

September 16, 2009

Dr. Jack C. Fisher presented remarks on the growing conflict between scientific enterprise and a politically-driven regulatory process, the subject of his current book project, *Silicone on Trial: Science, Regulation, and the Politics of Risk*. (Fisher reported that in retirement, he returned to school to take an MA in US economic history.)

The session began with an account of the development of the FDA from the Pure Food and Drug Act of 1906 and a fledgling agency of 50 to the 10,000-employee agency of today. Fisher then turned to a case study of the 10-year case against Dow Corning for its silicone breast implants served. This narrative served to raise a number of ethical, legal, and scientific issues including

- US attitudes towards risk and The Precautionary Principle
- The benefits and burdens of drug testing for efficacy as well as safety, a model in contrast to the European model of evaluating safety alone,
- The growing power of federal regulatory agencies and their impact on scientific discovery and medical marketing.

Participants raised questions about privacy issues in requiring breast implant recipients to participate in registries or trials studying risk; the impact of public opinion and politics on members of Congress charged with drafting federal regulations; the relationship between risk aversion and public skepticism about medical findings based on industry-sponsored trials. The session concluded with a discussion of how low levels of scientific literacy undermine the public's capacity to read news reports of scientific findings critically, thus assessing evidence, including evidence of risk, for themselves.