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Impact of COI Policies on Innovation:

Perspectives from Academic Medicine

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Association of
American Medical Colleges

Importance of Effective, Robust COI Policies

Maintaining integrity of research data through identification of potential sources of bias

Preserving public trust in research process and results

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Elements of COI Policies

- Guidance or limits on specific activities or relationships
- Identification of relevant financial interests
- Review of potential conflicts of interest
- Management of identified conflicts of interest

- Public disclosure of certain relationships

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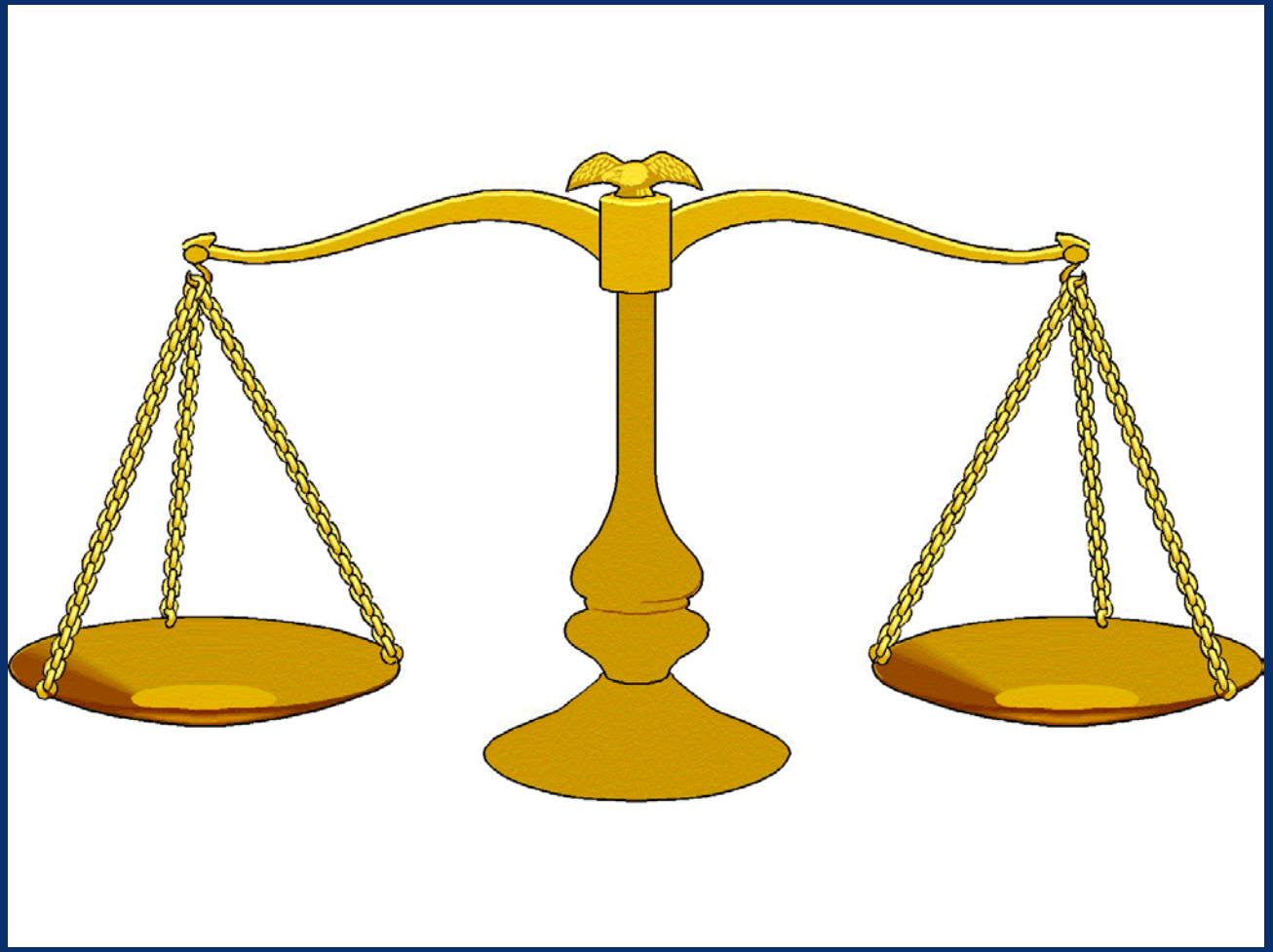
Are we getting the balance right?



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Potential Impacts on Innovation

- Financial Interest vs. Conflict of Interest
- Conflict of Interest vs. Misconduct
- Perception that all relationships with industry are tainted
- Transparency without context
- Multiple public sources of seemingly conflicting data present another layer of “administrative burden”

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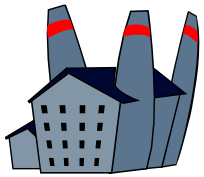
Investigator



Pharmaceutical Company

- $2500 consulting fee paid 8/15/13
- Flies from DC to Chicago for Scientific Advisory Board Meeting 12/15/13, stays one night and is paid $1000
- Second Advisory Board Meeting 2/15/14, paid $1000

- Dr. B reports to her institution no Significant Financial Interest
- Dr. B discloses to journal in March 2014 that she has a paid relationship with Company Rx
- Dr. B gives a presentation in May 2014 and discloses on a slide that she has received $4500 from Company Rx in the previous 12 months
- In September 2014, Dr. B discloses at a conference that she has received $1000 from Company Rx in the previous 12 months
- In September 2014, the “Sunshine” database shows a transfer of value to Dr. B of $5100

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Restoring Confidence in the Pharmaceutical Industry

Howard Bauchner, MD

Phil B. Fontanarosa, MD, MBA

LACK OF TRUST IN THE PHARMACEUTICAL INDUSTRY threatens the future of biomedical research. Although more than half of funded clinical trials in the United States are supported by indust
scientists, clinicians, and other
to advancing biom
of pati
issues
try-analyzed stud-
with leaders of the pharma-
about concerns they have regarding the erosion of trust in their companies. We also have had discussions with academic leaders and leading scientists about ways to improve the reputation of pharmaceutical industry research and have participated in initiatives to harmonize reporting by physicians, investigators, and others who have financial relationships with industry and other conflicts of interest.[2]

The last 2 decades have seen major changes in the pharma-

applications (NDAs) with information published in journal articles found that many clinical trials included in the NDAs were not published 5 years after drug a
been granted.[4] The study also fo
cies between the prim
conclusi
legal marketing
In addition, a recent study
icians devalue the credibility of industry-
ded trials, as compared with the same trials characterized as having National Institutes of Health funding or having no source of support listed, and were less likely to prescribe a drug evaluated in a clinical trial that was supported by industry, even if the study was of high quality.[5]

The pharmaceutical industry is confronted by other challenges. Society has become increasingly risk adverse, and patients are less tolerant of even rare adverse outcomes, which may not be detected even in large-scale randomized clinical trials designed as "efficacy studies," with highly selective populations. But because virtually no drug is entirely safe, rare adverse events are inevitable, and some serious adverse events might not manifest until the drug is used in

"Lack of trust in the pharmaceutical industry threatens the future of biomedical research."

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NDHI Principles Statement on Collaboration for Healthcare Advancement

1. **<u>The benefit of patients</u>:** Collaborations, must aim to benefit patients and put patients' interests first.

2. **<u>The autonomy of healthcare professionals</u>:** Healthcare professionals and scientists must be free to assess independently multiple sources of information and treat each patient in a manner consistent with the patient's needs.

3. **<u>Transparency</u>:** Patients and all those involved in healthcare should have reasonable access to relevant and meaningful information about how academic institutions, researchers, healthcare professionals, and medical products companies engage in collaborative relationships.

4. **<u>Accountability</u>:** All participants across healthcare must be responsible for their actions.

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Creating Safe Havens for Investigator Participation in Translational Research

2012 AAMC Forum on Conflict of Interest in Academe Meeting

March 29, 2012

AAMC COI Metrics Project

- Goal: To measure the impact and outcomes of the new rule on financial conflicts of interest in federally funded research
- Outcomes:
  - Institution-specific benchmarking
  - Aggregate, de-identified data provided to NIH
  - Model for “evidence-based regulation”

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AAMC COI Metrics Project Participating Institutions

Number of Participating Institutions: 76

COI Metrics Project Timeline

Fall 2012	**Registration** **(Basic Institutional Data)**
March 2013	**Historical Information** **(Prior to new rule)**
After August 2013	**First Annual Report** **(1 year post-implementation)**
After August 2014	**Ongoing annual reports** **(After 2nd and 3rd year)**

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Examples of Historical Data

- What did you do to prepare for the new rule?
  - Capital investments
  - Infrastructure changes
  - Personnel additions/changes
  - What was the non-monetary impact of the preparations?
- What did you review/find annually prior to the new rule?
  - How many individuals submitted annual disclosures?
  - How many Significant Financial Interests did you review?
  - How many Financial Conflicts of Interest did you identify and report?

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Examples of Annual Data

- Has any registration information changed?
- What are your ongoing administration costs and personnel needs for the rule?
- In the past annual disclosure cycle:
  - How many individuals submitted annual disclosures?
  - How many Significant Financial Interests did you review?
  - How many Financial Conflicts of Interest did you identify and report?
    - Of these, how many had a value of between $5,000 and $10,000?
    - How many were related to travel?

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AAMC COI Metrics Project

Next Steps

- Early analysis of data from before rule compliance deadline
  - Implementation costs
  - COI Review process and infrastructure
  - Non-financial impact on institutions and faculty

For more information:

www.aamc.org/metricsproject

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