Conflicts of Interest in Biomedical Research
(A Brief History)

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Mixed Messages from Congress

Are Conflicts of Interest Hazardous to Our Health?

Laws Encouraging University/Industry Collaboration
- Stevenson-Wydler Technology Transfer Act (1980)
- Federal Technology Transfer Act (1986)

Proposed Regulations 1989
Would have prohibited any financial interests in sponsors of their clinical trials

“Guidance” and Rulemaking

Hearings (Government Operations) 1988
Vigorous Protests from Research Community

AAMC and AAHC Issued Policy Guidance for Academic Health Centers (1990)

Physicians Should Not Buy or Sell Company's Stock until the Research Ends and the Results are Published (AMA, 1992)

Congress Enacted Law Requiring PHS to Establish Conflict of Interest Standards for Its Grantees (1993)

Proposed PHS Rules (1994)

Final Regulations
- 1995: NIH and NSF
- 1998: FDA
Unresolved Problems
- No clear limits established
- Universities may invoke waivers
- Uneven reporting at universities
- FDA reports are due after the fact
- Public assumes conflicts of interest when problems occur (University of Pennsylvania, Fred Hutchinson Cancer Research Center)

Back to the Drawing Board
- NIH/FDA “forum” (August 2000)
- New PHS/FDA “guidance”
- More congressional hearings

Best Practices
- Simplify conflict of interest policies
- Create user-friendly reporting forms
- Require conflict of interest committees to notify IRBs when serious conflicts are associated with clinical research
- Require IRB’s to determine which conflicts should be disclosed to potential research subjects

Best Practices (2)
- Prohibit finder’s fees, recruitment bonuses, and other enrollment incentives
- Prohibit clinical trials sponsored by companies in which either the institution or the investigator(s) hold equity
- Require additional training and supervision for faculty who want to be sponsor investigators
- Caution faculty, students, and staff about insider trading

THE END