

Understanding Science and Scientific Methods:

An Overview for Lawyers

SUMMARY – 28 November 2005

Class on 21 November 2005 covered Topic 4 on the Syllabus

- I. The Role of the Press (F & H, Appendix A): Most reporters did not understand the *Daubert* decision; **misreport most statistical analyses**; are **hostile to corporate defendants**; and commit the **Post Hoc Ergo Propter Hoc** fallacy.
- II. Breast Implants
 - A. **Time Line on Silicone Gel:** 1962: Silicone gel implants first used. 1980 law passed requiring manufacturers of medical devices to prove their safety. 1984 woman wins jury award of \$2 million. 1991 woman wins jury award of \$7 million. 1992 FDA commissioner David Kessler bans the implants. By 1992 1-2 million (no exact numbers!!) had used them.
 - B. ***There had been no systematic studies before 1992!***
 - C. The allegation was that silicone-gel implants (and later, other medical devices – **artificial joints, heart valves, shunts, tubing** – also, disposable needles and syringes [silicone lubrication]) caused **autoimmune disease**.
 - D. **April 1994** Class Action Settlement: \$4.25 billion of which \$1 billion was set aside for attorneys.

E. **June 1994** – First Scientific study published in the *New England Journal of Medicine* (assigned reading).

1. **Cases** – All women in Olmsted County, MN, who received a breast implant between 1964 and 1991 were included.
N=749.
2. **Controls (2 Types)** – (1) 2 women of the same age for each of the 749 Cases; (2) 2 women who had mastectomy but no reconstructive surgery.
3. **Outcomes** – Judged by Expert Panel of 4 Nurses.
4. An analysis of **Diagnoses, Clinical Signs or Symptoms**, and **Abnormal Laboratory Test Results showed no pattern of significant results.**

F. **Swedish study – 1998 British Medical Journal**

1. Basic Design – Compare Two Groups, (1) Those who had implant with [n=7442] (2) Those who had Breast Reduction [n=3353].
2. Used Swedish database of citizens so that all women in both groups from 1964-1993 were included.
3. **No significant differences between the two groups.**