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Specific CLENT Essention Science in the Courtroom "In this age of science, science should expect to find a warm welcome, perhaps a permanent home, in our courtrooms." "[I] n this age of science we must build legal foundations that are sound in science as well as in law." Brever, S. Introduction. In *Reference Manual on Scientific Evidence*. 3d Ed., Federal Judicial Center & National Research Counsel, National Academics Press, Washington, DC (2011).

CLIENT Essentials Expert Witnesses

- Clinicians are frequently required to render an opinion as to whether an adverse health effect is work-related in medicolegal proceedings.
- "It is incumbent upon the clinician to make certain that any opinion ... reflects careful analysis of ... all available clinical findings and high-grade scientific evidence."
- A Guide to the Work-Relatedness of Disease. 1979. Rev'd Ed., Kusnetz, S. and Hutchison, M., Eds., NIOSH Pub. No. 79-116.



CLIENT Essentials Credentials

- "Without more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible."
- "At a minimum, the expert testimony should include a description of the method used ... "
- "The expert's assurance that the methodology and supporting data [are] reliable will not suffice."

U.S. v. Hermanek, 289 E3d 1076, 1094 (9th Cir. 2002); Viterbo v. Dow Chem. Co., 826 F.2d 420, 424 (5th Cir. 1987); Mitchell v. Gencorp Inc., 165 F.3d 778, 781 (10th Cir. 1999) (citing Moore v. Ashland Chemical, Inc., 151 F.3d 269, 276 (5th Cir. 1998) (en banc); see also Hall v. United Ins. Co. of Am., 367 F.3d 1255, 1261-62 (11th Cir. 2004).

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• Publication

- Publication in a refereed journal is not, alone, an indication of either the quality or significance of research.
- Publication does not necessarily correlate with reliability.
- Publication is a relevant not dispositive consideration in assessing scientific validity of a technique, method, or theory on which an opinion is based.

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

CLIENT Essentials Gatekeeper Role

Daubert v. Merrell Dow Pharm., Inc.

- Supreme Court of the United States held that trial courts must act as "gatekeepers" to ensure that all scientific evidence is *relevant* and *reliable*, and
- Assists the jury in determining facts in issue
- Rule 702 of the Federal Rules of Evidence governs admissibility of expert testimony

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

CLIENT Essentials F.R.E. 702

- Testimony must be sufficiently based on reliable facts or data,
- Testimony must be the product of scientifically reliable principles or methods, and
- Witness must have **reliably applied** principles and methods to facts of case.

CLIENT Essentials F.R.E. 402

- Testimony lacking "sufficient bearing on the issue at hand to warrant a determination that it [is helpful to the jury]" is irrelevant and inadmissible.
 - Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it.
 - Trial courts must insure that speculative and unreliable opinions do not reach the jury.

CLIENT Essentials Daubert Factors

- Whether the expert's theory or technique can be or has been tested.
- Whether the expert's theory or technique has been subject to peer review and publication.
- Whether the actual or potential rate of error is known.
- Whether there are standards controlling the technique's operation.
- Whether expert's methodology is "generally accepted" in the relevant scientific community.

CLIENT Essentials Daubert Factors

- Not every factor is applicable or relevant to every *Daubert* inquiry.
- "[O]verarching subject is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission."
- In *Daubert II*, the Ninth Circuit Court of Appeals concluded that the factors were "illustrative" not "exhaustive" other factors ought to be considered.

CLIENT Essentials Advisory Committee

- "[W]hether expert is proposing to testify about matters growing naturally and directly out of research ... conducted independent of the litigation," or
- Whether opinions were developed "expressly for purposes of testifying ..."

R. 702 F.R.E., Advisory Comm. Notes.

• Testimony "based ... on ... pre-existing

- research unrelated to ... litigation provides the most persuasive basis for concluding the opinions were 'derived by the scientific method.""
- "Where ... expert testimony is not based on independent research ...

R. 702 F.R.E., Advisory Comm. Notes.

CLIENT Essentials Published Research

 "[E]xperts must explain precisely how they went about reaching their conclusions and point to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that they have followed the scientific method"

Burton v. CSX Transp., Inc., 269 S.W.3d 1 (Ky. 2008).







Definition CLENT Essentions Investigation Expert testimony must be based on actual knowledge, not ... Subjective belief Unsupported speculation Expert testimony is not scientifically reliable if opinion relies on imprecise methodology or inadequate investigation. "One who seeks to clothe his opinions in the garb of 'scientific certainty' must adhere to the strict standards of objectivity that that formal wear entails."

CLIENT Essentials An Inconvenient Truth

- Despite popular notions about "evidencebased medicine," ...
- Critical analysis of causation remains lacking in American courtrooms.
- What methodologies for determination of causation pass muster under *Daubert*?

CLIENT Essentials Methodology

- A multi-disciplinary method for the determination of causation is not a novel concept.
- In 1979, NIOSH proposed a logical methodology for determination of work-relatedness.
- The NIOSH *Guide* "presents one method for assembling and evaluating *evidence* that may be *relevant* in determining the work-relatedness of disease in an *individual*."

CLIENT Essentials The NIOSH Guide

- Consideration of evidence of disease
- Consideration of epidemiologic evidence
- Consideration of evidence of individual exposure
- Consideration of other relevant factors
- Consideration of the validity of testimony
- Evaluation and conclusion

A Guide to the Work-Relatedness of Disease, Rev'd Ed., Kusnetz, S. and Hutchison, M., Eds., NIOSH Pub. No. 79-116 (1979).

CLIENT Essentials Relevant or Relic?

- Greaves, WW, Das, R, Green-McKenzie, J, Sinclair, DC. 2018. *Work-Relatedness*. MDGuidelines®.Web, Hegmann, KT, Ed., www.mdguidelines.com. Reed Group, Ltd., acc'd Jan. 12, 2018.
- Guides to the Evaluation of Disease and Injury Causation, AMA (2008) (2d Ed. 2014).
- Occupational Medicine Practice Guidelines Evaluation and Management of Common Health Problems and Functional Recovery of Workers, ACOEM (2004) (rev'd 2008, 2011).

CLIENT Essentials Relevant or Relic?

- The AMA Guides to the Evaluation of Disease and Injury Causation observed that the most prevalent method for the determination of workrelatedness "[i]s that developed by the National Institute for Occupational Safety and Health... and ... adapted by the American College of Occupational and Environmental Medicine..."
- "Because this may be the most common structured method used and it does not seem to have major weaknesses, it is the method...used herein."

S C CLIENT Essentials A Legally Sufficient Method

- The NIOSH *Guide* is a logical method for collating and evaluating the medical, epidemiological, and technical information relevant to the determination of causation.
- **Conscientious** application of the NIOSH *Guide* is a reliable methodology for the determination of causation in medicolegal proceedings.



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cls Epidemiology in the Courtroom

- Expert testimony founded on epidemiological data is a fit subject for judicial notice.
 - R. 201(b) Fed. R. Evid.: A judicially noticed fact is one that is not subject to reasonable dispute.
 - The fact is generally known or capable of determination by resort to sources whose accuracy cannot be reasonably questioned.

Epidemiology is *populations-based*, but ... Substantial body of legal precedent establishes

- that epidemiologic evidence is critical to prove causation for individual litigants through *probabilistic means*.
- Courts frequently have recognized utility of epidemiological studies as evidence of *general* **and** *specific* causation.

Green, MD, Freedman, M, Gordis, L. Reference Guide on Epidemiology. In *Reference Manual on Scientific Evidence*. 3d Ed., Federal Judicial Center & National Research Counsel, National Academies Press, Washington, DC (2011).

CLIENT Essentials • Contemporary: Is the research reasonably

- contemporary consistent with current knowledge?
 Population Selection (selection bias): Are
- population selection (selection bias): Are populations well-defined and subjects selected to provide meaningful comparisons between study groups and time periods?
 - Matched as to all attributes except exposure, appropriately stratified by exposure, excluded based on actual or potential confounding?
 - Sufficient in number (*i.e.*, representative of the study population, adequately power the study)?

Evaluating ^{als} Individual Studies

- Case Definition: Is adverse health outcome of interest defined according to objective diagnostic criteria?
- Exposure Assessment: Is exposure to putative risk factor(s) directly measured and quantitated using a valid and reliable methodology or ...
 - Observed?
 - Self-reported?
 - Occupational title adopted as a surrogate?





CLIENT Essentials Evaluating Individual Studies

- Information Bias: Were known or potential sources of information bias recognized and accounted for (*e.g.*, recall bias, questionnaire/ interviewer bias, reporting bias, volunteer bias [non-randomized selection], compensation bias)?
- Confounding: Were confounding variables recognized and accounted for?
 - Multifactorial causes (*e.g.*, avocational exposures) and co-morbidities?
- Body habitus, lifestyle elections
- Potential confounders excluded or statistically adjusted?

Evaluating CLENT Essentials Individual Studies

- Exposure-Response Relationship (biological gradient):
 - Is the rate and/or severity of symptoms, disease, or disorder predicted by a change in the frequency, intensity, duration, or temporal pattern of exposure (*i.e.*, body burden or magnitude of the chemical, physical, psychological, or biologic factor)?



- What is the ordinal magnitude of the association (*i.e.*, *p* value, confidence interval, strength of association)?

CLIENT Essentials Evaluating Multiple Epidemiological Studies

- In Amorgianos v. Nat'l R.R. Pass. Corp., the court addressed the vital role of epidemiology in the determination of causation.
- There are several different forms of epidemiological studies in occupational medicine.
- These various designs differ in the evidentiary weight they have on a hypothesis that exposure causes an adverse health outcome.
- Amorgianos v. Nat'l R.R. Passenger Corp., 137 F. Supp. 2d 147 (E.D. N.Y. 2001).

Hierarchy of CLIENT Essentials Epidemiological Evidence

- In an epidemiological weight-of-the evidence analysis, higher quality study designs outweigh lower quality studies; provided, that they have no major flaws.
- Absent randomized controlled trials, the highest quality study is the prospective cohort study.

Greaves, WW, Das, R, Green-McKenzie, J, Sinclair, DC. 2018. Work-Relatedness. MDGuidelines®.Web, Hegmann, KT, Ed., www.mdguidelines.com. Reed Group, Ltd., acc'd Jan. 12, 2018.

CLIENT Essentials Amorgianos v. Nat'l R.R. Pass. Corp.

- "Even when an appropriately designed study yields evidence of a statistical association between a risk factor and an adverse health outcome..."
- "Epidemiologists generally do not *ipso facto* accept an association as proof of causation."
- "Reliance on one or a few studies is typically insufficient evidence of causation."
- "Epidemiologists generally look to several additional criteria to determine whether the association is indeed causal."

CLIENT Essentials A.B. Hill Guidelines

- · Strength of the association
- · Consistency of the association
- Specificity of the association
- · Temporality of the association
- Dose-response relationship
- Experimental evidence

Hill, AB, The environment and disease: Association or causation? 1965. Proc. Royal Soc. Med. 58:295-300; see also Susser, MW, Judgment and causal inference. 1977. Am. J. Epid., 105:1-15; Causal Inference. Rothman, KJ, (Ed.), Epidemiological Resources Inc., Chestnut Hill, MA, (1988); Savitz, DA, Interpreting Epidemiological Evidence: Strategies for study design and analysis, Oxford U. Press, NY, NY (2003).

General and Specific Causation "In a toxic-tort case ... the plaintiff must establish both general and specific causation through proof that the toxic substance is capable of causing, and did cause, the plaintiff's alleged injury." "The plaintiff must show that [s]he was exposed to the toxic substance and that the level of exposure was sufficient to induce the complained-of medical condition (commonly called a 'dose-response relationship')."



CLIENT Essentials The Dose is the Poison

- "An expert whose testimony is to be used to prove specific causation must establish that the individual was exposed to a sufficient amount of the substance to elicit the adverse health effect, and ..."
- "The chronological relationship between exposure and effect is biologically plausible, **and ...**"
- "The expert considered the likelihood that the chemical caused the disease in the context of other known causes."
- Adams v. Cooper Indus., 2012 U.S. Dist. LEXIS 85492 at *5 (E.D. Ky.).

CLIENT Essentials General Causation

- In *Adams*, the court stated, "[T]he issue of causation is not merely a question of science, but a question of law."
- The *Adams* court observed that the evidence presented by plaintiff's experts may have demonstrated that the defendants were responsible for an inadvertent release of chemicals, **and**
- The testimony may have demonstrated a causal association between such chemicals and disease; however ...

CLENT Essentials General Causation "[S]uch evidence did not prove that the defendants were legally culpable for plaintiff-decedent's death, because ..." "[I]t did not establish that the decedent was exposed to a sufficient quantity of the chemical to have caused his injury, and further, because it failed to exclude

other possible causes."

Id.

CLIENT Essentials The NIOSH Guide

- "The commonly seen statement 'in the absence of other obvious causes, the problem is work related' should not be used."
- "Such language is not reflective of the scientific basis upon which such opinions should rest, and does not provide adequate support for conclusions that must be made regarding ... legal responsibility."

A Guide to the Work-Relatedness of Disease, Rev'd Ed., Kusnetz, S. and Hutchison, M., Eds., NIOSH Pub. No. 79-116 (1979).





Id.

CLIENT Essentials A Diagnostic Fallacy

- This analysis is tantamount to concluding that because alternative causes had been eliminated ...
- The accident was the cause-in-fact, even though the etiology is unknown.
- "This is not an exercise in scientific logic, but in the fallacy of *post-hoc propter-hoc* reasoning, which is as unacceptable in science as in law."

CLIENT Essentials Differential Diagnosis

- "[M]erely claiming that an expert used differential diagnosis is alone insufficient to satisfy the reliability analysis under *Daubert*."
- "[C]alling something a 'differential diagnosis' ... does not... answer the reliability question but prompts three more:

Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 678 (6th Cir. 2011) (citing Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 674 (6th Cir. 2010); and Best v. Lowe's Home Ctrs., Inc., 563 F.3d 171, 179 (6th Cir. 2009) ("Not every opinion that is reached via a differential-diagnosis method will meet the standard of reliability required by Daubert").

- "Did the expert make an accurate diagnosis of the ... disease?

- "Did the expert reliably rule in ... possible causes ...?
- "Did the expert reliably rule **out** ... rejected causes ...?"
- If the court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

Id.

Essentials AMA Apportionment Guideline

- First, one must first consider all potential causes when apportioning responsibility for an injury or disease.
- Second, one must determine whether each of the potential causes identified is probable or possible.
- Probable causes are included in the apportionment, but possible causes are not.

AMA Guides to the Evaluation of Disease and Injury Causation, 2d Ed., Melhorn, JM, Talmage, JB, Ackerman, WE, Hyman, MH, Eds., AMA, Chicago, IL (2014).

CLIENT Essentials Civil Burden of Proof

- Civil burden of proof requires a determination, based on *admissible evidence*, that the probability an alleged cause resulted in injury or disease is > 50%.
- Whether cause and effect is more probable than not is different than statistical significance.

• Common error made by attorneys, judges, and expert witnesses is to conflate statistical

- expert witnesses is to conflate statistical significance with the legal burden of proof a *preponderance of evidence*.
- Misconception is that using an α of 0.05 imposes burden of proof greater than the civil burden of proof demands.
- Increasingly, courts recognize that epidemiological studies failing to demonstrate a statistically significant association ($p = \leq 0.05$) between exposure and outcome are inadmissible.

tials Reasonable Degree of Medical Certainty

- Expert opinions must be stated to a reasonable degree of medical certainty.
- Reasonable medical certainty reflects an objectively well-founded conviction that likelihood of one cause is greater than any other.
- Standard does not mean expert is *personally certain of cause or that cause is discernible to a certainty.*

Robinson v. Group Health Assoc., Inc., 691 A.2d 1147 (D.C. Ct. App. 1997) (citing Clifford v. U.S., 532 A.2d 628, 640, n. 10 (D.C. 1987).

Self-Reported Medical History

- "Literature confirms that individuals (patients) frequently provide inaccurate medical histories."
- "[I]n medical interviews separated by 1 year, 42% of initially reported historical complaints were forgotten. Only 41% of health care visits in the prior 12 months were recalled, and 28% of the visits claimed in the past 12 months never actually occurred."
- AMA Guides to the Evaluation of Disease and Injury Causation, 2d Ed., Melhorn, JM, Talmage, JB, Ackerman, WE, Hyman, MH, Eds., AMA, Chicago, IL (2014).

The history bias of litigant individuals (plaintiffs or claimants) compared with non-litigant individuals has been reported. Litigants demonstrated a statistically significant tendency to claim "superhuman" pre-injury functioning in 15 of the 16 areas assessed: General life problems; work or school problems; concentration, memory, depression, anxiety, irritability, confusion; decreased self-esteem; headaches; fatigue; sexual function; and family relationships lost after the

injury.

Id

CLIENT Essentials Litigant History

- Carragee, *et al.* reported on patients with neck or back pain after a motor vehicle accident.
- Compared medical records prior to a motor vehicle accident to the patients' stated histories.
- Study documented overwhelming tendency for motor vehicle injury claimants to falsely deny preexisting conditions of greatest relevance to persistent back and neck pain – previous back or neck pain, psychological distress, *etc.*
- Carragee, EJ. 2008. Validity of self-reported history in patients with acute back or neck pain after motor vehicle accidents. The Spine J. 8(2): 311-319.



	CLIENT Essentials Post Hoc Propter Ho Revisited
"I have syn exposed."	mptoms; therefore, I must have been
OR	Cause Effect
"I was exp my sympto	osed; therefore, it must have caused oms."

CLIENT EssentialsNon-Specific Symptoms

- Non-specific, subjective symptoms, including headache; fatigue; skin, eye, and throat irritation; dyspnea; nausea; gastrointestinal distress; myalgia, and neck and back pain **are ubiquitous**.
- They are more common in community symptom surveys when pollution, hazards, contamination, or health threats are perceived **real or not**.

Williams, CW and Lees-Haley, PR. 1993. Perceived toxic exposure: A review of four cognitive influences on perception of illness. J. Social Behavior & Personality. 8(3):489-506; Watson, D and Pennebaker, JW. 1989. Health complaints, stress, and distress: exploring the central role of negative affectivity. Psychol Rev. 96(2):234-54.

• "Symptom data are often used as an index of the health consequences, especially in cases of environmental exposure, or alleged overexposures to some perceived hazard.

• "Symptoms are ... unreliable measures because they are so colored by fears, various emotional triggers, and **especially by litigation**."

Lees-Haley, PR and Brown, RS. 1992. Biases in perception and reporting following a perceived toxic exposure. Percept. Mot. Skills. 75(2):531-44.



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