

The Science Fiction of Medical Causation
Negar Mattian, Esq.

Understanding Science of Causation is Important!

To Promote Truth & Justice Societal Welfare

Billions of Dollars Invested in Medical Research

Ignoring Science Leads to Bad Outcomes:
Inappropriately Significant Financial
Consequences for Employers



BIRTH DEFECTS TENTATIVELY LINKED TO SPERMICIDE USE

APRIL 4, 1985

Wells by Mailhafer v. Ortho Pharmaceut.,
615 F. Supp. 262 (N.D. Ga. 1985)

U.S. District Court for the Northern District of Georgia, Atlanta, Georgia

APRIL 4, 1985

Ortho Pharmaceutical Corporation, a Delaware corporation, and Ortho Pharmaceutical Corporation, a Delaware corporation, are defendants in this case. Plaintiff, Wells by Mailhafer, is a child born with a birth defect. Plaintiff's mother, Mrs. Mailhafer, is the plaintiff in this case. Plaintiff's mother, Mrs. Mailhafer, is the plaintiff in this case. Plaintiff's mother, Mrs. Mailhafer, is the plaintiff in this case.

CASE NUMBER
1:85-cv-00000

Poor Science in the Court Room

- Study found Spermicide use possibly linked to Birth Defects. Study authors cautioned: Findings "tentative and needed more study"
- Court awards \$5.1 million to Plaintiff.
- Newer studies find no relationship between spermicide and birth defects





Poor Science in the Court Room

- In 1974, a small case series of 24 children found 9 of them to have infantile spasms within 5 days of receiving whooping cough (Pertussis) vaccine
- Numerous law suits were filed and several vaccine companies abandoned the market.
- Subsequent National Childhood Encephalopathy Study (NCES) in 1988 found no permanent brain damage within 48 hours of vaccination (2 million doses)

More Examples . . .

Silicone Breast Implants

- \$12 billion in Litigation costs and removal from for almost a decade
- Research later proved implants to be safe

Elam v. Alcolac, Inc.

- Award of *\$40 million based on discredited theory (chemically induced AIDS)
- Plaintiff's evidence was based on tests that would not be condoned by today's standards.

*Judgment later reduced on appeal.

How the litigation over the Rx Bendectin changed science litigation history .



Part 1: Blum v. Merrell Dow

- 2100 lawsuits filed against Merrell Dow for its anti-nausea medication, Bendectin.
- Plaintiffs claimed birth defects due to maternal use of the drug.
- \$200 million dollars in damages.

Analysis: Blum v. Merrell Dow



- Defendant: No evidence to support abnormal development from Bendectin
- Plaintiffs: Animal studies, Utilized personal analysis

Initial Cases Court rules in favor of Plaintiffs



- Club feet very common
- Bendectin most studied drug in pregnancy
- No evidence of teratogenicity
- No excess risk above general population in users of Bendectin for birth defects

Part 2: Blum v. Merrell Dow

- U.S. Supreme Court finds Bendectin decision is **incorrect**
 - Establishes **Daubert** Standard:
 - Requires **reliable methodology**
 - **Not the sole credibility of an expert.**
1. Method can or has been tested.
 2. Known or potential rate of error.
 3. Subjected to peer review.
 4. Standards controlling the technique's operation, and.
 5. General acceptance of the method within the relevant community.

"Bendectin was the archetypical case of junk science scuttling a perfectly safe product," said Dr. Michael Greene, the director of maternal-fetal medicine at Massachusetts General Hospital in Boston. "It was a sad episode in American jurisprudence."

And once it was withdrawn from the market, surrounded by accusations that it caused birth defects, he said, doctors became afraid to give pregnant women any medications to relieve nausea and vomiting. That, Dr. Scialli said, led to an unfortunate situation.

Problems using Science to Litigate

- Absent Information
 - No studies that address issue(s) in dispute
 - Conjecture
- Bad/Old Information
 - Only available studies are poorly designed and arrive at incorrect conclusion
- Junk Science
 - Expert opinions ≠ best available information
 - Bad studies which contradict best available information

Workers' Compensation doesn't adopt Daubert Standard

"The legal establishment is all over this and says, 'Well, she works on a computer keyboard; de facto, the computer keyboard causes her carpal tunnel syndrome,'" he said. "You can't say that. If she happens to have carpal tunnel syndrome, it may have gotten worse if she never turned her computer on."

A number of factors may contribute to the development of CTS:

- **Age** - CTS is more common among older individuals.
- **Gender** - Women are more frequently afflicted.
- **Heredity** - Some people naturally have a narrower carpal tunnel in their wrists.
- **Medical conditions** - CTS is more prevalent among people with certain conditions, such as diabetes, rheumatoid arthritis or thyroid imbalance.

"Probably 90 percent of carpal tunnel syndrome is idiopathic - nobody knows why it occurs," said Barry Simmons, M.D., chief of the hand and upper extremity service in the department of orthopedic surgery at Boston's Brigham and Women's Hospital. "There's no answer ... but we do know that it's not caused by computer keyboard use."

Science, Causation and Workers' Compensation

The Court Desires Black and White

- More than 50%
- Substantial cause or 30-40%
- Reasonable degree of Medical Probability and not Possibility
- More Likely than Not

Medicine Delivers Grey

- Issues are addressed in terms of likelihood
- Cannot exclude possibilities
- Probabilities are not Definitive
- There are always Mitigating Factors and Exceptions

Science, Speculation and Causation

South Coast Framing, Inc. v. WCAB

- EE's death attributed to lethal combination of following medications:
 - Work Related: **Vicodin and Elavil**
 - Personal: **Ambien and Xanax.**
- Independent Medical Evaluator (IME) opines:
 - Blood levels of work related medications were consistent with prescription dose.
 - Blood levels of personal drugs were consistent with **overdose**

Science, Causation and Workers' Compensation

California Supreme Court holds the following:

- The evidence was "reasonable in nature, credible, and of solid value such that a reasonable mind might accept it as adequate to support its conclusion"
- Industrial injury need only be a contributing cause to the disability



"Could [of] Elavil, in combination with Ambien and Xanax, "contributed" to Clark's death?"



- "It's possible" and that Elavil **could be** an incremental contributor," although "the [Xanax] and [Ambien] being in the same class and at a much higher dose . . . kind of carried the day."
- Elavil is . . . "is way down there" as a cause of death and it would be "really **speculative** to place a percentage on it."
- "It would be closing your eyes and throwing a dart at a dartboard kind of stuff" or "just **pulling numbers** out of the sky."
- "I'd be loathe to see percent causation and we're dangling right down there," but it would be **medically improper** to sit here and say that I can pull a percentage out."
- Presumably, absent use of Norco and Elavil, Ambien and Xanax would still kill him

Science Fiction and Workers' Compensation

Applicant's slip-n-fall aggravated his pre-existing asymptomatic cancerous tumor and therefore cancerous tumor to be industrially aggravated.
City of Seymour v. Industrial Commission



- Even if the court finds the testimony of expert medical witnesses to be speculative and conjectural, it will not presume to substitute its own opinion for that of a medical expert's.



- Evidence or Rationale Needed to Support Opinion
- Explain mechanism in absence of supporting evidence
- Must explain why supporting evidence unavailable

Science Fiction and Workers' Compensation

Wrist pain felt from lifting a package was found to be Industrial.
McCray v. King Bio Inc



- No expert medical testimony
- Uncomplicated situation
- Letter from Plaintiff's Orthopedic Surgeon Explaining Industrial Causation



- Verified incident
- No Verified Diagnosis that Matched Accident
- Anatomic problem does not easily correspond to mechanism of injury

Promoting Use of Good Science in Workers' Compensation

Retrospective Evaluation of Causation of Injury or Condition

- Possibility
 - Impossible (Chance of Injury = 0%)
 - Incomplete information about circumstances
- Plausibility
 - Circumstances as described could lead to injury
 - Plausibility ≠ What actually happened
 - Plausibility = Possibility
 - Injury/Condition arose from plausible set of circumstances=causation
 - Injury/Condition exists
 - Circumstances exists
- Probability
 - Percentage chance that the injury/condition really happened with proposed set of circumstances

How do we socialize the difference between Evidence Based Medicine (EBM) and "causation" in our Workers' Compensation Cases?

Examine

Investigate

Incorporate

Examine Cases for Further Discovery



- More than \$50k Settlement
- CT where person worked for less than 1 year
- Internal diagnosis
- Questionable Mechanism of Injury
- Significant treatment recommended in acute phase
- Chemical, biological, and infectious agents
- Underlying degenerative condition is aggravated by small incident
- Major Injury caused by Minor Accident

Investigate Factors in Determining Causation

Injuries due to Chemical, Biologic and Radiation

- exposure, duration, internal dose

Physical Injuries due to transfer of energy or force

- amount of force, duration and tissue damage

Incorporate Research and Expert Opinions

- Interventional studies that determine effectiveness of treatment
- Epidemiological studies to identify risk factors
- Expert Opinion (in the absence of adequate studies)

Examine Case

- Employee discovered dead over a scrubber machine.
- Toxicology report revealed Employee had methamphetamine in her system.
- Cause of death was determined to be "complications of subarachnoid hemorrhage (SAH) due to complications of acute methamphetamine intoxication".
- The subpoena records also indicate that the Applicant was seen alive 30 minutes prior to her being found unconscious.

- ✓ Internal Diagnosis
- ✓ 250k Potential Settlement
- ✓ Questionable Mechanism of Injury

Investigate all Significant Facts

7/23/13 @ 1:22am	Jon Smith saw the EE awake and conscious in the food court (NOTE: This doesn't make sense because security camera showed her passed out at 1:15am.)
7/23/13 @ 1:32am	Security Officer discovers EE on scrubber, slumped and unresponsive. Paramedics are called.
7/23/13 @ 1:38am	Mail Security (Jon Smith) was in food court and spotted EE on the "mobile floor cleaning machine" appearing to be leaning over the side. He then went and hit a "Detect Button" and took a second look and saw EE from the front and saw she appeared to actually leaning over asleep. He went in front of the Warnabe Fernat space and attempted to wake her, when she was unresponsive he tried again and saw she was not breathing.
7/23/13 @ 1:40am	Mail Security calls 911 and tried to summon other employees with the radio and no response was received.
7/23/13 @ 1:42am	Paramedics arrived and EE was allegedly not breathing. EE moved to ambulance outside. 20 minutes are spent trying to resuscitate EE.
7/23/13 @ 2:16am	Paramedics obtain a pulse from EE and then commence transporting her.
7/25/13	EE body received at the City and County of SF Office of Chief Medical Examiner.

- AFFIDAVIT OF EMPLOYER REPRESENTATIVE**
- My name is Jon Smith.
 - I am employed by Acme Corp.
 - I am employed in the position of Regional Manager. I oversee all property, equipment, customer service, and employee support.
 - I have worked for Acme Corp Services Inc since 1998.
 - I was working for Acme Corp Services Inc on 7/23/13.
 - I am familiar with Jon Doe.
 - Mr. Employee was assigned as a crew lead on 7/23/13.
 - On 7/23/13, she was assigned to operate the Scrubber Machine (Cushman) (photo attached).
 - I am personally familiar with the Cushman Machine. I have used and operated it since 1998.
 - The Scrubber Machine is operated after the seal has been closed to the public.
 - Only one person operates the Scrubber Machine.
 - The Scrubber Machine only physically requires a person to step up on it and sit down, then it is on, and then they have to make it a machine and use the steering wheel to direct the direction of the machine.
- EE: The Scrubber Machine is a very sensitive job. It does not require any special physical activity that would be more than 11. The Scrubber machine is a machine used for a public job. The Scrubber Machine is not over the three sets per day.**

Investigate Non-Industrial Factors (Comorbidities for SAH)

- ✓ Gender: Females are 1.7 times greater risk than men
- ✓ Hypertension: 2 ½ times greater risk than normotensive
- ✓ Cigarette Smoking: 2-3 times greater risk than non-smoker
- ✓ Family History: 3 times greater risk if first-degree relative experiences stroke (Employee's brother died of a stroke at age 37).
- ✓ Methamphetamine Use: 5 times greater risk of hemorrhagic (bleeding) stroke as well as increased risk of ruptured of aneurysm (Methamphetamine detected in EE. Signs of chronic use: Poor dentition; Missing teeth). Methamphetamine use associated with subarachnoid hemorrhage (ruptured aneurysm).
- X Physical Exertion: moderate or extreme exertion

Incorporate Experts

It is my opinion, based on the totality of the data reviewed in this incident, that the toxic blood levels of 660 ng/ml methamphetamine and 100 ng/ml of amphetamine its active metabolite were the likely primary cause of the SAH experienced by [REDACTED] on July 23, 2013.

Forensic Toxicologist
Medical/Legal Consulting

Work-relatedness: There is no support in the literature that suggests SAH is triggered by work stress or the types of activities [REDACTED] was performing at work (housekeeping duties and/or driving a scrubber). In terms of increased heart rate or blood pressure associated with her activities and as a trigger for SAH, these activities are not associated with sufficient physical exertion to trigger a SAH.

Pamela J. Anderson-Mahoney, Ph.D.
Director, Epidemiology Resources

Attributing Work Relatedness

- Patient Contribution (Primary Cause):
 - Hypertension: Increases baseline BP
 - Methamphetamine: Increases baseline BP
 - Cigarette smoking: Increases baseline BP
- Work Contribution threshold in California is only 1%
 - Need to show that physical exertion at work did not contribute to condition in predisposed employee

Distinguish between "Sole Cause" and "Contribution to Condition"

- Experts Must:
 - Be familiar with jurisdictional Workers Compensation Law concerning work-relatedness
 - Understand distinction between contribution and causation
 - Focus on claimant's situation (predisposing factors) and apply studies not rely upon generalizations
 - Defend against the "straw" that contributed to condition

Incorporate Research

Work-related stress: There is no evidence in the literature that identifies work-related stress as a risk factor for SAH. The performance of housekeeping duties is characterized as light exertion with normal breathing according to a study on triggers for heart attacks. (Mittleman et al. 1993) The one study that I could find on the subject reports no association between work stress and SAH (Shiue et al. 2010).

Depose Doctor

1. Please confirm coroner's cause of death . . .
2. Please confirm the risk factors associated with stroke including comorbidities
3. Please confirm the presence of methamphetamine described in the toxicology report
4. Please confirm that physical exertion from any job activity is speculative.
5. Specify amount, frequency and duration of physical exertion
6. If you believe occupational contribution:
 - Be Specific
 - Substantiate
 - Quantify
 - Detailed explanation (rationale)


