

## 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 **9 August 1999 – FDA** states that Bendectin was not withdrawn from the market for reasons of safety or effectiveness.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**B. Questions that the Supreme Court was called upon to Resolve: (1) **Is the Frye standard superceded by Rule 702 of the Federal Rules of Evidence?** (2) **If Frye still holds then does it require that expert scientific testimony to have been peer reviewed (the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)?****