

Lecture 32 Science & Law

Magnitude of the problem

- 100,000 chemical compounds in the environment
- Most are unregulated

Saccharin - Substance #1

- artificial sweetens a major business
- early 1970s, cyclamate, banned
- saccharin, caused cancer in rats

Rat studies

- rats fed high doses of saccharin
- second generation male rates developed bladder cancer
- Delaney Amendment (1960s)
- Congress overrode ban in late 1970s

Animal test

- dose, equivalent of 1000 cans/day
- study rats and offspring
- found the bladder cancer in male offspring

Concept of “mega-mouse” experiment

- acceptable risk = 1/10,000 (3,000 effects)

Added consideration

- there is no evidence that the substitution of diet drink in a diet helps control weight

Benzene - Substance #2

- epidemiological studies show causes workplace leukemia
- 1979, OSHA proposed lowering standard to 1 ppm

Response

- challenged in court
- Supreme Court agreed
- Conclusion, must demonstrate that lower standard will save lives

Consequences?

- impossible to demonstrate no effect, especially when time is not limited
- dose response not an exact science
- relationship between animals studies and human studies can be uncertain

Bendectin - Substance #3

- used, beginning late 1960s to relieve morning sickness during early pregnancy
- 1984 two mother brought suit against manufacturer, Merrell Dow Pharmaceuticals Inc.

Daubert case

- 1972/73 took Bendectin during pregnancy
- son born with serious birth defects
- learned of possible links in 1983 when Bendectin taken off the market (voluntarily)
- checked medical records, found had been prescribed Bendectin
- 1984 joint suit against Merrell Dow

Schuller case

- 1979, second mother prescribed and took
- 1980, children born with major birth defects (missing hand)
- 1984 when drug withdrawn, joined suit

Defendants response to suit,

- Steven H. Lamm, MD, submitted two page affidavit, saying no effects
- reviewed literature, showed no difference in risk

Conclusion

- **Based on my review of the scientific literature, I conclude that maternal use of Bendictin during the first trimester of pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect (1989)**

Plaintiff's response - relied on extensive scientific data:

Courts ruling:

- **made two points**
- **1925 ruling, called the Frye case or Frye rule**

Plaintiff's problems

- **Plaintiff's appealed to the Supreme Court**

Supreme court case

- **Plaintiff's brought in new experts**
- **Supreme Court, referred back into the lower courts**
- **lower courts reviewed and essentially reaffirmed the initial ruling**
- **Conclusion: provides judges with authority to make decisions about admissible science**

Substance #4

- **1/5th of all deaths in US linked to smoking**
- **effects of smoking have been known for 30+ years**
- **trends in smoking and deaths clear (1950s-1980s)**

Conclusions:

- **there is no doubt that smoking is a leading cause of death in the U.S.**
- **there is no doubt that smoking is addictive**

Policy regarding smoking

- **1967 on campaign to reduce and regulate**