

Evidence-Based Medicine – A Foundation for Risk Management in Compensation Environments

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Objectives

- Understand the legal principles that govern the admissibility of scientific evidence
- Identify an evidence-based methodology for the determination of causation in compensation environments

Science in the Courtroom

- “In this age of science, science should expect to find a warm welcome, perhaps a permanent home, in our courtrooms. The legal disputes before us increasingly involve the principles and tools of science. Proper resolution of those disputes matters not just to the litigants, but also to the general public—those who live in our technologically complex society and whom the law must serve.”

Breyer, S., J., S.Ct., *Reference Manual on Scientific Evidence*, 2d Ed., Federal Judicial Center (2000)

Science in the Courtroom

- “Our decisions should reflect a proper scientific and technical understanding so that the law can respond to the needs of the public. **[I]n this age of science we must build legal foundations that are sound in science as well as in law.**”

Breyer, S., J., S.Ct., *Reference Manual on Scientific Evidence*, 2d Ed., Federal Judicial Center (2000)

Expert Witnesses on Causation

- Clinicians are frequently required to render an opinion as to whether an adverse health effect is work-related in compensation environments.
- “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.”

Expert Witness Qualifications

- As a threshold inquiry, the trial court must determine whether the expert has the requisite qualifications to offer the opinions he provides.
- Expert testimony may be admitted into evidence only if “the expert is qualified to testify competently regarding the matters he intends to address . . .”

Credentials Alone Insufficient

- “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.”

The Court’s “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

FED. R. EVID. 702

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

FED. R. EVID. 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.
- Trial court must insure that speculative and unreliable opinions do not reach the jury.
- “Expert evidence can be both powerful and quite misleading [for a jury of non-scientists] because of the difficulty in evaluating it.”

“Scientific Knowledge”

- Subject of the expert’s testimony must be “scientific . . . knowledge.”
- Inference or assertion proposed by the expert must be derived by the “**scientific method.**”
- “[P]roposed testimony must be supported by appropriate validation or good grounds.”
- “Admissible expert testimony must be based on actual knowledge and not subjective belief or unsupported speculation.”

Daubert’s Two-Prong Test

- *Daubert* established a two-prong test to determine the admissibility of an expert’s testimony:
 - Reasoning and methodology underlying the testimony must be scientifically reliable
 - Methodology must be applicable to the facts of the case

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 rate, 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.

Application of *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.”

“Illustrative Not Exhaustive”

- In *Daubert II*, the Ninth Circuit Court of Appeals concluded that the factors were “illustrative” not “exhaustive”
- Other factors ought to be considered

Opinions Formulated for Litigation

- “[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 . . .”
- Testimony “based ... on ... pre-existing research unrelated to ... litigation provides the most persuasive basis for concluding the opinions were ‘derived by the scientific method.’”

Reference to Published Research

- When expert testimony is not based on independent research...
- There must be objective evidence that testimony is based on “scientifically valid principals”
- Conclusions ‘have been subjected to ... scientific scrutiny through peer review and publication’

Advisory Committee Notes

- Whether the expert is proposing to testify about matters growing naturally and directly out of research conducted independent of the litigation
- Whether he has developed his opinion expressly for purposes of testifying
- Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion

Advisory Committee Notes

- Whether the expert has adequately accounted for obvious alternative explanations
- Whether the expert is being as careful as he would be in his professional work outside paid litigation
- Whether the field of expertise claimed by the expert is known to reach reliable results

The “Analytical Gap” Test

- In *General Elec. Co. v. Joiner*, the U.S. Supreme Court expanded the scope of a court’s inquiry on admissibility:
 - “[C]onclusions and methodology are not entirely distinct from one another
 - Trained experts commonly extrapolate from existing data, **but ...**

The “Analytical Gap” Test

- Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence . . . connected to existing data only by the *ipse dixit* of the expert.
- A court may conclude that there is simply too great an analytical gap between the data and the opinion.”

The “Intellectual Rigor” Test

- Expert witnesses must employ the “same level of intellectual rigor that characterized the practice of an expert in the relevant field”
- Court has a duty to ensure that the expert’s methods can withstand strict scrutiny from his peers

Publication Alone Insufficient

- 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

Heightened Scrutiny for “Hired Guns”

- Courts must evaluate whether the expert is a “hired gun” or a person whose opinion in the courtroom will withstand the same scrutiny that it would among his professional peers
- Expert is being as careful as he would be in his regular professional work outside his paid litigation consulting
- If expert is the ‘quintessential expert for hire,’ court may apply *Daubert* factors with greater rigor

Methodology and Investigation

- Expert testimony must be based on actual knowledge, not...
 - Subjective belief
 - Unsupported speculation
- Expert testimony is not scientifically reliable (*i.e.*, is inadmissible) 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.”

“Differential Diagnosis”

- “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.”

Diagnostic Fallacy

- In *Black v. Food Lion, Inc.*, plaintiff slipped and fell in supermarket
- Causation expert diagnosed the plaintiff with “fibromyalgia syndrome”
- Expert purported to engage in a “differential diagnosis”
 - Excluded all preceding and subsequent causes
 - Deduced that the accident was the only remaining cause
 - Relied on temporal association between fall and onset of symptoms

Diagnosis By Exclusion

- Exclusion of all other explanations does **not** necessarily establish accident (or exposure) as cause
- Expert failed to acknowledge insufficient epidemiologic evidence of causation
 - Many diseases and disorders are **idiopathic**
 - Failed to recognize fibromyalgia has no known etiology

Diagnostic Fallacy

- “This analysis amounts to saying that because [the physician] thought she had eliminated other possible causes of fibromyalgia, even though she does not know the real ‘cause,’ it had to be the fall at Food Lion.
- 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.”

Epidemiology in the Courtroom

- 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

Case Reports – a Biased Perspective

- Describes experience of a single patient under a physician’s care with health outcome apparently related to exposure
 - **Anecdotal** - not epidemiological
 - Descriptive design – **generates hypothesis**
 - Cannot be used to test for presence of an association

Case Reports – a Biased Perspective

- Lack of control groups (*i.e.* persons that differ in disease or exposure status from subjects) limits interpretation
- Subject to multiple sources of information bias
- Can suggest an association where none actually exists
- Rarely proves observed relationship is causal

Case Reports – a Biased Perspective

- Apparent disease clusters in the presence of “risk” factor, however suggestive, may be unremarkable events that have little or nothing to do with hazardous exposures (*i.e.*, merely coincidental)
- Case reports “[d]o not demonstrate a causal link sufficient for a finder of fact in court.”

Cross-Sectional Studies

- Cross-sectional studies compare the *prevalence* of disease or health status...
- Between groups of workers classified with respect to exposure
- Case reports and cross-sectional designs are “preliminary...investigations” to screen for possible workplace hazards – a hypothesis generating design

Cohort Studies

- Test for *incidence* of an adverse health consequence over time...
- In a randomly selected population of exposed workers, *and...*
- A randomly selected population of unexposed workers
- Highest quality evidence of causation – a hypothesis testing design

Association *cf.* Causal Association

- “Even when an appropriately designed study yields evidence of a statistical association between a given substance [or physical factor] and a given health outcome, ...

Guidelines for Causal Inference

- Epidemiologists generally do not accept such an association by itself as proof of a causal relationship.”
- Epidemiologists generally look to several additional guidelines to determine whether a statistical association is indeed causal.
- Reliance on one or a few studies is typically insufficient evidence of causation.

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 for intervention

General Causation

- **General causation** - reliable and consistent epidemiological evidence that workplace factor is generally capable of causing disease
 - Epidemiologic research focuses on *general* causation
 - Provides profile of type of individual likely to contract disease after exposure to risk factor
- Epidemiological evidence of general causation is a condition precedent for proof of specific causation

Specific Causation

- **Specific causation** – reliable evidence that the workplace factor caused disease in an individual worker
 - Worker must establish not only that exposure is generally capable of causing disease, but also...
 - The exposure was the cause-in-fact of his disease

The “Dose is Still the Poison”

- “[E]xpert testimony . . . meets *Daubert’s* ‘fit’ requirement only if testimony proves
 - Exposure to the particular substance
 - At the dose that plaintiff was exposed
 - For the duration plaintiff was exposed
 - Can cause the particular disease of which plaintiff complains

General and Specific Causation

- Generally, an outcome is occupational if:
 - The medical findings of disease are compatible with the effects of a disease-producing agent . . . to which the worker has been exposed
 - There exists in the worker’s occupational environment . . . exposure to an agent . . . sufficient to have caused the disease
 - The weight of evidence supports that the disease is of occupational rather than non-occupational origin

Proof of Causation

- Establishing the causality of an occupational injury or disease is often a difficult task
- In contrast to a traumatic injury, a cause-effect relationship between disease and risk factors in the workplace may be unclear
- *Daubert* requires a valid and reliable methodology for proof of causation

“An Inconvenient Truth”

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

Evidence

- **Evidence** – information or data that furnishes or tends to furnish proof
 - **Direct evidence** – evidence that tends to prove without inference
 - **Circumstantial evidence** – evidence from which proof can be inferred
- **Relevant evidence** – evidence having a tendency to make any fact of consequence to the determination of truth or falsity more probable or less probable than it would be without the evidence.

Evidence-Based Medicine

- Classic definition of evidence-based medicine is Sackett's:
 - “The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”
- In the decade since Sackett articulated this definition, both law and science have evolved

An Alternative Definition

- The conscientious and methodological application of state-of-the-art knowledge of the medical, epidemiological, technical, psychological, and clinical sciences to all decisions relating to the diagnosis, etiology, and treatment of injury and illness among individual patients – a multi-disciplinary approach that may require consultation with colleagues in other disciplines.”

Proposed Methodology for Determination of Causation

- A multi-disciplinary method for the determination of causation is not a novel approach
- 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*.”

The NIOSH *Guide*

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

The NIOSH *Guide* – Relevant or Relic?

- Contemporary adaptations of the NIOSH *Guide*:
 - *Occupational Medicine Practice Guidelines – Evaluation and Management of Common Health Problems and Functional Recovery of Workers*, ACOEM (rev'd 2008)
 - *Guides to the Evaluation of Disease and Injury Causation*, AMA (2008)

Aggravation

- **Aggravation** could be construed exacerbation of symptoms or progression, natural or otherwise, of the underlying pathology
 - **Modulation of symptoms** as the result of occupational exposures is characteristic of both occupational and non-occupational injuries and illnesses
 - Progression according to **natural history of disease**, coincident with occupational exposure, should not constitute a criterion for inferring work-relatedness

Precipitation

- **Precipitation** could be construed as manifestation, natural or otherwise, of an underlying pathology, but ...
 - Manifestation of symptoms, coincident with occupational exposure, should not constitute a criterion for inferring work-relatedness
 - Critically distinguish pathogenesis from activity intolerance

A Cautionary Statement

- “With occupational diseases, what appears to be ‘obvious’ is often subject to controversy, and it is important to assemble complete information wherever possible in order to assure an equitable decision.”
- This is particularly true in compensation environments

Legal Burden of Proof

- Common error made by attorneys, judges, and expert witnesses is to confuse statistical significance (*p* value) with the **legal burden of proof**
 - Misconception that using an α of .05 imposes burden of proof greater than **civil burden of proof by a preponderance of the evidence**
 - Increasingly, courts recognize that epidemiological research failing to demonstrate statistically significant association between exposure and outcome are **inadmissible**

Civil Burden Of Proof

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

“Reasonable 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*

Conclusion

- 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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