



# CAUSATION

## The Bedrock of Toxic Tort Litigation

By

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# SCIENCE v. MEDICINE

## in the COURTROOM



- 1. Toxicology is the science of causation; clinical medicine is not science.**
- 2. Scientific medical research may qualify for a basis for causative opinions.**
- 3. Physicians are diagnosticians and may not be qualified to offer causative opinions.**
- 4. Science is science and medicine is medicine.**

# CAUSATION

in

## DIFFERENT VENUES



- **Regional Court**
- **State Court**
- **Federal Court**
- **Workman's Compensation**
- **Railroad Worker's Compensation**
- **Maritime**

# CAUSATION VENUES



- **Daubert - Federal Court**
- **Frye - Mississippi and elsewhere**
- **Havner - Texas**
- **Foret - Louisiana**
- **Others???**

# FRYE v. UNITED STATES (1923)



**U. S. Court of Appeals held that expert testimony based on novel scientific evidence is inadmissible unless the technique used by the expert is “generally accepted” as reliable in the relevant scientific community.**

# FEDERAL RULES of EVIDENCE 702 (1975)



**“ 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.”**

# DAUBERT v. MERRELL DOW PHARMACEUTICALS (amended FRE 702)



**The Supreme Court stated that:**

**”the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant but reliable.”**

**”this involves a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.”**

# DAUBERT v. MERRELL DOW PHARMACEUTICALS (amended FRE 702)



**The court identified four factors to assist a judge in assessing a scientific expert's methodology:**

- **Whether the theory or technique can be and has been tested.**
- **Whether it has been subjected to peer review and publication.**
- **The technique's known or potential error rate.**
- **The established criterion of "general acceptance".**
- **Court in role as "gatekeeper".**

# DAUBERT v. MERRELL DOW PHARMACEUTICALS (amended FRE 702)



**A witness qualified as an expert, by knowledge, skill experience, training or education may testify in the form of an opinion or otherwise if:**

- **The testimony is based upon sufficient facts or data.**
- **The testimony is the product of reliable principles and methods.**
- **The witness has applied the principles and methods reliably to the facts of the case.**

# DAUBERT v. MERRELL DOW PHARMACEUTICALS (amended FRE 702)



## **Additional factors that are likely to be considered:**

- **Original research or opinions based on others' research.**
- **Possible biased viewpoint of researcher.**
- **Perspective from consideration of broader picture.**
- **Unjustifiable extrapolation - gap between actuality and opinion proffered.**
- **Alternative explanations - have they been ruled out?**
- **Professionalism - employment of same intellectual rigor as in non-litigious matters.**
- **Reliability of field expertise - see Science v. Medicine in the Courtroom**

# TYPES of EVIDENCE USED to ESTABLISH CAUSATION

- **Exposure/dose information.**
- **Medical testimony on diagnosis and differential diagnoses.**
- **Medical history including medication history.**
- **Familial history.**
- **Social history - smoking, drinking, drugs.**
- **Peer-reviewed literature relating exposure/dose to diagnosed disease:**
  - **in man - epidemiology - industrial hygiene.**
  - **in animals - control, dose-response.**
  - **in vitro - understanding the disease process.**
  - **mechanistic studies in man and animals.**
- **If drug, then clinical trials.**
- **If drug, then adverse events reports.**
- **Possible alternative causes.**

# HILL SET of CRITERIA for CAUSATION (MODIFIED)



- 1. STRENGTH**
- 2. CONSISTENCY**
- 3. SPECIFICITY**
- 4. TEMPORALITY**
- 5. BIOLOGICAL GRADIENT**
- 6. PLAUSIBILITY**
- 7. COHERENCE**
- 8. EXPERIMENTAL EVIDENCE**
- 9. ANALOGY**

# 1. STRENGTH

- **A strong association is more likely to be causal than a weak one.**
- **Weak associations are more likely to be explained by undetected biases**
- **The fact that an association is weak does not rule out a causal connection - example: smoking and cardiovascular disease or passive smoking and lung cancer**
- **The fact that an association is strong does not rule out alternative causation - example: Down's Syndrome and birth rank where age is the confounder.**



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CRITERIA

(modified)



## 2. CONSISTENCY

- **Repeated observation of an association in different populations under different circumstances.**
- **Lack of consistency does not rule out a causal association since some effects are produced by their cause only under unusual circumstances - example: transfusions can cause HIV infections but only when the virus is present.**
- **Understanding the mechanism of a causal relationship will help in establishing consistency - example: vinyl chloride and specific DNA adducts in the liver.**
- **Consistency serves only to rule out hypotheses that the association is attributable to some factor that varies across different studies.**



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CRITERIA

(modified)



### 3. SPECIFICITY

- **Requires that a single cause leads to a single effect, not multiple effects.**
- **Although this criterion has some merit, relating a single causal agent with a single outcome, excluding all others is nonsense.**
- **Example - vinyl chloride causes angiosarcoma which is very specific but it also causes hepatocellular carcinoma and astrocytomas, among other effects.**
- **Example - smoking causes lung cancer but it also causes cardiovascular disease, emphysema and many other effects.**
- **It is not logical that causes of a single effect cannot be expected to lack other effects.**
- **This criterion may be applicable in some cases where the specificity is related to an unusual disease such as angiosarcoma or cardiovalulopathies (FenPhen) but should not be a requirement of all causal analyses.**



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## 4. TEMPORALITY

- **Cause must precede the effect in time.**
- **This is an objective criteria.**



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## 5. BIOLOGICAL GRADIENT

- **Incidence of causal effect increases with dose.**
- **Human studies may not necessarily show linear increases of specific disease with dose since confounders cannot be totally eliminated - alcohol, food, alcoholism, drunkenness.**
- **Some effect may be produced from a single dose - PPA and hemorrhagic stroke.**
- **Animal studies show linear responses since confounders are controlled - these studies are considered objective.**
- **Acute effects(solvent intoxication) vs chronic effects(cirrhosis of the liver).**
- **Thresholds may not produce any effects up to a certain dose level (TCE exposure).**
- **Death rates are higher among non-drinkers that among moderate drinkers (inverse dose-response) but highest among heavy drinkers!**



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## 6. PLAUSIBILITY

- **Biologic plausibility of the hypothesis - does the relationship make sense after considering the underlying base of scientific knowledge.**
- **Mechanistic studies can offer insights into this criterion.**
- **This is only objective if the observer maintains his objectivity.**
- **Does the hypothesis violate any biological premises?**
- **Are the criteria used to establish this factor accepted in the scientific community.**
- **Vinyl chloride and increased brain cancer incidence - Does vinyl chloride reach the brain?**
- **In-utero PCB exposure and delayed development in neonate - Does PCB reach the brain and have an influence on synaptogenesis in the fetus and neonate?**



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## 7. COHERENCE

- **This factor relates to the disease itself and the fact that a possible association with an offending agent must not conflict with the natural history and biology of the disease.**
- **The effects of smoking on the bronchial epithelium is consistent with the development of lung cancer.**
- **The presence of conflicting information may refute a hypothesis - ie: Smoking does not cause smallpox.**
- **The absence of coherent information may not be used to dismiss the potential for a causal relationship.**
- **There is some overlap here with plausibility.**



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## 8. EXPERIMENTAL EVIDENCE

- **Evidence from animal experimentation (usually available) or controlled human experimentation (rarely available except in clinical trials).**
- **Animal experiments**
  - **highly controlled**
  - **dose-response**
  - **multiple species**
  - **short-term, long-term**
  - **specialized to measure specific effects.**
- **Epidemiology - uncontrolled experiments.**
  - **alternative causation and confounders.**
  - **risk ratios and statistical significance or lack thereof.**



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## 9. ANALOGY

- **Proposed analogies should be justified and subject to scrutiny.**
- **Some analogies are obvious (exposures to solvents and acute neurological effects) but others are imaginative and may not be legitimate.**



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# ACTUAL CASE REPORTS



- **Soft drink contamination with copper.**
- **Vinyl chloride and industries hiding findings of acroosteolysis and cancer.**
- **Tobacco and Dalbey's minipulation of animal data to make it positive.**
- **Hexavalent chromium inhalation - for Plaintiff and Defense.**
- **Pantopaque and arachnoiditis.**
- **FenPhen and cardiovalvulopathies.**

# SUMMARY



- **Amended FRE 702 continues to set forth a liberal standard designed to permit the admission of expert testimony that will provide the trier of fact with an understanding of the evidence.**
- **The expert's methods and conclusions should be analyzed as distinct and opinions reasonably derived from reliable methodologies should not be rejected just because other experts might disagree.**
- **Daubert factors are flexible, non-exclusive and no single factor is fatal; not all factors will apply equally in all cases.**
- **Vigorous cross examination, presentation of contrary evidence and confounding factors and careful instruction on the burden of proof are the traditional and appropriate means of attacking evidence in court.**
- **Vinyl chloride and industries hiding findings of acroosteolysis and cancer.**
- **Tobacco and Dalbey's manipulation of animal data to make it positive.**
- **Hexavalent chromium inhalation - for Plaintiff and Defense.**
- **Pantopaque and arachnoiditis.**
- **Fen Phen and cardiovalvulopathies.**

# The End

