Conflicts of Interest in Research:

Industry Relationships with the IRB

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PHARMACEUTICAL R&D IN THE NEW MILLENNIUM

OPPORTUNITY

- Scientific and Medical Breakthroughs
- Technology Breakthroughs

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CHALLENGE

- Complexities of Scientific Environment/Regulatory Hurdles
- Cost Containment

D-COST 11,523

SCIENCE:

A TRUTH-SEEKING PROCESS

BIAS IN RESEARCH:

Bias hinders the Search for the truth.

BIAS IN RESEARCH:

- **Clinical Trials are Experiments—>Designed to Minimize Bias.**
- **Conflicts of Interest Induce Bias in Research.**

BIAS IN CLINICAL TRIALS

- The Investigator
- The Nurse
- The Technician
- The Patient
- The Patient's Relatives
- The Drug Company

BIAS IN RESEARCH:

- **One Of The Major Efforts Of The Clinical Protocol Is To Minimize Bias.**
- **The IRB Should Be Sufficiently Sophisticated That It Can Recognize A Study With Potential Bias.**

The Industry and the IRB

The Industry and the IRB

- **Under what circumstances, for a clinical study, does the Industry interact with the IRB?**
- **What kinds of interactions occur?**

The Industry and the IRB

- **Two, curiously dichotomous circumstances govern contact by the Industry with the IRB.**
- **The path is determined by the identification of the principal investigator.**

The Industry and the IRB <u>First Path:</u>

In a Phase II or III study, the industry study manager (who might be a clinical scientist or might be a physician) works with a principal investigator (typically an academician) who, in turn, deals with the IRB.

<u>The industry study manager would not even *think* about contacting the IRB.</u>

The Industry and the IRB <u>Second Path:</u>

In a Phase I study, the industry owns its own Clinical Research Unit. The director of the unit (typically a physician) <u>*is*</u> the principal investigator, and presents each study directly to the IRB.

<u>The industry study manager is now the principal investigator; contact with the IRB is expected and natural.</u>

The Industry and the IRB

Issues (I)

- **The IRB needs to have some independence from the principal investigator, whether the IRB is academic, contract, or otherwise.**
- **The IRB should have some accountability for its actions.**

The Industry and the IRB

Issues (II)

Should the IRB talk to the principal investigator?

OR

Should the protocol, etc, be mailed to the IRB for a decision?

The Industry and the IRB

Issues (III)

Accreditation is a good idea.

THE CHAIN OF TRUTH IN DRUG DISCOVERY AND DEVELOPMENT

- **Molecular Development**
- ↓
- **Synthesis Scale-Up**
- ↓
- **Basic Pharmacology**
- ↓
- **Early Toxicology**
- ↓
- **Pharmaceutical Development**
- ↓
- **Phase I in Humans**
- ↓
- **Phase II in Humans**
- ↓
- **Phase III in Humans**
- ↓
- **Registration**

BACKUP SLIDES

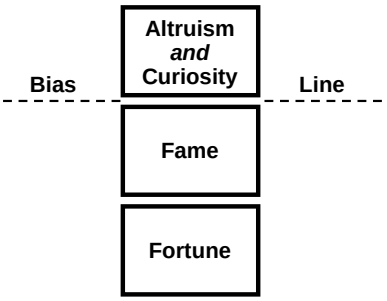
FORCES WHICH MOTIVATE SCIENTISTS:

Altruism *and* Curiosity

Fame

Fortune

FORCES WHICH MOTIVATE SCIENTISTS:



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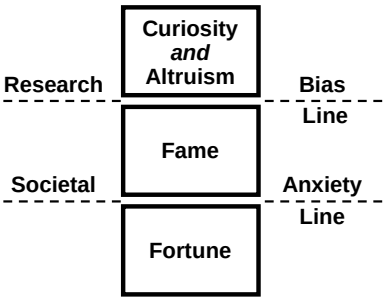
FORCES WHICH MOTIVATE SCIENTISTS:



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