

Understanding Science and Scientific Methods:

An Overview for Lawyers

SUMMARY – 14 November 2005

Class on 7 November 2005 Covered 3.c. and 3.d. (part) on the Syllabus

A. Bendectin Time-Line

1. Bendectin: A combination of 10mg of **doxylamine succinate**, a **sedative antihistamine** used in some over-the-counter antihistamines and sleep aids; and 10mg pyroxidine hydrochloride (**Vitamin B6** – sold over-the-counter).
2. **First marketed in 1957**
3. **Lawsuits Begin in 1977.**
4. **9 June 1983 – Merrell Dow withdraws Bendectin from market -- *33,000,000 women had used it.***
5. **9 August 1999 – FDA** states that Bendectin was not withdrawn from the market for reasons of safety or effectiveness.

B. What is the Scientific Consensus on Bendectin?

1. ***No consistent relationship between Bendectin and any birth defect has ever been found.***
2. Birth Defects (Congenital Abnormalities) are Common – ***The exact rate – the baseline probability – is unknown – However it is between 1 – 7% with 3% being the most cited figure.*** Given a 3% rate and a population of 33,000,000 pregnant women,

990,000 malformed infants would result by chance. **The rate of limb reduction effects is about 1/3000 so 11,000 should occur by chance in such a large population.**

II. Frye v. United States, 1923. General Acceptance. Frye permits the experts who know the most about a procedure to experiment and to study it. In effect, they form a kind of **technical jury**.

III. William Daubert et al. v. Merrell Dow Pharmaceuticals, Inc. 1993.

A. Bendectin:

1. The expert testimony on behalf of the plaintiffs did not pass the Frye -- “general acceptance by the scientific community” – standard.
2. The experts employed by the lawyers for the plaintiffs in the various Bendectin trials relied upon animal evidence, chemical structure (“test tube”) analysis, and reanalysis (meta-analysis) of the published studies.

B. Questions that the Supreme Court was called upon to Resolve: (1) Is the Frye standard superceded by Rule 702 of the Federal Rules of Evidence? (2) If Frye still holds then does it require that expert scientific testimony to have been peer reviewed (the meta analyses)?