Relative Risk Greater Than 2.0
in the American Court System

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The 1994 U.S. Supreme Court decision in *Daubert v. Merrell Dow* requires federal trial court judges to act as gatekeepers of scientific evidence.
American courts are increasingly discussing the concept of $RR>2$ in the context of proof of causation in toxic tort cases.
Decisions Counts Referring to RR>2 for the Years 1982-2002
We will discuss

• How some courts are viewing the epidemiological concept of RR>2 in toxic tort litigation

• Problems with treating epidemiological concepts like RR>2 as bright-line rules in the litigation context
Plaintiff has the burden of proving causation

**General causation in the legal arena**
Can substance X cause disease Y?

**Specific causation in the legal arena**
Did the exposure to substance X cause the Plaintiff’s disease?
The legal standard of proof which a plaintiff must meet is

**preponderance of the evidence**

i.e., is it “*more likely than not*” that the injury was caused by the exposure?
Of those courts that see an analogy between RR>2 and “more likely than not”

- Many say RR>2 is **sufficient** to prove specific causation

- A minority says RR>2 is **required** to prove specific causation and a few even demand it to prove **general** causation

- A minority won’t even let the expert witness testify without published evidence of RR>2
Of those courts requiring RR>2 as a bright line

• Some refuse to let an expert witness cite any study having RR>2 unless it is also statistically significant at p<0.05

• Some refuse to let an expert witness rely on reanalysis or meta-analysis

• No courts appear to appreciate that RR is merely a statistical point estimate
Problems with requiring epidemiological studies with RR>2

- Healthy Worker Effect
- Accrual Problem
- Remedial Action
- Dose Issue
If the goal is to approximate “more likely than not”, is it appropriate for courts to require both RR>2 and statistical significance in this context?
A specific example


<table>
<thead>
<tr>
<th>Cumulative Lifetime Benzene Exposure (ppm-years)</th>
<th>Leukemia Subtype</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ANLL (N = 11)</td>
</tr>
<tr>
<td>≤4*</td>
<td>1.00</td>
</tr>
<tr>
<td>&gt;4–8</td>
<td>0.52 (0.05–5.0)</td>
</tr>
<tr>
<td>&gt;8</td>
<td>7.17 (1.27–40.4)</td>
</tr>
</tbody>
</table>

*Reference category.
ANLL, acute nonlymphocytic; CLL, chronic lymphocytic leukemia; CML, chronic myeloid leukemia.
Here is something to think about
Conclusion

• Increasing consideration of the RR>2 criterion
• A minority of courts are seeking to apply RR>2 and statistical significance level as bright line rules, without adequate appreciation of the meaning
• There are serious drawbacks to reliance on epidemiological concepts as bright line legal rules