Relative Risk Greater Than 2.0 in the American Court System

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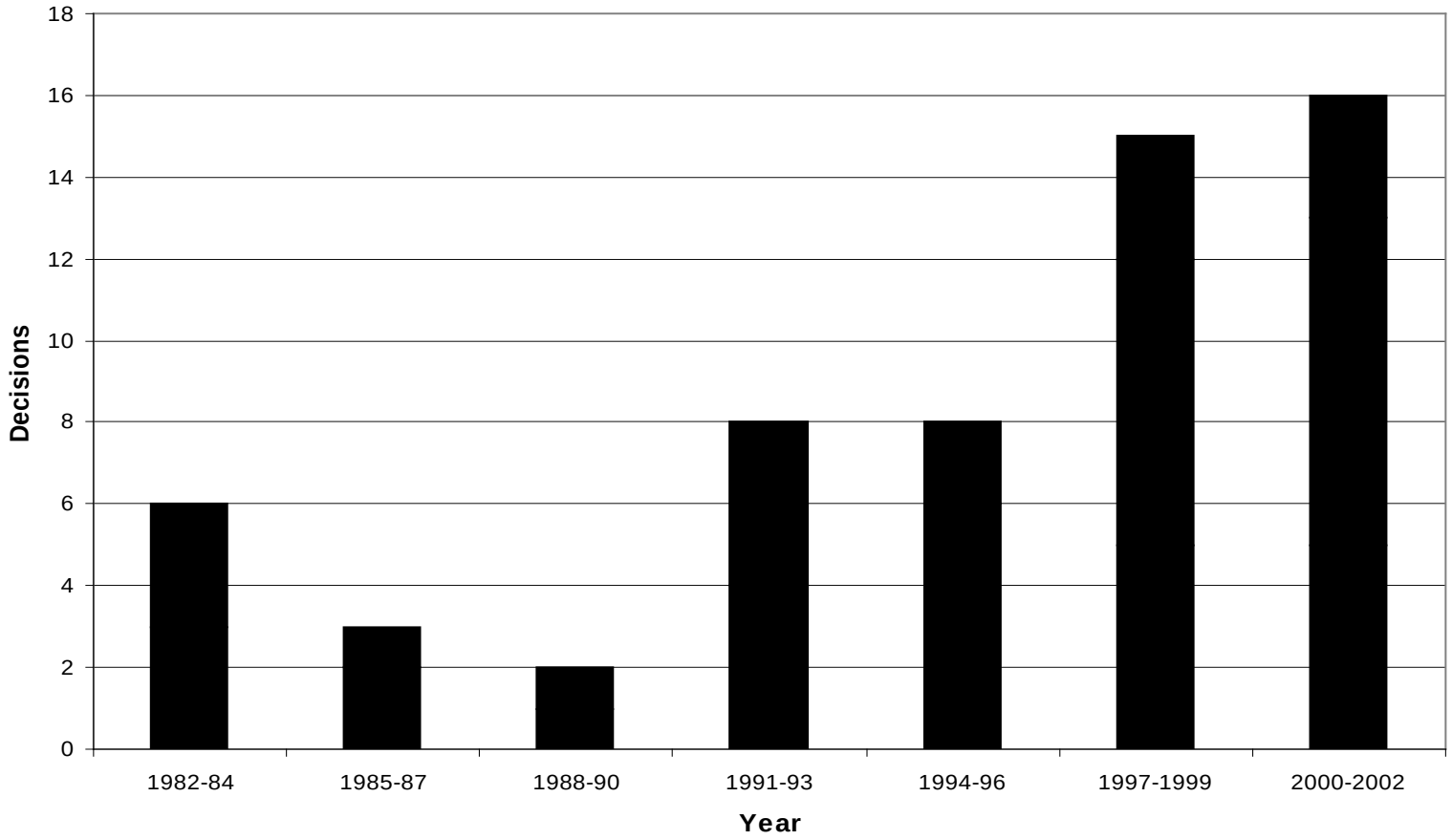
The 1994 U.S. Supreme Court decision in *Daubert v. Merrell Dow* requires federal trial court judges to act as gatekeepers of scientific evidence.

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?

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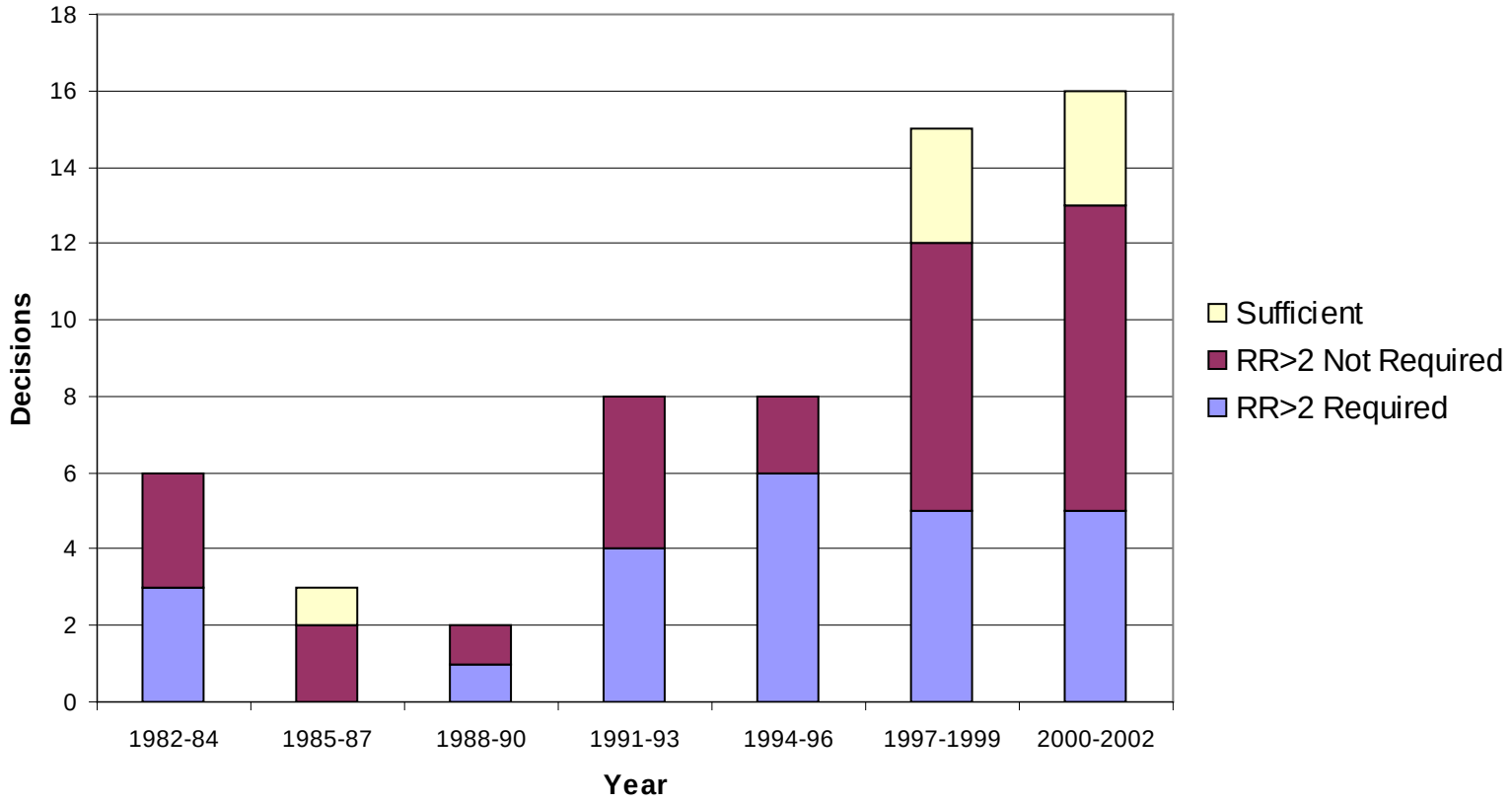


Of those courts that see an analogy between RR>2 and “more likely than not”

- 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

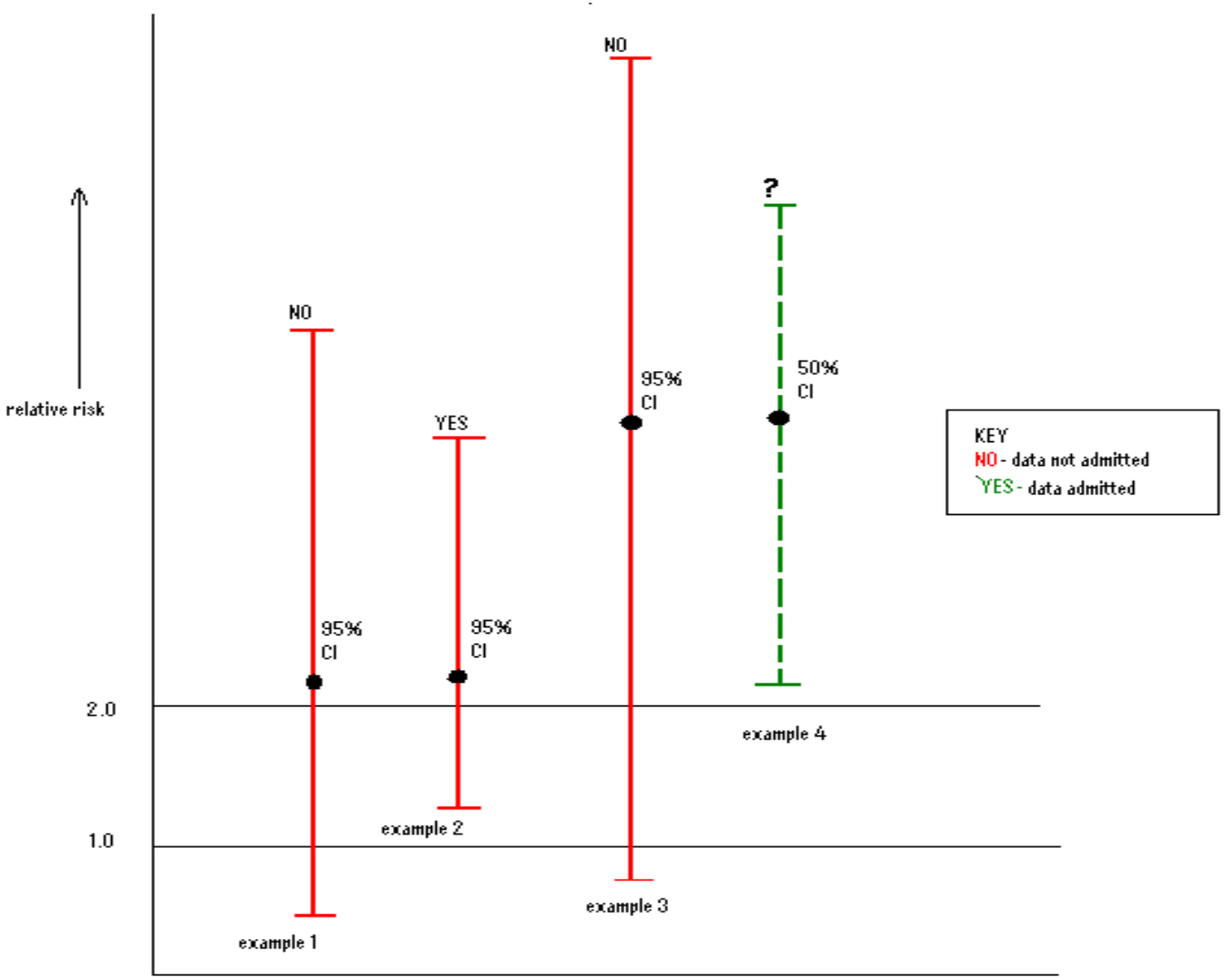
Reference Glass et al. epidemiology 2003; 14:569-577

TABLE 6. Association of Leukemia Subtype With Cumulative Benzene Exposure From Conditional Logistic Regression Analysis

Cumulative Lifetime Benzene Exposure (ppm-years)	Leukemia Subtype		
	ANLL (N = 11)	CLL (N = 11)	CML (N = 6)
≤4*	1.00	1.00	1.00
>4–8	0.52 (0.05–5.0)	2.76 (0.42–18.1)	-
>8	7.17 (1.27–40.4)	4.52 (0.89–22.9)	0.91 (0.08–9.8)

*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