

Assuring Integrity while Facilitating Innovation in Medical Research

IMPACT OF CONFLICT OF INTEREST POLICIES ON INNOVATION

June 5, 2013



IOM Proposed Questions

- **What is the industry perspective on the impact of COI policies on medical innovation? Has the relationship between industry and academia changed because of COI policies?**
- **Have institutions and investigators been impacted by COI policies? Has there been an impact on publicly funded research (e.g. CTSA's)?**
- **What are the drivers of success to spark development and commercialization of needed medical products? Have COI policies been a help or a hindrance to success?**

Background and Study Objectives

Background

- The desire to preserve public's trust in the credibility and transparency of biomedical research has prompted many public and private institutions to adopt more restricted conflict of interest (COI) regulations.
- There is significant concern that tightening of COI policies across and within many institutions (*e.g. academia, government, industry*) could be impeding access to and sharing of crucial scientific and clinical research knowledge

Study Objectives

- Map the different stakeholders impacted by COI policy restrictions
- Collect expert views on what constitutes a COI
- Understand how tightened regulations on COI have impacted stakeholder's work, with a particular focus on the ability to get access to and/or share scientific knowledge.

Project primarily focused on evaluating the impact of COI on three main aspects of Research & Development



Examples

- All receiving PHS funding must disclose financial relationships
- Research collaborations between researchers, industry, and government (NIH) governed by policies
- Trial PIs required to disclose relationships
- FDA committees for drug evaluations must disclose financial relationships
- Companies required to report all gifts to physicians, including samples

Those Impacted

- Academic and Research Institutions
- Government: NIH Research
- Industry: Basic Research/Drug Discovery
- Industry: Drug Development
- Physicians/Trial PIs
- FDA
- Physicians/Experts on FDA Panels
- Industry: Drug Approval
- Advocacy Groups: Pushing for unbiased but quick evaluations
- Industry: Drug Success
- Physicians/Medical Centers Prescribing Therapies
- Physicians writing Treatment Guidelines

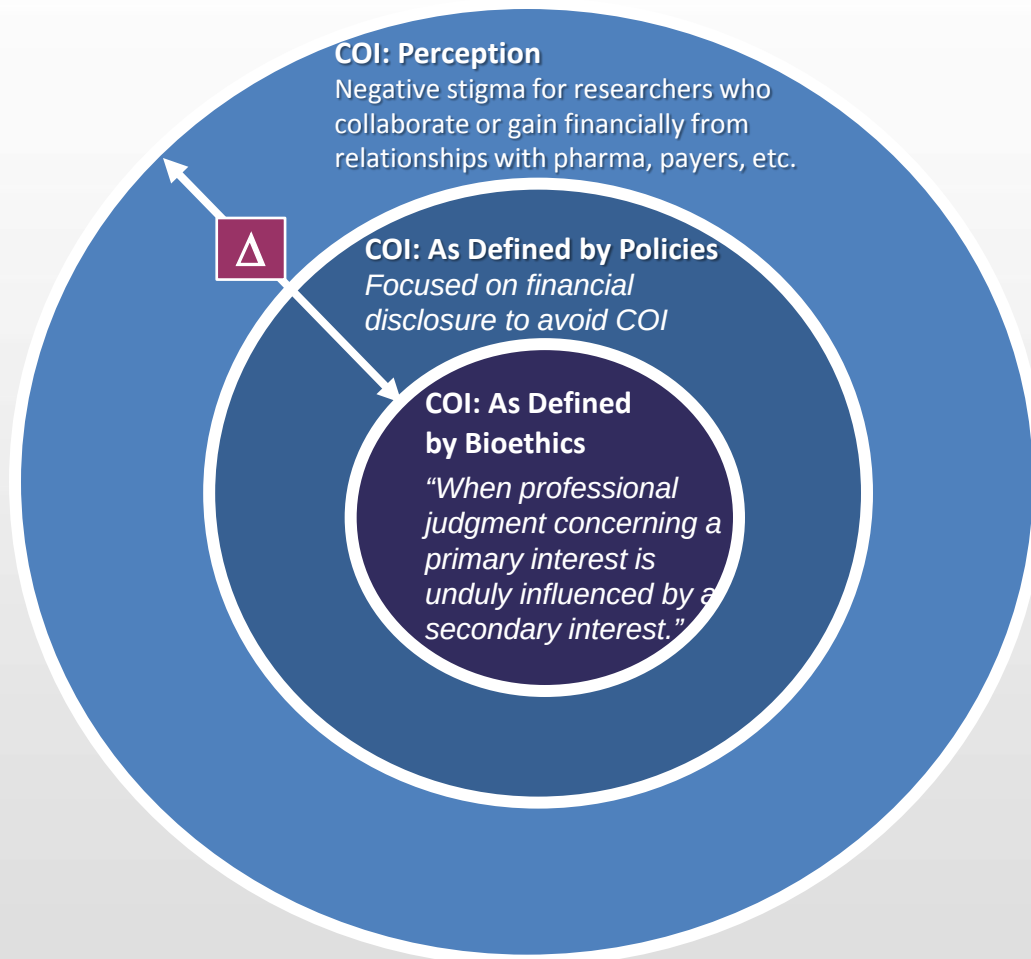
Project Design

Interviews with stakeholders (n=25-30) representing a broad range of institutions



Conflict of Interest: Definition

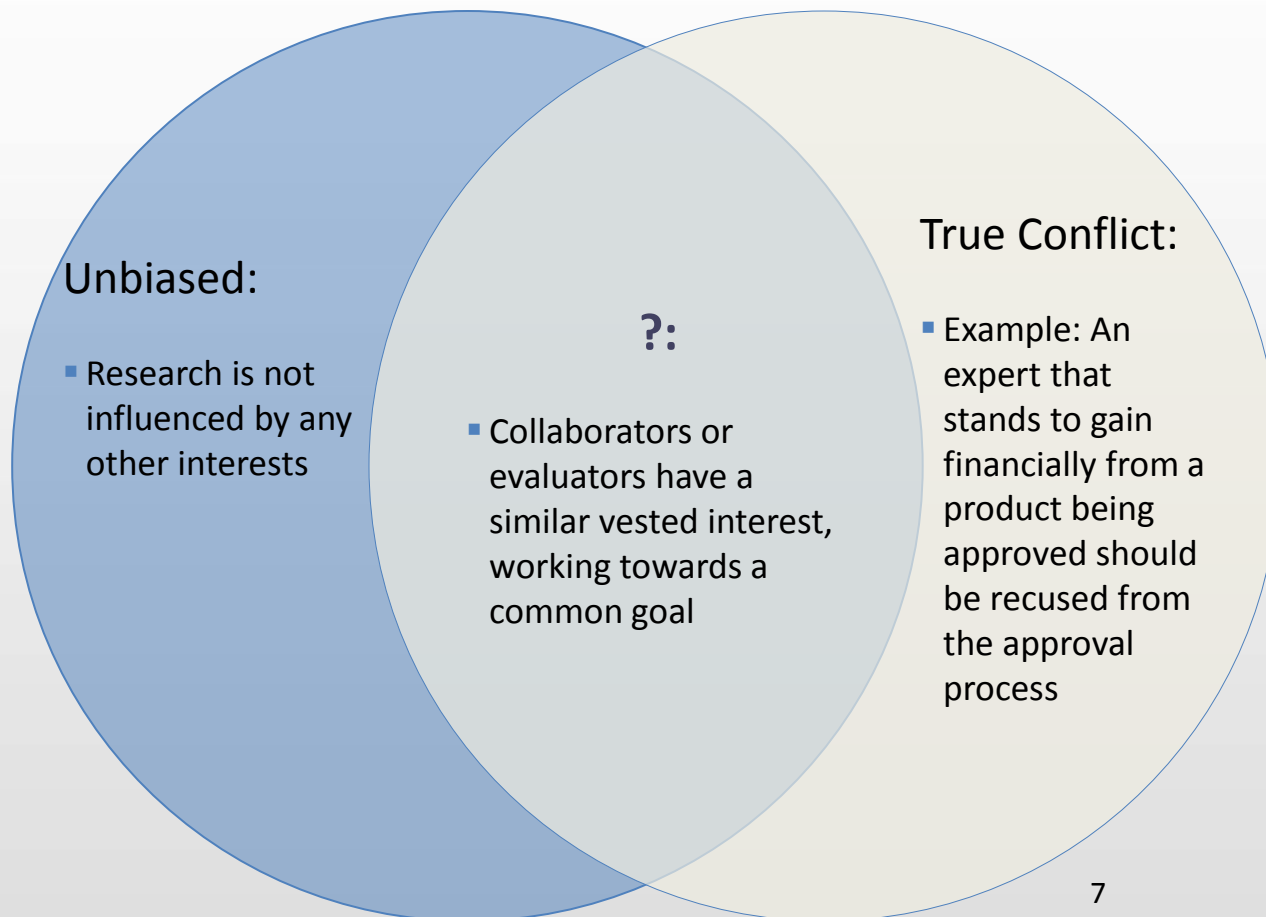
While the term COI means the presence of improperly influenced judgment, more frequently it refers to a perceived COI due to a financial relationship with industry



- In order to avoid a true COI, stakeholders require disclosure of relationships that could influence judgment or the integrity of research
- Since financial relationships are the most straightforward to quantify and track, the most focus is on financial relationships
- As a result, in many cases a definite assumed conflict is attached to research or collaborations with pharma, payers, or others that result in financial gain

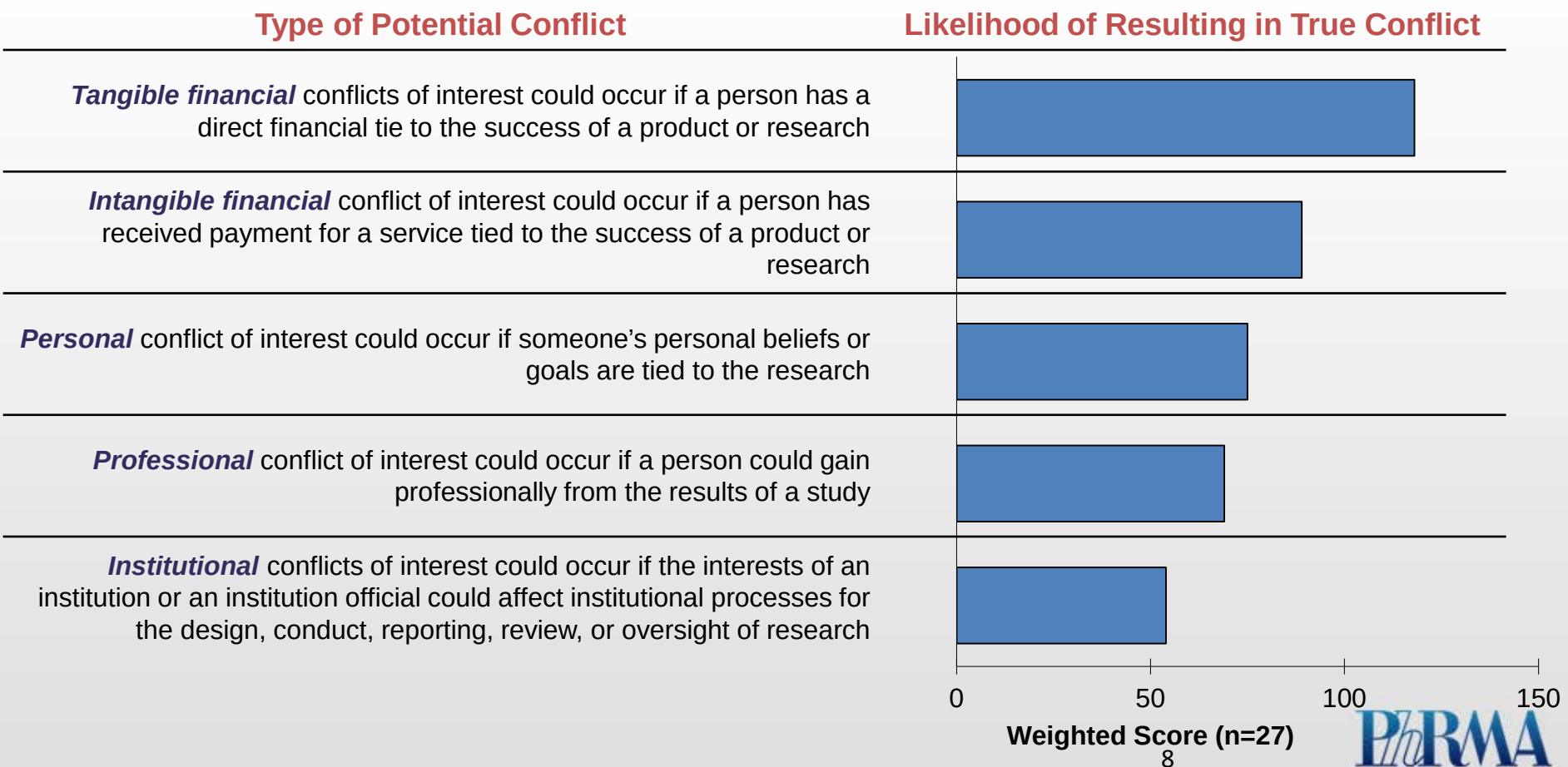
Conflict of Interest: Spectrum

Full disclosure of financial relationships is important to avoid future conflicts. The difficulty lies in then determining when a true conflict is present vs. a perceived conflict.



Types of Conflict

Policies are largely focused on financial relationships due to the ease of tracking them and because they are thought to be the most likely relationship to result in a true COI.



Relationships of Key Stakeholders

Influencers impact the COI policies of the stakeholders responsible for maintaining research and treatment integrity. The impact of these policies on patients remains a key question.

Policy Makers



Government
(Congress, HHS)

Influencers



Media



Professional Medical
Associations (*Institution
Specific*)



Advocacy Groups

Key Stakeholders Responsible for Enacting COI Policies



Academic/Research/
Medical Centers



Physicians and
Researchers



Industry



Government
(FDA, NIH)



Professional Medical
Associations (*Physician
or Disease Specific*)



Patients

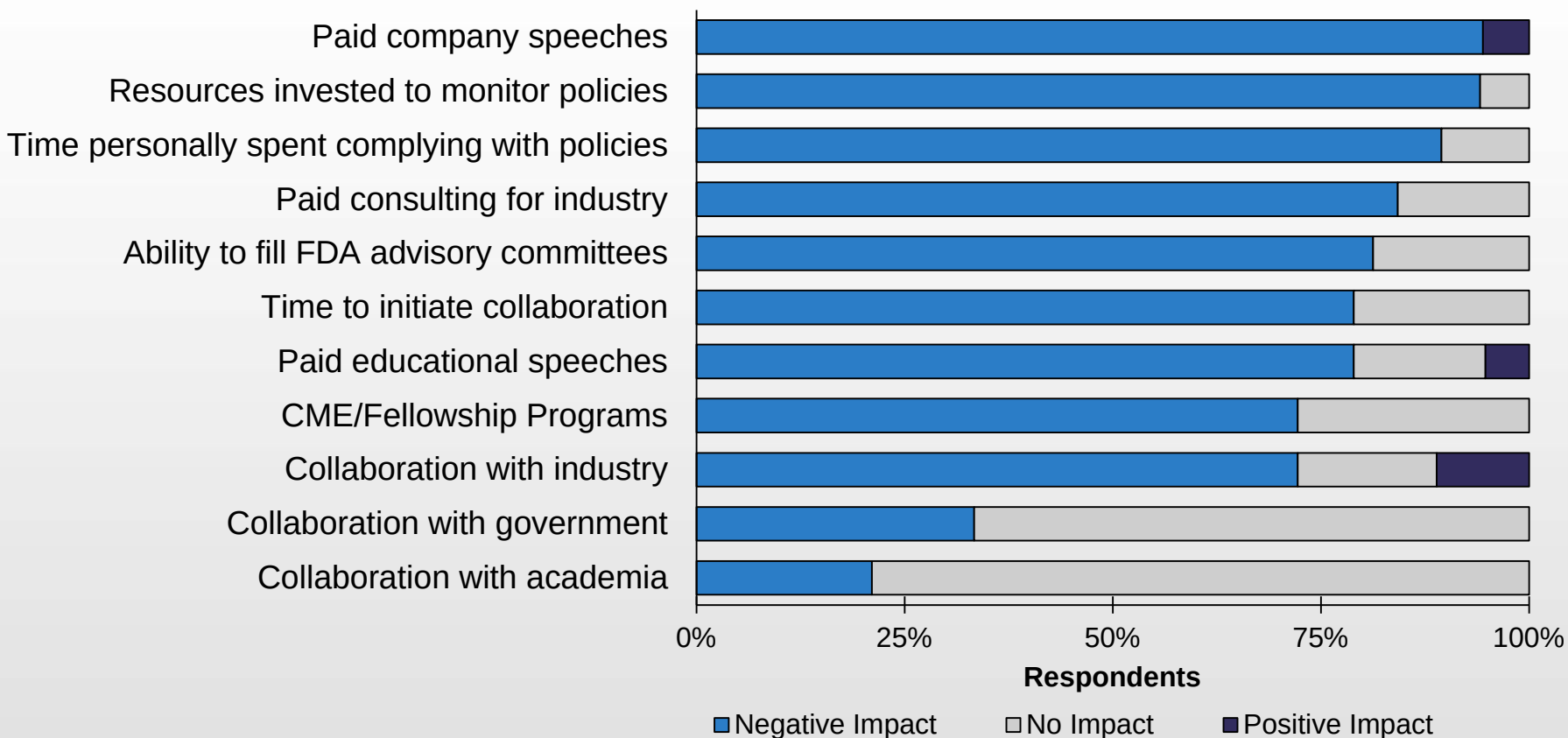
Effects of COI Policies/Perceptions

Key Effects of COI Policies/ Perceptions	Description
 Impaired Collaboration	▪ Decreased ability for experts to collaborate on research through studies, consulting, etc., particularly with industry
 Increased Resource Burden	▪ More resources/time required to be compliant with COI policies and monitor COI disclosures
 Limited FDA Access to Best Experts	▪ Inability of FDA to fill advisory committees with best expertise
 Decreased Physician Education	▪ Less funding, fewer events and less expertise for CME and physician education
 Decreased Communication	▪ Company-sponsored talks, physician talks on behalf of companies

Impact of COI on Academic Research Activities

Impact of COI Policies

n = 16-19 academic researchers*



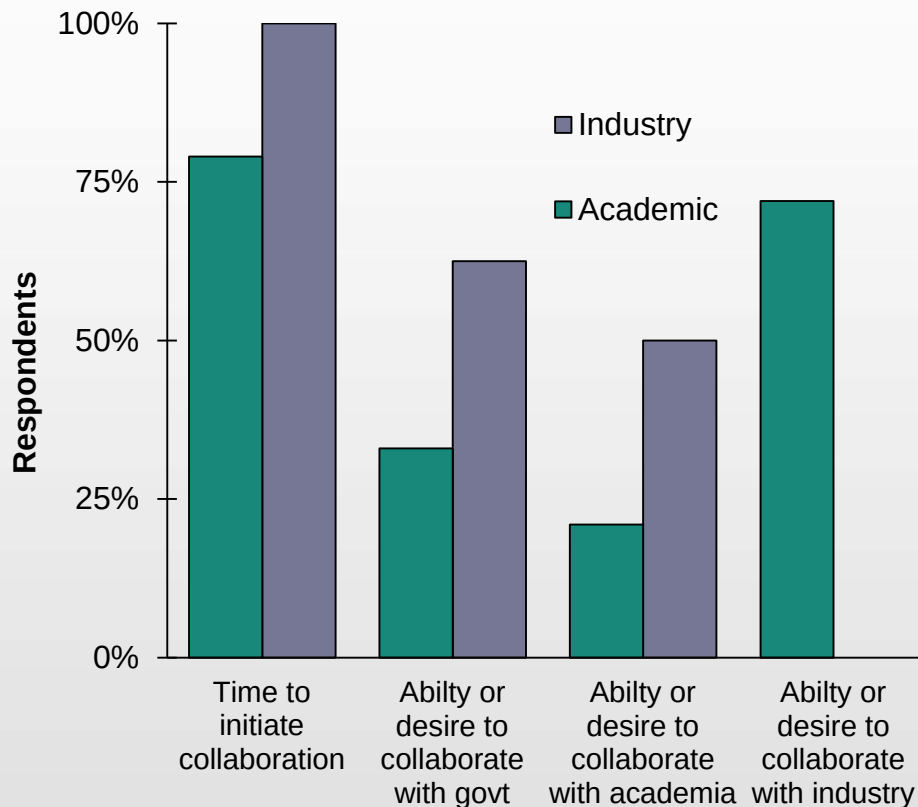
* Respondents were able to select "Don't know" for each factor, so ns vary from 16-19 for each bar.

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Impact of COI on Industry Research Activities

Impact of COI Policies

n = 8 industry researchers, n = 18-19* academic researchers*



Feedback

- *"The number of potential collaborations with industry are reduced. My research productivity is therefore reduced." – Academic Researcher*
- *"[Policies] have made it very difficult for companies to work with academic investigators who are prescribers, even if the work is entirely nonclinical." – Industry Researcher*
- *"The perception of conflict of interest makes working and collaborating with industry incredibly difficult." – Government Researcher*

* Respondents were able to select "Don't know" for each factor, so N's vary for each bar.

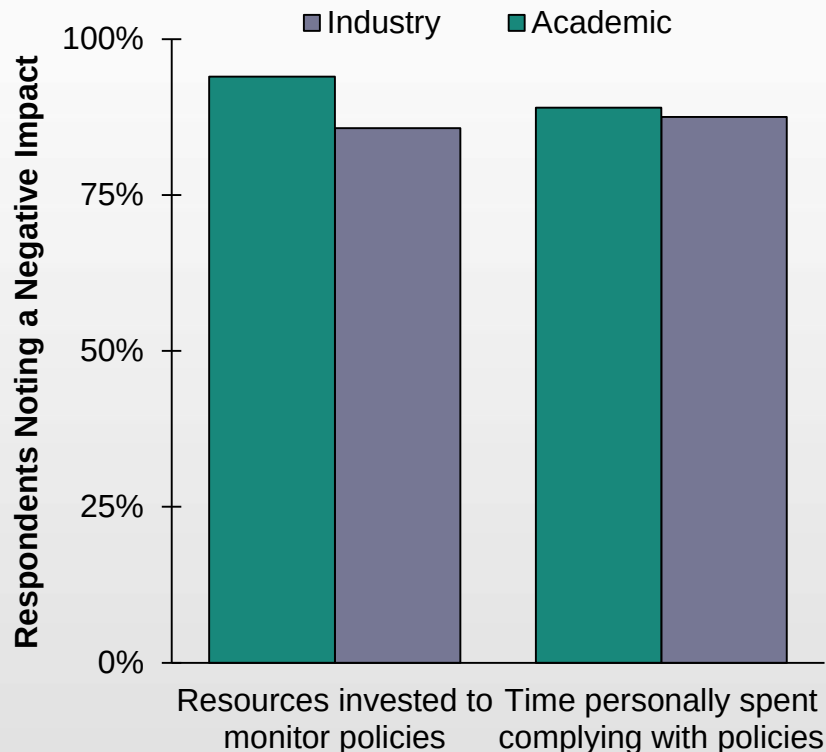
Question: Q18 In your opinion, in the past 1-3 years, have conflict of interest policies and rules had an impact on any of the following? Q22 In your opinion, in the past 1-3 years, has fear of being perceived as having a potential conflict of interest had an impact on any of the following?

Source: Health Advances survey and analysis.

Impact: Resource Burden by Stakeholder

Impact of COI Policies

n = 7-8 industry researchers, n = 17-19* academic researchers*



* Respondents were able to select "Don't know" for each factor, so N's vary from 7-17 for each bar.

Question: Q18 In your opinion, in the past 1-3 years, have conflict of interest policies and rules had an impact on any of the following? Q22 In your opinion, in the past 1-3 years, has fear of being perceived as having a potential conflict of interest had an impact on any of the following?

Source: Health Advances survey and analysis.

Industry

- “The **increase in resources and money required** to enact these policies is probably more than before because of greater technology required and more complex policies – for instance it **used to take about 3 months for a company to set up a policy or compliance program, now it can take up to a year.**” — Legal Expert

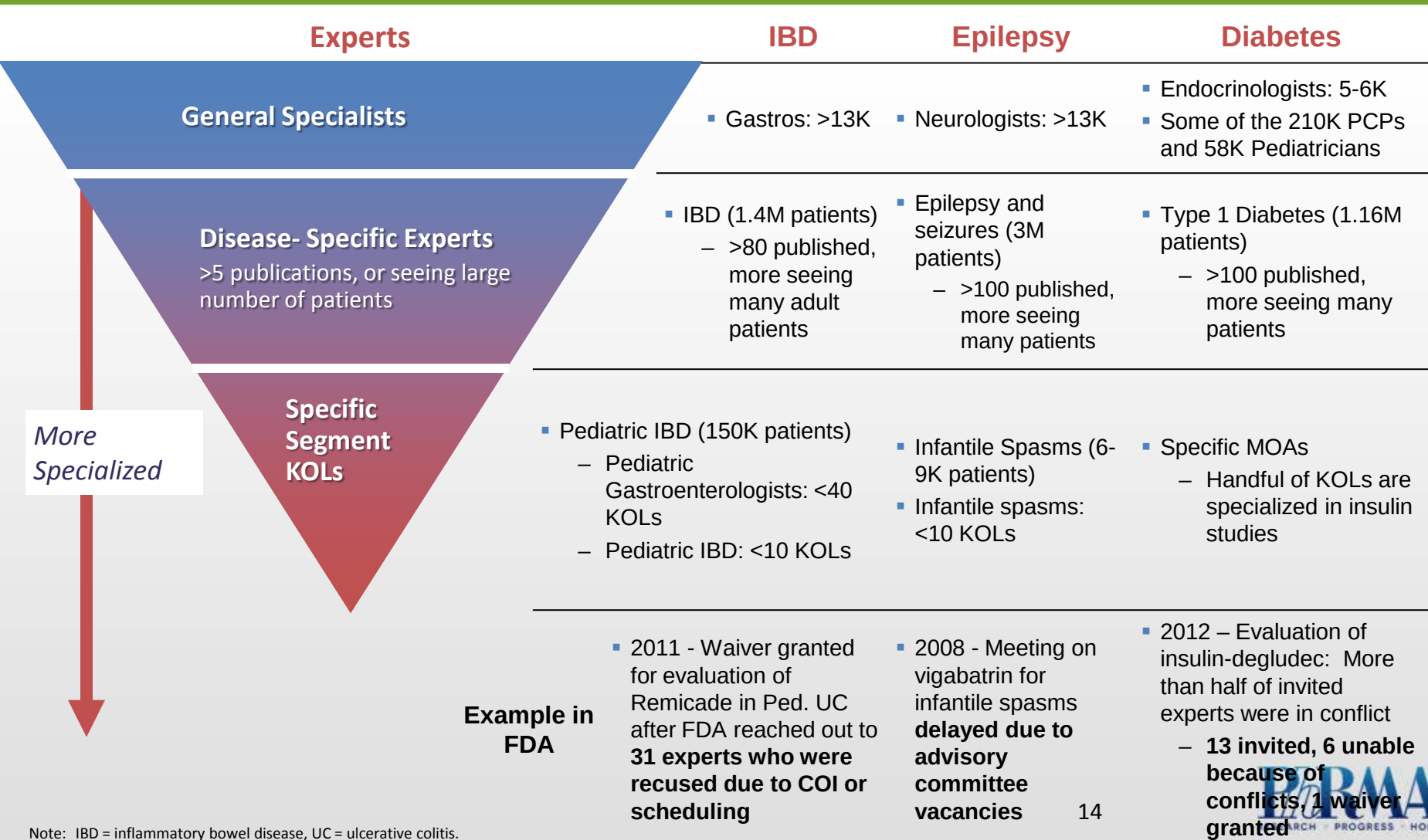
Academia

- “We recognize that there are **burdens on investigators**, some of which are measurable, some of which are not quantifiable but are certainly well known to the institution.” – AAMC
- “Conflict of interest policies do **dramatically increase the additional regulatory burden for institutions and individuals and add to costs** because more administrators are needed and more time is lost complying with the policies.” – Academic Researcher

Government

- “It’s created a new industry of full time COI ethics people, a specialty that **costs an enormous amount of money and slows everything down**, and then there are also the people who are on the committees that review everything and that **takes their time away from their primary duties.**” – Government Researcher

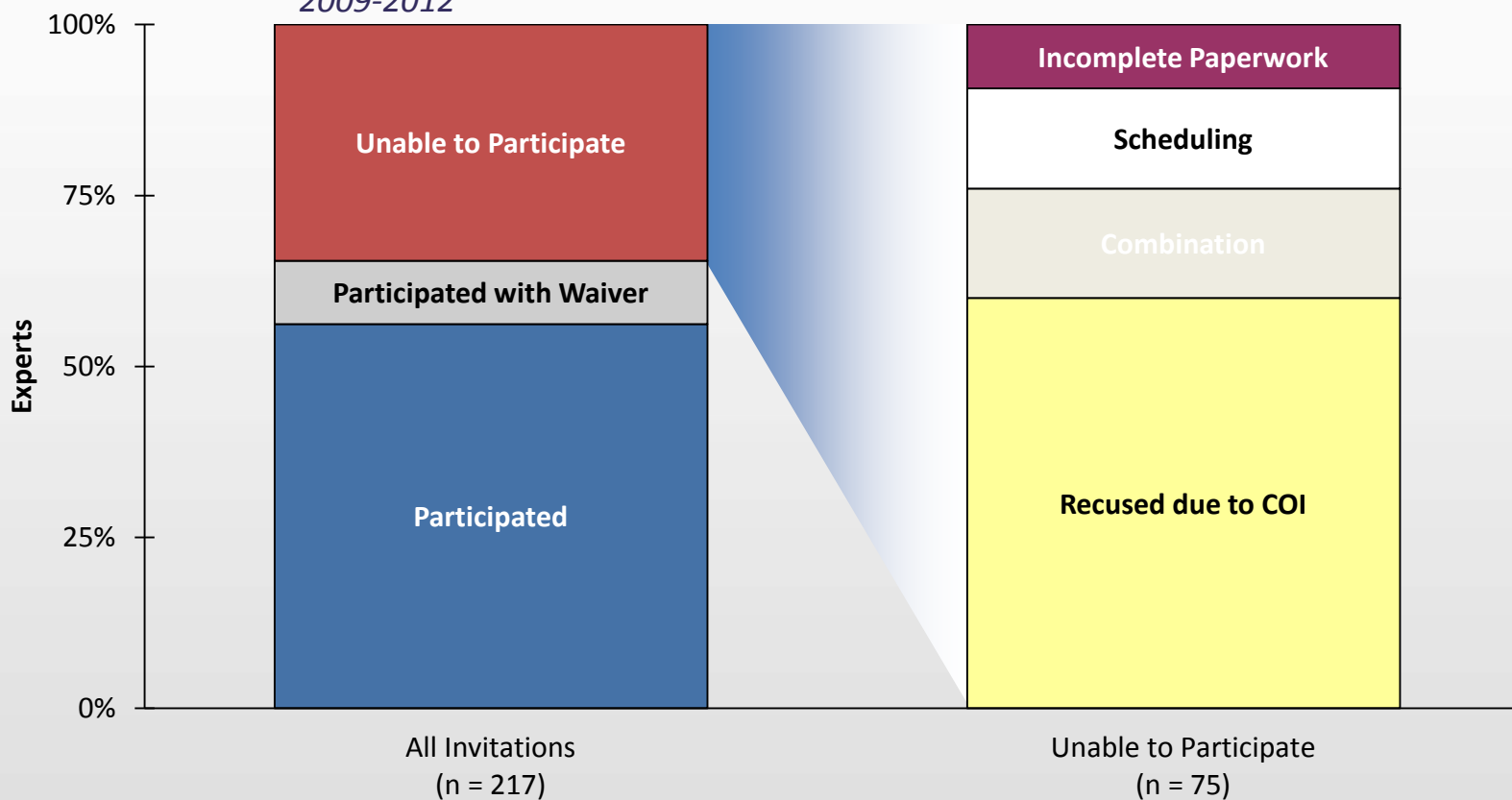
FDA Committees: Experts



Reasons for Advisory Committee Declines

Outcome of Invitations to Serve on FDA Advisory Committees Where Waivers Were Granted

2009-2012



Note: The combination outcomes are an unspecified combination of COI, scheduling, and/or paperwork.
Source: Health Advances interviews and analysis, FDA website.

FDA Committee: Factors Impacting Recruitment

The low recruitment of FDA panels is due to a variety of factors

Potential Reasons for Low Recruitment on FDA Panels

Policy

- Current guidelines are too strict on what constitutes a COI
- Experts are either not allowed to participate or not even invited

Perception

- After all the negative publicity, people are afraid of being perceived as having a COI and electing not to serve

Not COI

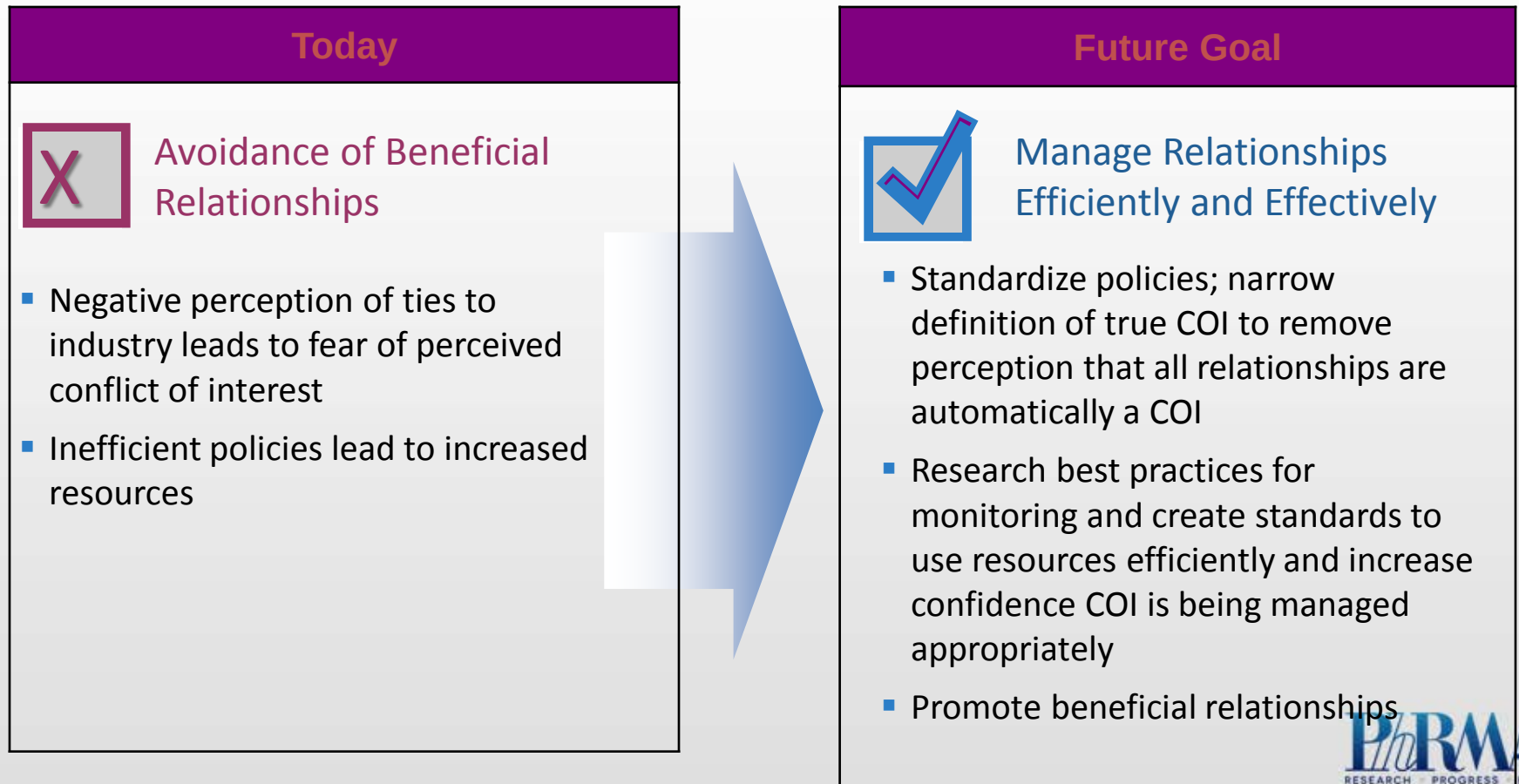
- Vacancies are unrelated to COI policy, and instead related to resources or expert availability

Executive Summary

- While the actual term “*conflict of interest*” means the presence of improperly influenced judgment, more frequently it refers to a ***perceived*** COI due to a financial relationship with the industry.
- Extreme instances of true COI have sparked attention and led to negative perceptions of industry relations and stricter policies which have increased fear of perceived COI and burden of compliance. Specifically, our research found that COI policy restriction has led to:
 - **Impaired Collaboration**
 - **Increased Resource Burden**
 - **Limited FDA Access to Best Experts**
 - **Decreased Physician Education**
 - **Decreased Promotional Relationships**

Future Approach to Handling COI

Currently, COI is largely handled through avoidance. There is an opportunity to manage COI and promote shared access to scientific knowledge without concerns of conflict.



Q&A