

# **Conflicts of interest: setting the stage**

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# My conflicts of interest

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- Ethics Advisory Committee, Roche

# Outline of talk

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- 1. What is a conflict of interests (COI)?**
- 2. What are the goals of COI policies?**
- 3. What are the unintended adverse consequences of COI policies?**
- 4. How might COI policies be improved?**

# 1. What is a COI?

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# Conflict of Interest in Medical Research, Education, and Practice

[www.nap.edu/catalog.php?record\\_id=12598](http://www.nap.edu/catalog.php?record_id=12598)



# What is a conflict of interest?

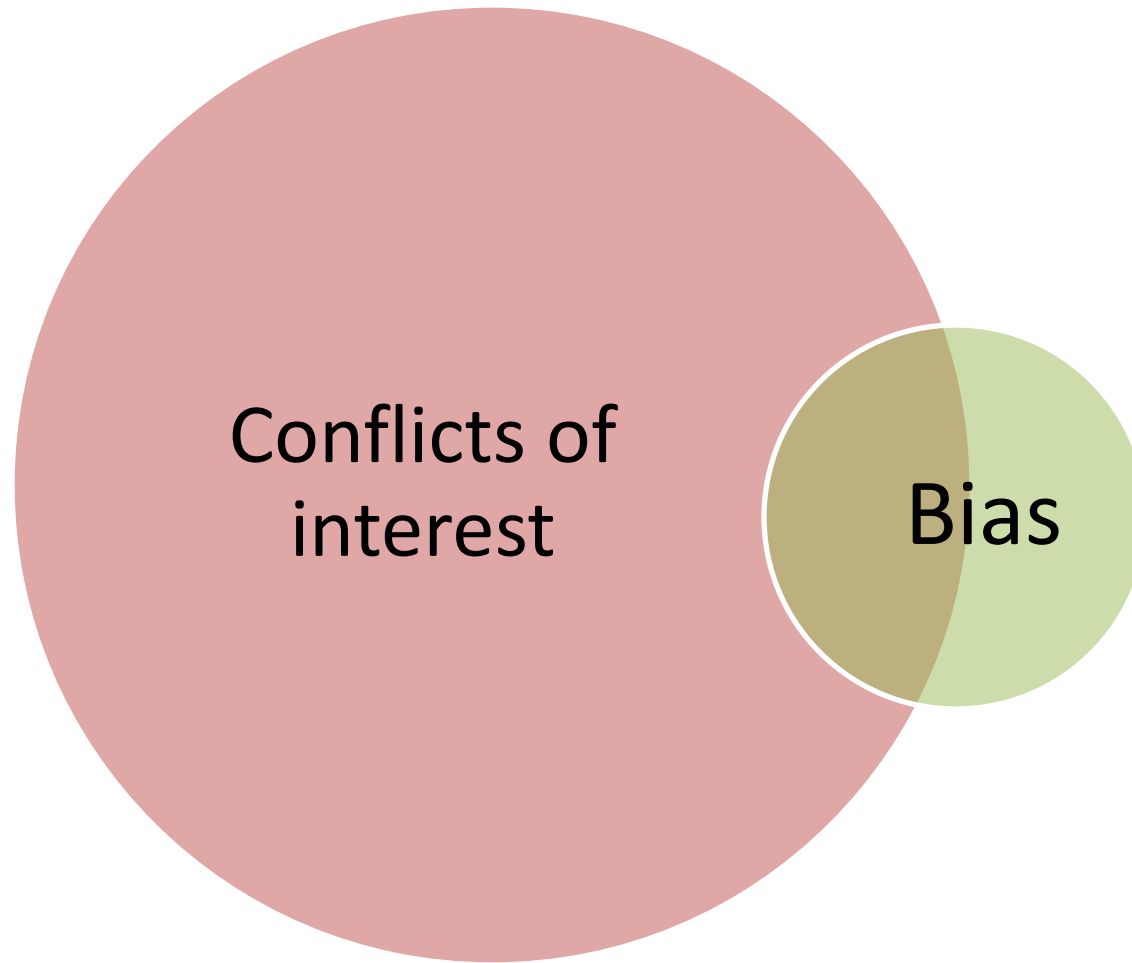
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- **Primary interest**
  - Well-being of patients
  - Integrity of research and education
- **Secondary personal interests**
  - Financial gain
  - Professional, intellectual commitment

# What is a conflict of interest?

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- **Unacceptable risk** that primary interest **unduly** influenced by secondary interest
- **Conclusions may be biased**





# Limitations of term “conflict of interests”

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- **Inference of misbehavior**
  - ‘Academic-industry relationships more neutral
- **“Potential” and “perceived” may not be helpful**

## 2. What are the goals of COI policies?

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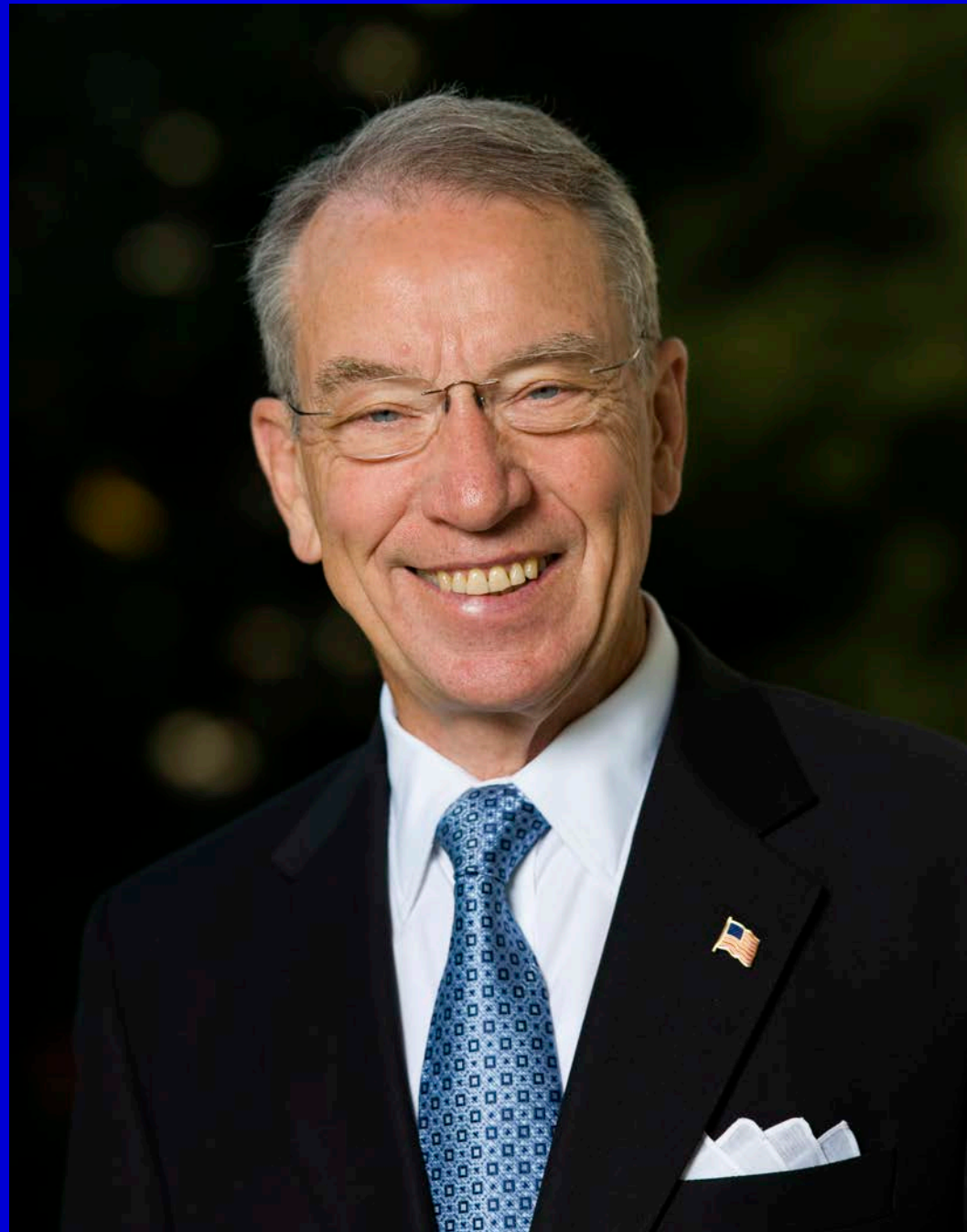
- **Identify relationships that raise significant concerns about undue influence**
  - Cases in which bias led to significant harm to patients











## 2. What are the goals of COI policies?

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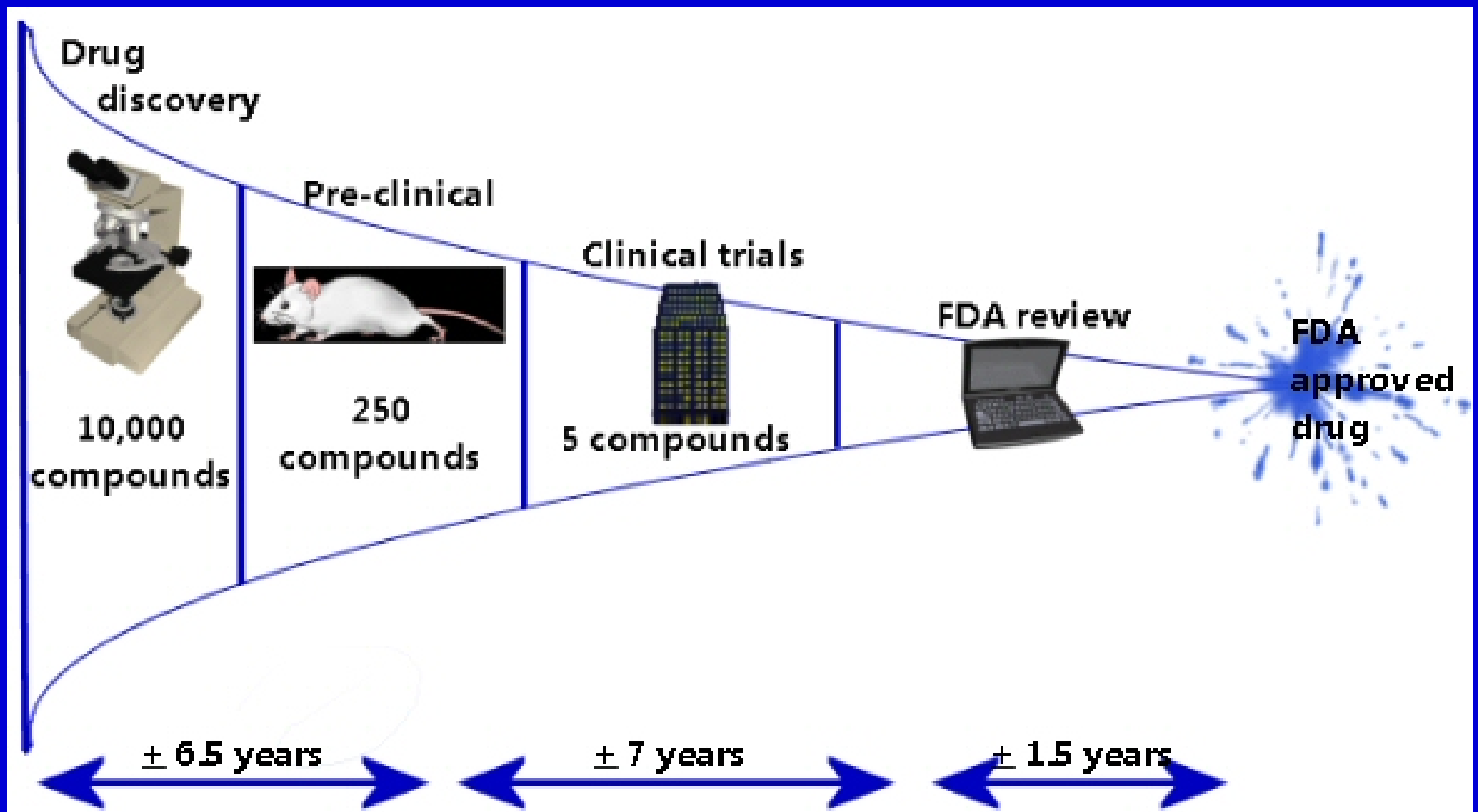
- **Identify relationships that raise significant concerns about undue influence and bias**
  - Cannot assess or manage unless disclosed
  - Seek to prevent undue influence, not react to bias after it occurs



## 2. What are the goals of COI policies?

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- **Not discourage relationships that foster desirable aims**
  - New therapies for patients



# What are the assumptions underlying COI policies?

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**More disclosure = transparency**

# What are the assumptions underlying COI policies?

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**More disclosure = transparency**



**Less undue influence and bias**

**Greater accountability + trust**

### **3. What are the unintended adverse consequences of COI policies?**

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# Unintended adverse consequences

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- **Inconsistent disclosures**
  - Multiple disclosures
    - Grant, abstract or manuscript, CME talk, committee
    - Many accessible to public
  - Trigger suspicion, allegations
    - But disclosure requirements inconsistent
  - Proposals for standard format

# Unintended adverse consequences

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- Undue administrative burdens and opportunity costs
- Deter desirable academia-industry collaborations

## 4. How can COI policies be improved?

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# Criticisms of COI policies

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- **Responses out of proportion to problems**
  - Overreaction to egregious cases
- **Undue burdens on MDs and institutions**
- **Undermine goals of research**

# Criticisms of COI policies

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- Weak and inconsistent
- Not enforced

# Evaluation of COI policies

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- **Need empirical research to base COI policies on evidence, not assertions or conjecture**
  - Effective in achieving goals?
  - Unintended adverse consequences?
  - Administrative and opportunity costs?

# Take home message

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- **COI policies must balance countervailing goals, values, interests**
  - Professional standards may have advantages over regulations





