

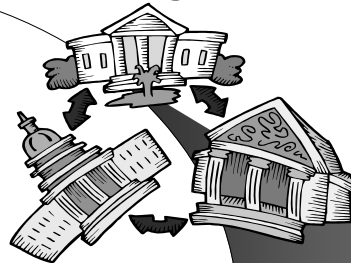
## Conflicts of Interest in Biomedical Research (A Brief History)

PRIM&R Conference  
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## Mixed Messages from Congress



## Laws Encouraging University/Industry Collaboration

- Stevenson-Wydler  
Technology  
Transfer Act (1980)
- Bayh-Dole Patent  
and Trademark  
Amendments (1980)
- Federal Technology  
Transfer Act (1986)



## Are Conflicts of Interest Hazardous to Our Health?



Hearings (Government Operations)  
1988

## “Guidance” and Rulemaking

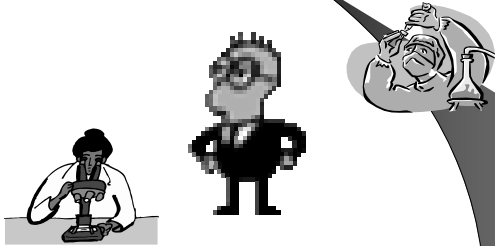


## Proposed Regulations 1989



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

**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**

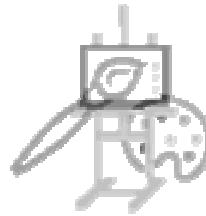


- 1995: NIH and NSF
- 1998: FDA

## 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**

