion outweighs their value as explanation or support or are unfairly prejudicial. If otherwise inadmissible facts or data are disclosed before the jury, a limiting instruction by the court shall be given upon request.

It is proper and sufficient to make a *Daubert* objection during trial. However, a court could adopt a local rule or scheduling order in a particular case requiring that *Daubert* objections be raised before trial or they are waived. A party objecting based on *Daubert* should also object based on TEX. R. EVID. 403, arguing that probative value is outweighed by charges or prejudice or confusion. This is an independent basis to exclude the evidence.

D. ADMISSIBILITY/NO EVIDENCE CHALLENGE

Under *Robinson* and *Havner*, a party in a Texas civil proceeding can attack the admissibility and legal sufficiency of the evidence, on the ground that the expert testimony does not meet the necessary standards of reliability and relevance.

In *Robinson*, the Texas Supreme Court addressed the proper standard for the admission of expert testimony under TEX. R. EVID. 702. *See Robinson*, 923 S.W.2d at 556. 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.

The court held that Rule 702 requires the proponent to show not only that an expert is qualified, but also that the expert's testimony is relevant to the issues in the case and is based on a reliable foundation. *Robinson,* 923 S.W.2d at 556. To be relevant, the proposed testimony is subject to the traditional analysis of relevancy under TEX. R. EVID. 401 and 402, and therefore it must be sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute. To be reliable, the scientific techniques or principles underlying the expert's testimony must be well grounded in the methods and procedures of science. *Id*. at 557. The court set out the following non-exhaustive list of factors a trial court may consider in determining the reliability of the underlying techniques or theories and thus the admissibility of an expert's testimony under Rule 702: 1) the extent to which the theory has been or can be tested; 2) the extent to which the techniques rely on the subjective interpretation of the expert; 3) whether the theories have been subjected to peer review and/or publication; 4) the techniques' potential rate of error; 5) whether the underlying theories or techniques have been generally accepted as valid by the relevant scientific community; and 6) the nonjudicial uses which have been made of the theories or techniques.

In *Havner*, the Texas Supreme Court addressed whether the evidence at issue in that case was legally sufficient, *i.e*., some evidence, to support the jury's finding of causation. *See Havner*, 953 S.W.2d at 711. The evidence in *Havner*, which the trial court admitted, was scientific expert testimony. *See id.* The court noted that under a traditional legal sufficiency review, a reviewing court is to consider the evidence in the light most favorable to the verdict. The court said, however, that in conducting a legal sufficiency review, for a reviewing court to not look beyond the expert's testimony to determine reliability would be to engage in a "meaningless exercise of looking to see only what words appear in the transcript of the testimony, not whether there is in fact some evidence." *Id*. at 712. Thus, the court held that when determining whether expert testimony is some evidence, the reviewing court must undertake an almost de novo-like review and, like the trial court, look beyond the expert's bare testimony to determine the reliability of the theory underlying it. The court then undertook an examination of the reliability of the evidence on which Havner's experts relied. In determining reliability, the court stated, "While Rule 702 deals with admissibility of evidence, it offers substantive guidelines in determining if the expert testimony is some evidence of probative value." *Id.* Thus, the *Havner* court applied the same factors it had set out in *Robinson*, stating that although the issue in *Robinson* was the admission of evidence, "the same factors may be applied in a no evidence review of scientific evidence." *Id*. at 714.

Thus, we know from *Havner* that a determination of reliability is appropriate for both admissibility and legal sufficiency. *See Havner*, 953 S.W.2d at 712. Courts have recognized *Havner* as having adopted the same test for the two inquiries. *See Minnesota Mining and Mfg. Co. v. Atterbury*, 978 S.W.2d 183 (Tex.App.-Texarkana 1998, pet. denied). In *Atterbury*, the court stated that under *Robinson* and *Havner*, a defendant has "two bites" at the same "*Daubert* apple." *Atterbury*, 978 S.W.2d at 192. If the defendant objects to the reliability of the evidence before or at trial, as he should to preserve a no-evidence objection, and the trial court excludes the evidence, the reviewing court views the trial court's decision by the lenient abuse of discretion standard. If the trial court overrules the defendant's objection, the defendant may seek review of the trial court's decision in a sufficiency of the evidence point of error to an appellate court. *Id.*

"To preserve a complaint that scientific evidence is unreliable and thus, no evidence, a party must object to the evidence before trial or when the evidence is offered." *Kerr-McGee Corp. v. Helton, No*. 02-0356, 133 S.W.3d 245, 251 (Tex. 2004) (quoting *Maritime Overseas Corp. v. Ellis*, 971 S.W.2d 402, 409 (Tex.1998)). This complaint cannot be raised for the first time after trial. An objection made after the jury has returned its verdict comes too late. *Id.* at 251-52 (quoting same). The purpose of the timeliness requirement is twofold: to allow the offering party "an opportunity to cure any defect" and to prevent "trial and appeal by ambush." *Id.* (quoting same). In *Helton*, the Supreme Court found a reliability objection was timely and sufficient to preserve the parties' no-evidence complaint based on reliability when the objection was made by motion to strike expert's testimony after cross-examination and while the expert could be recalled. *Id.*

However, it should be noted that a *Maritime* objection is not needed to preserve a no-evidence challenge to conclusory expert testimony. *Coastal Transport Co. v. Crown Central Petro. Corp.*, 136 S.W.3d 227, 232 (Tex. 2004).

> We believe that *Maritime Overseas* is distinguishable, however. In that case, the expert's underlying methodology was at issue: the defendant argued that "the court of appeals should have examined whether any well-founded scientific methodology supported the jury's actual damages award." *Id.* at 405. We concluded that examination of the expert's underlying methodology was a task for the trial court in its role as gatekeeper, and was not an analysis that should be undertaken for the first time on appeal. *Id.* at 412. This rule allows the trial court to exercise its discretion in making a determination of whether the expert testimony is sufficiently reliable. *Id.* It also ensures that a full record will be developed, and that appellate courts will be able to evaluate the legal and factual sufficiency of the evidence without looking beyond the appellate record. *Id.*
>
> Even in *Maritime Overseas*, however, we recognized that an objection to the admissibility of the expert testimony may not be needed to preserve every no-evidence challenge; instead, we

> drew a distinction between challenges to an expert's scientific methodology and "no evidence challenges where, on the face of the record, the evidence lacked probative value." *Id.* at 412. When the expert's underlying methodology is challenged, the court "necessarily looks beyond what the expert said" to evaluate the reliability of the expert's opinion. *Havner,* 953 S.W.2d at 712. When the testimony is challenged as conclusory or speculative and therefore non-probative on its face, however, there is no need to go beyond the face of the record to test its reliability. We therefore conclude that when a reliability challenge requires the court to evaluate the underlying methodology, technique, or foundational data used by the expert, an objection must be timely made so that the trial court has the opportunity to conduct this analysis. However, when the challenge is restricted to the face of the record: for example, when expert testimony is speculative or conclusory on its face, then a party may challenge the legal sufficiency of the evidence even in the absence of any objection to its admissibility.

Coastal Transport Co., 136 S.W.3d at 233.

III.
MEDICAL CAUSATION IN TOXIC SUBSTANCE CASE

A. GENERAL AND SPECIFIC CAUSATION

To prove medical causation in a toxic substance (includes medications) case, the plaintiff has the burden of proving both general causation and specific causation. *Havner*, 953 S.W.2d at 714; *Frias v. Atlantic Richfield Co.,* 104 S.W.3d 925, 928 (Tex. App. – Houston [14th Dist.] 2003, pet. denied) ("Causation in toxic tort cases requires both general and specific causation."); *Daniels v. Lyondell-Citgo Refining Co.,* 99 S.W.3d 722, 729 (Tex. App. – Houston [1st Dist.] 2003, no pet.) ("Proof of both general and specific causation are required to defeat a no-evidence toxic tort summary judgment."); *Allison v. Fire Insurance Exchange*, 98 S.W.3d 227, 239 (Tex. App. -- Austin 2002, no pet.) ("Toxic tort cases require proof of both general and specific causation about the effects of the toxic substance."); *Missouri Pacific R. Co. v. Navarro*, 90 S.W.3d 747, 754 (Tex. App. – San Antonio 2002, no pet.) ("In *Havner*, the supreme court also discussed the plaintiff's burden to prove both general causation and specific causation in a toxic tort case.").

"General causation" requires proof that the substance is capable of causing the particular type of disease or condition (*complained of by the plaintiff*) in the general population, while "specific causation" requires proof that the substance caused the plaintiff's particular disease or condition. *Havner*, 953 S.W.2d at 714.

B. REASONABLE MEDICAL PROBABILITY

To survive a legal sufficiency challenge, a medical expert's general and specific causation opinion must be based on reasonable medical probability. *Burroughs Welcome Co. v. Crye*, 907 S.W.2d 497, 500 (Tex.1995). An expert's *ipse dixit* (bare assertion) that his or her general and/or specific causation opinion is based on *reasonable medical probability* will not survive a legal sufficiency challenge. *Burroughs Welcome Co. v. Crye*, 907 S.W.2d 497, 500 (Tex.1995) (Whether an expert's causation opinion is based upon reasonable medical probability must be determined by the substance and context of the testimony rather than the *ipse dixit* of the expert.); *Weiss*, 989 S.W.2d at 125 ("The scintilla test cannot be met by producing a bare expert opinion. [*citations omitted*] Nor may it be met by assurances that generally accepted scientific principles were used or by using 'magic words' like 'reasonable medical probability'" citing *Schaefer v. Texas Employers ' Ins. Ass 'n*, 612 S.W.2d 199, 204-05 (Tex.1980). "Rather, we must delve into expert opinion to determine reliability, which we judge by examining the *Robinson* factors.").

Thus, in *Havner*, the Texas Supreme Court held that an expert's testimony that a substance "*could*" with scientific certainty cause a disease or disorder or the finding in a study that a substance "*can*" cause a disease or disorder is not evidence that in reasonable probability it does. 953 S.W.2d at 729. Relying on this language in *Havner*, another Texas court held that statements in a learned treatise that *"suggests"* that a substance can cause a particular disease or that indicate that such a causal relationship is a "*biomedical plausibility*" is not reliable evidence of causation. *Exxon Corp. v. Makofski*, 116 S.W.3d 176, 187 (Tex. App. – Houston [14th Dist.] 2003, no pet.); *see also Revels v. Novartis Pharmaceuticals Corp.,* 1999 WL 644732, at *4 (Tex. App.-- Austin 1999, pet. denied).

C. GENERAL CAUSATION EVIDENCE

1. EPIDEMIOLOGICAL STUDIES:

"Epidemiological studies examine existing populations to attempt to determine if there is an *association* between a disease or condition and a factor suspected of causing that disease." *Havner*, 953 S.W.2d at 715. Courts have recognized that "epidemiological studies" are "the most useful and conclusive type of evidence" of general causation. *Brock v. Merrell Dow Pharms., Inc*., 874 F.2d 307, 311 (5th Cir.), *modified on rehearing*, 884 F.2d 166 (5th Cir. 1989). However, epidemiological studies can only establish an association, not causation. *Havner,* at 718. "For example, studies have found that there is an association between silicone breast implants and reduced rates of breast cancer. This does not necessarily mean that breast implants caused the reduced rate of breast cancer." *Id*.

Even though epidemiological studies can only establish an association and not causation, the Texas Supreme Court recognized that epidemiological studies could be relied upon to support an expert's general causation opinion if the studies reflect a "statistically significant" association between the substance at issue and the particular disease or condition in question. A study reflects a "statistically significant" association if the study shows: (i) a relative risk of at least 2 for developing a particular disease or condition, and (ii) has a confidence level of at least

95% at a confidence interval that does not include the number 1. *Havner*, 953 S.W.2d at 715, 716, 723-724; *Frias,* 104 S.W.3d at 928 ("At a minimum, to be considered reliable scientific evidence of general causation, epidemiological studies must: (1) reflect that the risk of an injury or condition in the exposed population is more than double that in the unexposed or control population; and (2) have a "confidence level" of 95%."); *Daniels*, 99 S.W.3d at 729.

A relative risk of 2 reflects that "the probability of causation exceeds fifty percent in the exposed population," which means that "the risk of an injury or condition in the exposed population was more than double the risk in the unexposed or control population." *Havner,* 953 S.W.2d at 715-16.

A confidence level of 95% reflects that the study is capable of repetition with the same results ninety-five percent of the time. *Havner*, 953 S.W.2d at 723. "A confidence level can be used in epidemiological studies to establish the boundaries of the relative risk. These boundaries are known as the confidence interval. . . . The confidence interval tells us if the results of a given study are statistically significant at a particular confidence level. . . . A confidence interval shows a 'range of values within which the results of a study sample would be likely to fall if the study were repeated numerous times.'" *Id.*

"If, based on a confidence level of 95%, a study showed a relative risk of 2.3 and had a confidence interval of 1.3 to 3.8, we would say that, if the study were repeated, it would produce a relative risk between 1.3 and 3.8 in 95% of the repetitions. However, if the interval includes the number 1.0, the study is *not statistically significant* or, said another way, is inconclusive. This is because the confidence interval includes relative risk values that are both less than and greater than the null hypothesis (1.0), leaving the researcher with results that suggest both that the null hypothesis should be accepted and that it should be rejected." *Id.*; *see Makofski*, 116 S.W.3d at 183-84 (epidemiological study did not support general causation opinion because the confidence interval included the number 1).

Additionally, the authors of the study must conclude that a causal relationship exists between the substance and the disease or condition because even a statistically significant study will not support a general causation opinion if its authors are unwilling to find a causal relationship. *Navarro*, 90 S.W.3d at 757 (citing *General Electric Co. v. Joiner*, 522 U.S. 136, 145, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)); *see Makofski*, 116 S.W.3d at 186; *Revels v. Novartis Pharmaceuticals Corp.,* 1999 WL 644732, at *4.

A medical causation expert cannot simply extrapolate from one type of disease or condition to another, or lump different types of diseases or injuries (*i.e.* liver diseases, liver injuries, cancers, lung diseases, lung injuries, leukemia, etc.) together to provide the necessary foundational support for an experts' general causation testimony. To the contrary, *Havner* teaches that studies that analyze a different type of disease or injury or a different form of a disease or injury (other than the one complained of by the plaintiff) or that lump several different diseases or injuries together do not, and cannot, provide support for a general causation opinion. 953 S.W.2d at 725; *Makofski*, 116 S.W.3d at 188 (We cannot treat an epidemiological study regarding one type of leukemia as if it applied to another type of leukemia.); *Navarro*, 90 S.W.3d at 757 (The expert's general causation testimony was held to be unreliable because "[w]hen

referring to diesel exhaust as a carcinogen, [the expert] only testified that exposure causes cancer--he did not refer to a particular type of cancer other than lung cancer."); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (study showing link between halothane and cirrhosis not reliable scientific evidence of causal link between halothane and chronic active hepatitis [liver inflammation]); *Savage v. Union Pac. R.R. Co.*, 67 F. Supp. 2d 1021, 1036 (E.D. Ark. 1999) ("One simply cannot assume that just because a substance causes a particular kind of cancer, it will cause another type.").

In *Havner*, the Texas Supreme Court made it clear that the studies relied upon by a medical causation expert must show a statistically significant association between the substance at issue and the *particular type* of disease or condition complained of by the plaintiff, not a similar type of disease or condition. In *Havner,* an infant was born with a limb reduction birth defect which the plaintiff alleged was caused by the mother's use of the drug Bendectin during pregnancy. To prove causation, the plaintiff's expert relied upon statistically significant studies which showed that the drug Bendectin could cause "birth defects other than limb reduction defects." The Texas Supreme Court rejected the expert's general causation testimony based upon these studies because these studies only showed that the drug Bendectin could cause "birth defects," not specifically "limb reduction [birth] defects" which was the particular type of injury suffered by the infant. The Supreme Court said: "These studies cannot of course support a finding that Bendectin causes *limb reduction defects*." 953 S.W.2d at 725.

In *Havner*, the Texas Supreme Court held that "sound methodology also requires that the design and execution of epidemiological studies be examined." 953 S.W.2d at 719. "[T]his means the expert must identify the study, get it admitted into evidence, and explain how the methodology of the study is scientifically reliable." *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d183,198 (Tex. App.– Texarkana 1998, pet. denied). "[W]here an expert does not know the methodology behind the study, the rate of error, or the effects of population variation, his reliance on that study cannot support his ultimate conclusion." *Id.* at 200. Also, in *Havner*, the Supreme Court noted that "an expert cannot dissect a study, picking and choosing data, or 're-analyze' the data to derive a higher relative risk if this process does not comport with sound scientific methodology." 953 S.W.2d at 720.

Moreover, in *Havner* the Texas Supreme Court held that, when a party relies upon epidemiological evidence, a single epidemiological study that shows a statistically significant association between a substance and the particular disease or condition complained of by the plaintiff will be insufficient to support a medical expert's general causation opinion. 953 S.W.2d at 727; *Minnesota Mining & Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 191,198 (Tex. App.– Texarkana 1998, pet. denied) ("one epidemiological study would not prove that it is more probable than not that an association exists."). While "properly designed and executed epidemiological studies may be part of the evidence supporting causation," "a single study would not be viewed as indicating that it is 'more probable than not' that an association exists." *Havner*, 953 S.W.2d at 717, 727; *Frias* 104 S.W.3d at 928.

Havner recognized that replication of results is a basic requirement of the scientific method as scientists cannot be assured that the results of any individual study are not due to bias, confounding or chance. *See Wade-Greaux* , 874 F. Supp. at 1452 ("A 'confounding factor' is an

exposure to one agent that is temporally associated with exposures to other agents, such that they appear to be having the same effect." A well-conducted epidemiology study will use statistical techniques to eliminate the possible effects of confounding factors. "[E]pidemiologists generally require several individual positive studies linking a specific exposure with a particular outcome before they draw any conclusions as to an association."). The inability to replicate a study calls into question the data therein, the analytical model utilized, the conclusions reached and, at times, all aspects of the study. Thus, absent evidence from valid and replicated epidemiological studies, *Havner* holds that a single study showing a statistically significant association cannot support general causation testimony.

2. CASE REPORTS/ADVERSE EVENT REPORTS:

A medical causation expert will often resort to case reports and adverse event reports (adverse event reports are filed through the reporting system of the U.S. Food and Drug Administration ("FDA")) to support his or her general causation opinion. Case reports and adverse event reports are a form of anecdotal evidence which reflect nothing more than that one event followed another. Federal Judicial Center, *Reference Manual on Scientific Evidence* 90-91 (2000).

A case report is simply a physician's observations of a particular patient, which notes the possible association between a substance and a disease or condition. *Revels v. Novartis Pharmaceuticals Corp.,* 1999 WL 644732, at *3 (Tex. App.-- Austin 1999, pet. denied) (not designated for publication); *Glastetter v. Novartis Pharmaceuticals Corp*., 252 F.3d 986, 989 (8th Cir. 2001) ("A case report is simply a doctor's account of a particular patient's reaction to a drug or other stimulus, accompanied by a description of the relevant surrounding circumstances."). In *Revels*, the Austin Court of Appeals rejected a medical expert's general causation opinion which was supported in part on case reports, including a case report of a challenge/re-challenge test conducted on a patient using the substance. *Revels,* 1999 WL 644732 at *4-5.

Texas courts do not consider case reports (and case studies) to be reliable scientific evidence of general causation. *Havner*, 953 S.W.2d at 720. In *Havner*, the Texas Supreme Court expressly held that case reports (and, accordingly, expert testimony based upon case reports) are not reliable evidence of general causation. As the Supreme Court explained:

> physicians following scientific methodology would not examine a patient or several patients in uncontrolled settings to determine whether a particular drug has favorable effects, *nor would they rely on case reports to determine whether a substance is harmful. . . .* [A]necdotal or particularized evidence accomplishes no more than a false appearance of direct and actual knowledge of a causal relationship[.]

953 S.W.2d at 720 (emphasis added). Citing *Havner,* the Austin Court of Appeals held that because "[case] reports do not purport to prove a causal relationship between the drug and the adverse event," "case reports are not 'scientifically reliable' evidence and should be rejected as a

basis on which an expert may base his or her opinion." *Revels v. Novartis Pharmaceuticals Corp.,* 1999 WL 644732 at *3, 4 (Tex. App. -- Austin 1999, pet. denied).

Texas courts are not alone in rejecting case reports (and case studies) as a factual foundation for general causation testimony. "Case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls." *Hall v. Baxter Healthcare Corp*., 947 F. Supp. 1387, 1411 (D. Or. 1996). "Case reports make little attempt to screen out alternative causes for a patient's condition. They frequently lack analysis. And they often omit relevant facts about the patient's condition." *Glastetter*, 252 F.3d at 989-90. *See also In re Diet Drugs Prod. Liab. Litig*., MDL No. 1203, 2001 U.S. Dist. LEXIS 1174, at *48 (E.D. Pa. 2001) ("anecdotal case reports . . . are universally recognized as insufficient and unreliable evidence of causation"); *In re Breast Implant Litig*., 11 F. Supp. 2d 1217, 1230 (D. Colo. 1998) ("Case reports can give rise to a question about causation; epidemiology answers the question[.]")

"[T]he generally accepted view in the scientific community is that [case reports] can be used to generate hypotheses about causation, but not causation conclusions. . . . [S]cientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies." *Haggerty v. Upjohn Co*., 950 F. Supp. 1160, 1164 (S.D. Fla. 1996), *aff'd*, 158 F.3d 588 (11th Cir. 1998); "[C]ase reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation." *Casey v. Ohio Med. Prods*., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). "This Court concludes that plaintiff's experts' reliance on anecdotal case reports to support their causation opinions is contrary to both good scientific practice and the *Daubert* case law.

Such testimony is not 'scientific knowledge' and will not assist the trier of fact, and the data are not of a type reasonably relied on by experts in the field." *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F.Supp.2d 434, 542 (W.D. Pa. 2003) "The same problems that make case reports and [adverse event reports] unreliable for purposes of analyzing a medical causation issue also undermine plaintiff's experts' reliance on a few medical treatises. A second-hand statement in a treatise that merely recites anecdotal information from case reports can be no more reliable than the case reports themselves. Thus, plaintiff's experts' medical causation opinions are not bolstered by their reliance on a few treatise excerpts that have the same reliability problems as case reports." *Id.*

An adverse event report is very similar to a case report. "Adverse drug experience [adverse event report]" is defined as "[a]ny adverse event *associated* with the use of a drug in humans, *whether or not considered drug related*." 21 C.F.R. § 314.80(a) (emphasis added). Thus, the FDA's own definition of adverse event report recognizes that the adverse events that must be reported may not be causally "related" to the use of the drug. Anyone can submit an adverse event report to the FDA, but manufacturers are required to report to the FDA "each adverse drug experience that is both serious and unexpected." 21 C.F.R § 314.80(c)(l)(i).

The FDA recognizes that adverse event reports are not evidence of a causal relationship between the drug and the event:

> A report or information submitted by an applicant under this section (and any release by the FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect.

21 C.F.R. § 314.80(k).

Over a decade ago, FDA's Surveillance and Data Processing Branch of the Division of Epidemiology and Surveillance published a "Brief Description [of Adverse Reaction Reporting System ("ARRS")] with Caveats of [the] System." According to the FDA, "[t]he primary purpose for maintaining the [ARRS] data base is to serve as an early warning or signaling system . . ." Brief Description with Caveats of System, Surveillance and Data Processing Branch of the Division of Epidemiology and Surveillance, Dec. 1988, at p. 1 ("Dec.1988 FDA Caveats"); *see also* Nov. 1991 FDA Caveats, at p. 1.

These FDA Caveats further state that:

> For any given report, there is no certainty that the suspect drug caused the reaction. This is because physicians are encouraged to report all suspected adverse drug events, not just those that are known to have been caused by the drug. The event may have been related to an underlying disease for which the drug was given, to other drugs being taken concurrently, or may have occurred by chance at the same time the suspected drug was taken.
>
> Accumulated case reports cannot be used to calculate incidence or estimates of drug risk.
>
> Numbers from these data must be carefully interpreted as reporting rates and not occurrence or incidence rates. True incidence rates cannot be determined from this data base. Comparisons of drug safety cannot be made from these data.

June 25, 1998 FDA Caveats, at p. 2, ¶¶ 3-5.

Thus, the FDA acknowledges that adverse event reports do not prove a causal relationship because the event reported "may have been related to an underlying disease for which the drug was given, to other drugs being taken concurrently, or may have occurred by chance at the same time the suspected drug was taken." *Id.* Moreover, the FDA recognizes that "[a]ccumulated case reports cannot be used to calculate incidence or estimates of drug risk.

Numbers from these data must be carefully interpreted as *reporting rates and not occurrence or incidence rates*. Comparisons of drug safety cannot be made from these data." *Id.*

Texas courts have likewise rejected adverse event reports as a foundational basis for an expert's general causation opinion. In *Reynolds v. Warthan,* the Tyler Court of Appeals specifically held that, because adverse event reports are inherently unreliable, the trial court "properly excluded the [adverse event] reports," holding that "[t]hese documents did not establish a causal link between [the medication] and the reported symptoms; rather, they created a suspicion without any medical proof." 896 S.W.2d 823, 827-28 (Tex. App. -- Tyler 1995, no writ); *see Revels v. Novartis Pharmaceuticals Corp.,* 1999 WL 644732 (Tex. App.-- Austin 1999, pet. denied) (FDA's finding that Parlodel causes strokes based on adverse event reports is not reliable evidence of general causation); *accord, Eli Lilly & Co. v. Marshall*, 850 S.W.2d 155, 156 n.2 (Tex. 1993)(adverse event report "does not presume causal relation to the product"). In *Havner*, the plaintiff's medical expert sought to rely on adverse events reports to support his general causation opinion. The trial court held these reports were inadmissible as unreliable hearsay. *Merrill Dow Pharmaceuticals, Inc. v. Havner*, 907 S.W.2d 535, 547 n. 14 (Tex. App. – Corpus Christi 1995), *rev'd on other grounds*, 953 S.W.2d 706 (Tex. 1997).

Other jurisdictions have universally rejected adverse event reports as a factual foundation for general causation testimony. *Haggerty v. Upjohn Co.*, 950 F.Supp. 1160, 1164 (S.D. Fla.1996) ("[T]he generally accepted view in the scientific community is that [the expert's] methodology [case reports, spontaneous reports of adverse medical events collected by the FDA, and animal studies] can be used to generate hypotheses about causation, but not causation conclusions . . . [S]cientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies."), *aff'd*, 158 F.3d 588 (11th Cir.1998); *Soldo v. Sandoz Pharmaceuticals Corp*., 244 F.Supp.2d 434, 541 (W.D. Pa. 2003) ("Accordingly, this Court agrees with the conclusions reached by the courts in the Parlodel TM cases cited above--and by numerous other courts throughout the country--that case reports, [adverse event reports] and other anecdotal information based on temporal proximity between exposure to a substance and alleged injury simply do not constitute reliable support for plaintiff's experts' causation opinions.").

3. IN VIVO ANIMAL STUDIES

Medical experts attempt to rely on *in vivo* animal studies to support his or her general causation opinion. It is well recognized that there are two substantial scientific problems in attempting to extrapolate animal studies to humans: "First, animal study results must be extrapolated to another species – human beings – and differences in absorption, metabolism, and other factors may result in interspecies variation in responses. . . . The second difficulty with inferring causation from animal studies is that the high doses customarily used in animal studies require consideration of the dose-response relationship and whether a threshold no-effect dose exists. Those matters are almost always fraught with considerable, and currently unresolvable, uncertainty." Federal Judicial Center, *Reference Manual on Scientific Evidence,* 346 (2d ed. 2000).

In *Havner*, the Texas Supreme Court was confronted with the issue of whether animal studies could be used to prove that Bendectin could cause limb birth defects in humans. *Havner*, 953 S.W.2d at 728-29. The Court concluded that these animal studies were legally insufficient to prove general causation because the dosage levels administered to the animals exceeded the recommended human dose and because no attempt was made to extrapolate these high dosage levels to humans. *Id.* at 729. Thus, these animal studies could not support a finding of causation. *Atterbury*, 978 S.W.2d at 199 (citing *Havner*, 953 S.W.2d at 729-30).

Similarly, in *General Electric Co. v. Joiner*, 522 U.S. 136, 144-45 (1997), the United States Supreme Court pointed out that the expert made no attempt to explain how or why he could extrapolate his opinions from the animal studies, and rejected animal studies as evidence of causation. The Court further reasoned that the dosage levels given in the studies were much higher than the plaintiff's exposure, and the type of disease developed by the animals in the animal studies was different than the disease contracted by the plaintiff. *Id.*

Courts overwhelmingly hold that drawing causation conclusions in humans from animal studies, in the absence of confirming human epidemiology, is insufficient to satisfy admissibility (reliability) standards. *Wade-Greaux*, 874 F.Supp. at 1480. "To ensure that the expert's conclusion based on animal studies is reliable, there must be 'a scientifically valid link'--such as supporting human data--'between the sources or studies consulted and the conclusion reached." *Soldo*, 244 F.Supp.2d at 546; *Allen v. Pennsylvania Eng'g Corp.,* 102 F.3d 194, 195 (5th Cir.1996) ("Where, as here, no epidemiological study has found a statistically-significant link between EtO exposure and human brain cancer; the results of animal studies are inconclusive at best"); *Renaud v. Martin Marietta Corp., Inc.,* 972 F.2d 304, 307 (10th Cir.1992) ("The etiological evidence proffered by the plaintiff was not sufficiently reliable, being drawn from tests on non-human subjects without confirmatory epidemiological data."); *Richardson v. Richardson-Merrell, Inc.*, 857 F. 2d 823, 830 (D.C. Cir. 1988) (animal studies raise only a suspicion of causation in humans).

The reason for requiring confirming human epidemiology is that "[e]xtrapolations from animal studies to human beings are not considered reliable in the absence of a credible scientific explanation of why such extrapolation is warranted." *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1366 (N.D. Ga. 2001), *aff'd*, 295 F.3d 1194 (11th Cir. 2002) (*citing* Hall, 947 F. Supp. at 1410).

4. IN VITRO STUDIES:

In vitro studies are studies conducted on cells in a test tube or petri dish. *In vitro* studies are even considered less reliable than animal studies for drawing causation conclusions because of the problems associated with extrapolating findings "from the artificial setting of tissues to whole human beings." Federal Judicial Center, *Reference Manual on Scientific Evidence,* 346 (2d ed. 2000).

In *Havner*, the Texas Supreme Court rejected a medical expert's reliance on *in vitro* studies to support his general causation opinion noting that the fact a substance may adversely effect cells *in vitro* is "the beginning, not the end of the scientific inquiry and proves nothing

about causation without other scientific evidence." 953 S.W.2d at 729; *Richardson,* 857 F.2d at 830 ("Positive results from *in vitro* studies may provide a clue signaling the need for further research, but alone do not provide a satisfactory basis for opining about causation in the human context."); *Blum v. Merrell Dow Pharms., Inc.*,705 A.2d 1314, 1323 (Pa. Sup. Ct. 1997) (*In vitro* studies "without an epidemiologically demonstrated association" contribute nothing to the demonstration of causation in humans); *Wade-Greaux*, 874 F. Supp. at 1464 (*in vitro* studies "provide no scientific evidence of what actually occurs in human fetal development."); *Allen*, 102 F.3d at 198 ("[T]he cell biology data show only that EtO has mutagenic and genotoxic capabilities in living organisms, not that it necessarily causes brain cancer in humans . . . That EtO may have these effects on living cells or genes is the beginning, not the end of the scientific inquiry . . .").

5. DECISIONS OF REGULATORY AND ADVISORY BODIES

In *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194 (5th Cir. 1996), the plaintiff suffered from brain cancer, which he alleged was caused by his exposure to ethylene oxide while working in a hospital. Plaintiff filed a product liability suit against the manufacturer of the ethylene oxide. Plaintiff's medical expert sought to prove general causation (*i.e.,* that ethylene oxide can cause brain cancer in the general population), and his testimony was based, in part, upon conclusions reached by regulatory agencies and health care organizations that ethylene oxide was a human carcinogenic. The Fifth Circuit excluded the expert's general causation testimony because the basis for his testimony, *i.e.,* health organization and agency conclusions, was insufficient to raise a fact issue on general causation. In so holding, the Fifth Circuit wrote:

> Regulatory and advisory bodies such as IARC, OSHA and EPA utilize a "weight of the evidence" method to access the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure.
>
> The methodology [employed by these bodies] results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. *The agencies' threshold of proof is reasonably lower than that appropriate in tort law, which "traditionally make[s] more particularized inquiries into cause and effect" and requires a plaintiff to prove "that it is more probable than not another individual has caused him or her harm."*

Id. at 198 (emphasis added) (citation omitted); *Mitchell v. Gencorp, Inc.,*165 F.3d 778, 783 n. 3 (10th Cir. 1999); *Siharath*, 131 F. Supp. 2d at 1365-66 (FDA determinations and conclusions do not support an expert's causation testimony); *Soldo*, 244 F.Supp.2d at 543 ("FDA ordinarily does not attempt to prove that the drug in fact causes a particular adverse effect. FDA has never concluded (and could not so conclude, given its own standards, even at the regulatory level) that Parlodel TM causes stroke, based upon ADEs or case reports or any other evidence."); *see also Revels v. Novartis Pharmaceuticals Corp.,* 1999WL644732 (Tex. App.-- Austin 1999, pet. denied) (FDA's finding that Parodel causes strokes is not reliable evidence of general causation).

Similarly, in *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 991 (8th Cir. 2001), the Eighth Circuit held that FDA's determination that the drug Parlodel can cause strokes was not reliable scientific evidence to support a general causation opinion. In so holding, the Court wrote:

> The FDA's approach [in rescinding its approval of a prescription drug] differs from ours in another critical aspect. The FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability. 'The methodology employed by a government agency results from the preventive prospective that the agencies adopt in order to reduce public exposure to harmful substances.'[citations omitted]. The FDA's 1994 decision that Parlodel can cause strokes is ***unreliable proof of medical causation*** in the present case because FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval.

6. STATEMENTS OF PRODUCT MANUFACTURER OR SUPPLIER:

Some experts may resort to statements or selected excerpts found in product manufacturer's or supplier's warnings, material safety data sheets, promotional materials, e-mails, and other corporate documents as a basis for his or her general causation opinion. Texas courts have recognized that the medical expert must establish that the conclusion or opinion reflected in the statement or excerpt satisfies the reliability standards set forth in *Robinson*/*Havner/Gammill* before such statements or excerpts can be relied upon to support an expert's general causation opinion.

In *Coastal Tankships U.S.A. Inc. v. Anderson*, 87 S.W.3d 591 (Tex. App.- Houston [1st Dist.] 2002, pet. denied), the Houston First Court of Appeals addressed this specific issue in deciding whether there was legally sufficient evidence that naphtha caused the decedent to develop bronchiolitis obliterans organizing pneumonia (BOOP). To prove general causation, plaintiff relied upon the product supplier's naphtha material safety data sheet (MSDS). In the MSDS, the product supplier stated that naphtha could irritate mucous membranes and the respiratory tract and act as an asphyxiant; could, upon overexposure, lead to headache, nausea, drowsiness, fatigue, pneumonitis, pulmonary edema, and central nervous system depression; and could cause stomach irritation, unconsciousness, congestion, and hemorrhaging of the lung and internal organs.

The Court held that the supplier's statement in the MSDS was not reliable evidence of causation because "no expert established that . . . the naphtha MSDS, . . . on which [plaintiff] now relies met the appropriate *Daubert/Robinson/Jordan* inquiry as to general causation. It is this evidentiary gap that is fatal to [plaintiff's] claims." *Id*. at 611. In a footnote following this statement, the Court noted that, "*because there is no evidence of what tests were conducted in compiling the MSDS, the MSDS has limited value in determining causation*." ***Id.*** at 611 n. 32.

In summary, the Court stated:

> Put another way, if [plaintiff] had produced only [the physician's] differential diagnosis (as stated in the medical records, discharge summary, and other notes), *the naphtha MSDS*, and [the physician's] statement that chemical pneumonia can cause BOOP, would he have carried his *Daubert/Robinson/Jordan* burden? He would not. *Cf. Havner*, 953 S.W.2d at 717-28. How, then, can those same evidentiary fragments survive the sufficiency challenge made here and below? They cannot. It was [plaintiff's] burden to provide expert testimony linking these evidentiary pieces together through the lens of *Daubert/Robinson/Jordan*. *See Gammill*, 972 S.W.2d at 718; *Allen,* 796 S.W.2d at 763 (expert testimony required). [Plaintiff] failed to meet this burden.

Id. at 611.

Similarly, in *Brookshire Bros., Inc. v. Smith*, 2003 WL 21756411 (Tex. App. – Houston [1st Dist.] 2003, no pet.), the plaintiff allegedly suffered RADS from his exposure to certain commercial cleaners. Plaintiff's expert based his general causation opinion (that the cleaners could cause RADS in the general population) on the product supplier's MSDS and warning labels which identified RADS as an injury that could result from high levels of exposure to the cleaners. The Court held that this was not reliable scientific evidence to support the expert's general causation opinion:

> The record shows that Dr. Friedman based his causation opinion on the MSDS and the warning labels of the commercial cleaners Smith used. Dr. Friedman's extensive reliance on the MSDS and warning labels was nevertheless insufficient because neither the MSDS nor the warning labels, standing alone, provide the type of specific, detailed showing of scientific reliability required to accord evidentiary value to an expert's opinion . . . Smith is correct in asserting that the MSDS and the warning labels identified particular toxins in the commercial cleaners. Lime-A-Way's MSDS and warning label, for example, identified asthma or RADS as a potential injury that could result from high levels of exposure. But the MSDS and warning labels did not demonstrate, scientifically, that the particular toxins at issue generally cause RADS. . . . There was no evidence produced at trial that discussed the scientific foundation used in formulating the conclusions contained in either the MSDS or the warning labels. Thus, even with the MSDS and warning labels, an evidentiary void concerning general causation remained in Dr. Friedman's opinion. This void could have been remedied only by an established, scientific connection between the commercial cleaners and RADS.

Id. at 4.

Also, in *Soldo*, the court held "phrases plucked from corporate documents" and the pharmaceutical company's "causation assessments" in adverse event reports do not provide reliable scientific evidence of causation because the foundation data relied upon, and methodology used, in making such statements were unknown and not established to be scientifically reliable. 244 F.Supp.2d at 545-46. The court further concluded that the product supplier's causation assessments in adverse event reports which are prepared for entirely different purposes than the scientific determination of causation in controlled settings, would be grossly misleading to a finder of fact and the likelihood of misleading the finder of fact would greatly outweigh any probative value. *Id.* at 546.

7. SUBSTANCES IN SAME CLASS:

Oftentimes, a substance, like a chemical or medication, will have a molecular structure similar to other chemicals or medications and are thus considered to be in the same class as the substance at issue. This similarity is not sufficient to permit a medical expert to support his or her general causation opinion about a particular substance by showing the harmful effects of different substance in the same class.

Chemicals and medications in the same class will have a different molecular structures. These deviations in molecular structure can radically change a particular substances properties and propensities. *Glastetter v. Novartis Pharmaceuticals Corp,,* 252 F.3d 986, 990 (8th Cir. 2001). For this reason, courts have held that "testimony extending general conclusions about similar drugs does not meet *Daubert's* requirement of reliability." *Brumbaugh v. Sandoz Pharmaceutical Corp.,* 77 F.Supp.2d 1153, 1156 (D. Mont. 1999); *Mitchell v. Gencorp Inc.,* 165 F.3d 778, 782 (10th 1999) ("Missing from [the plaintiff's evidence] is additional testimony explaining what these similarities are and how the similarities cause the human body to respond to Defendant's chemicals in a manner similar to benzene.").

D. SPECIFIC CAUSATION EVIDENCE

At the outset, it should be recognized that, if there is no admissible general causation testimony, it is not necessary for a court to reach the specific causation issue. *Daniels v. Lyondell-Citgo Refining Co.,* 99 S.W.3d 722, 730 (Tex. App. – Houston [1st Dist.] 2003, no pet.) ("Because [plaintiffs] failed to present summary judgment proof sufficient to raise a fact question concerning general causation, we need not address their second point of error asserting that they offered sufficient proof of specific causation."); *Allison*, 98 S.W.3d at 240 ("Because [plaintiff] did not establish a reliable foundation for the admission of general causation evidence, we need not address the evidence relating to specific causation."); *Coastal Tankships*, 87 S.W.3d at 609-10 ("In the toxic-tort context, a plaintiff must establish general causation for a differential diagnosis to be relevant to show specific causation.").

In *Havner*, the Texas Supreme Court recognized that a plaintiff must prove causation by doing more than simply introducing into evidence statistically significant studies. *Id.* at 720. To "meet the 'more likely than not' burden of proof," a plaintiff must "offer . . . 'particularistic'

proof that the substance harmed the individual [specific causation]." *Id.* at 714. This may be done by showing that the claimant is similar to those in the studies:

> This would include proof that the injured person was exposed to the same substance, that the exposure or dose levels were comparable to or greater than those in the studies, that the exposure occurred before the onset of injury, and that the timing of the onset of injury was consistent with that experienced by those in the study. [citation omitted]. Further, if there are other plausible causes of the injury or condition that could be negated, the plaintiff must offer evidence excluding those causes with reasonable certainty. *See generally E.I. du Pont de Nemours & Co. v. Robinson,* 923 S.W.2d 549, 559 (Tex.1995) (finding that the failure of the expert to rule out other causes of the damage rendered his opinion little more than speculation); *Parker v. Employers Mut. Liab. Ins. Co.*, 440 S.W.2d 43, 47 (Tex.1969) (holding that a cause becomes "probable" only when "in the absence of other reasonable causal explanations it becomes more likely than not that the injury was a result")."

Havner, 953 S.W.2d at 720; *see Daniels v. Lyondell-Citgo Co., Ltd.,* 99 S.W.3d 722, 728 (Tex. App. – Houston [1st Dist.] 2003).

In *Coastal Tankships,* the Houston Court of Appeals recognized that a properly conducted and explained "differential diagnosis" could also be used to prove specific causation, but could not be used to prove general causation. *Id.* at 609. A "differential diagnosis" is a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes. *Neal v. Dow Agrosciences L.L.C.*, 74 S.W.3d 468, 473 n. 3 (Tex. App. – Dallas 2002, no pet.) (citing *Minnesota Min. And Mfg. Co. v. Atterbury*, 978 S.W.2d 183, 194 n. 9 (Tex. App. - Texarkana 1998, pet. denied).

A differential diagnosis based upon the physician's recitation that he has examined the patient and has done a history of the patient and has concluded that X (the substance) caused the patient to suffer with Y (the injury) will be insufficient to prove specific causation. *Atterbury*, 978 S.W.2d at 199. However, "[i]f the physician explained the exact methodology that he used in arriving at the conclusion, including discussing the exact other causes that have been ruled out and the generally accepted literature that he relied upon in making that conclusion, the differential diagnosis evidence *could be* sufficient to prove specific causation." *Id.* (emphasis added).

Whether relying on a "differential diagnosis" or some other methodology to prove specific causation, our Supreme Court has squarely held that an expert opinion regarding specific causation is not reliable unless the expert rules out reasonable alternative causes of the alleged injury other than the defendant's actions or product. Thus, in *Robinson* the Court concluded:

> Dr. Whitcomb conducted no testing to exclude other possible causes of the damage to the Robinsons' pecan orchard, even though he admitted in his deposition that many of the symptoms could be caused by something other than contaminated Benlate. . . An expert who is trying to find the cause of something should carefully consider alternative causes. Dr. Whitcomb's failure to rule out other causes of the damage renders his opinion little more than speculation

Id. at 558-59. The Supreme Court reiterated that principle in *Havner*, stating: "if there are other plausible causes of the injury or condition that could be negated, the plaintiff must offer evidence excluding those causes with reasonable certainty." 953 S.W.2d at 720 (citing *Robinson* and *Parker v. Employers Mut. Liab. Ins. Co.*, 440 S.W.2d 43, 47 (Tex. 1969)).

Similarly, in *Weiss v. Mechanical Associated Services, Inc.*, 989 S.W.2d 120, 126 (Tex. App.– San Antonio 1999, pet. denied), the court affirmed summary judgment for the defendants in a case involving injuries allegedly caused by exposure to a chemical, because "none of Weiss' experts were able to rule out other potential causes of Weiss' illness with reasonable certainty." *Accord, Martinez v. City of San Antonio*, 40 S.W.3d 587, 595 (Tex. App.–San Antonio 2001, no pet.) ("The opinions of Matson and Baynes, when offered to prove Alamodome site lead caused appellants' injuries, constitute no evidence because Matson, in arriving at his lead calculation, failed to rule out alternative sources of the lead contamination."); *Austin v. Kerr-McGee Refining Corp.*, 25 S.W.3d 280, 293 (Tex. App.-Texarkana 2000, no pet.) (affirming summary judgment for defendants; trial court properly excluded plaintiffs' scientific evidence because, among other reasons, plaintiffs "failed to exclude other plausible causes with reasonable certainty"); *Williams v. NGF, Inc.*, 994 S.W.2d 255, 257 (Tex. App.–Texarkana 1999, no pet. h.) (affirming summary judgment for defendant because plaintiffs "failed to produce evidence which excluded the possibility that . . . other flowers or chemical agents used on them were the cause of her injuries"); *Mitchell Energy Corp. v. Bartlett*, 958 S.W.2d 430, 448 (Tex. App.–Fort Worth 1997, pet. denied) ("Dr. Basset's failure to rule out other causes of the presence of hydrogen sulfide in appellees' water renders his opinion 'little more than speculation.'").

A medical expert's *ipse dixit* (bare assertion) that in reasonable medical probability the substance at issue caused the claimant's complained of disease or condition and that the expert's *ipse dixit* that he or she has ruled out other plausible causes of claimant's complained of disease or injury with reasonable certainty will not support a specific causation opinion. Under *Atterbury*, the medical expert should discuss how he or she concluded that claimant in fact suffers from the complained of disease or condition; the expert should discuss the exact other causes that have been ruled out as the cause of the claimant's complained of disease or condition; the expert should also explain the exact diagnostic methodology (technique) that he or she used in arriving at the diagnosis and in ruling out other causes of the complained of disease or condition with reasonable medical certainty; and the expert must discuss the generally accepted literature supporting the diagnostic methodology (and get it admitted into evidence) that he or she used in reaching the diagnosis and in ruling out other plausible causes. *See Atterbury*, 978 S.W.2d at 199; *Soldo,* 244 F.Supp.2d at 554-56 (experts' specific causation testimony based on a differential diagnosis was excluded because the experts "did not demonstrate any valid

diagnostic methodology--any 'sufficient diagnostic technique'--for excluding" other plausible causes as the sole cause of the plaintiff's injury.).

As with general causation testimony, *Robinson/Havner* directs the court to look beyond the mere *ipse dixit* of the medical expert's specific causation opinion and consider whether the diagnostic methodology or technique utilized by the expert in reaching his or her conclusions and in ruling out other plausible causes of the claimant's disease or condition is scientifically reliable under the *Robinson* factors.