



# ACCME at the International Pharmaceutical Compliance Summit

Philadelphia  
March 2005



**Murray Kopelow, MD, MSC, FRCPC**

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# Disclosures

**No financial  
relationships with any  
commercial interests**

## ACCME's Mission

...the identification, development, and promotion of standards for quality continuing medical education utilized by physicians in their maintenance of competence...

## ACCME's Responsibility

...to assure physicians, the public, and the CME community that CME programs meet the ACCME's criteria for compliance with the Essential Areas.

1982

# Continuing Professional Development

Achieving Licensure

Maintenance of Licensure ( Requirements by members of **FSMB** )

Achieving Certification

Maintenance of Certification(Requirements by members of **ABMS**)

## Under Graduate

Medical  
Education  
(Accreditation  
by **LCME**)

## Graduate

Medical  
Education  
(Accreditation  
by **ACGME**)

## Continuing Medical Education

- Provider accreditation by **ACCME**;
- Activity Accreditation by **AAFP**
- Credit systems by membership organizations (ex: **AMA**, **AAFP**)

Medical  
Student

Resident

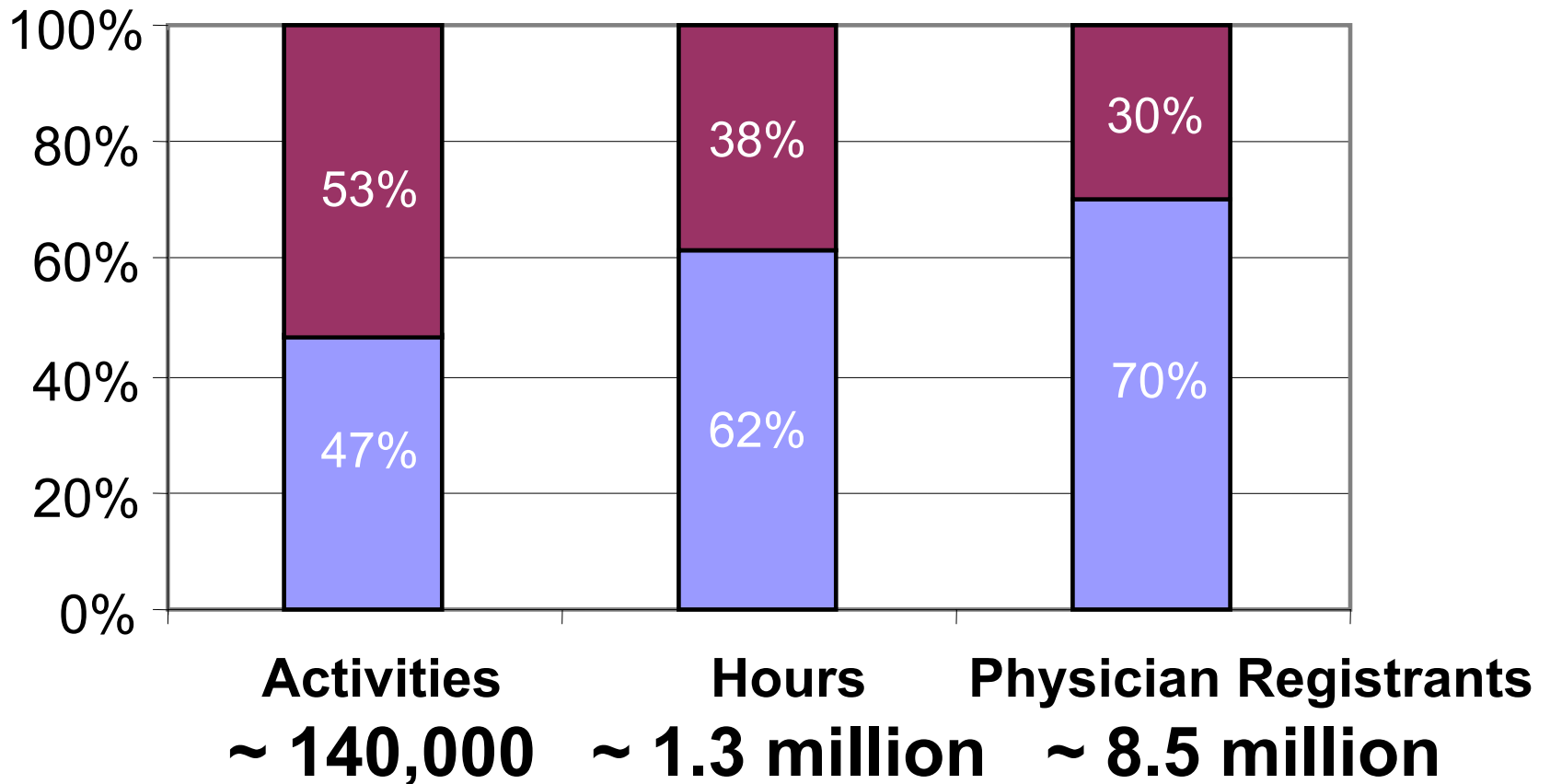
Licensed


Specialist

Credentialed

Practice

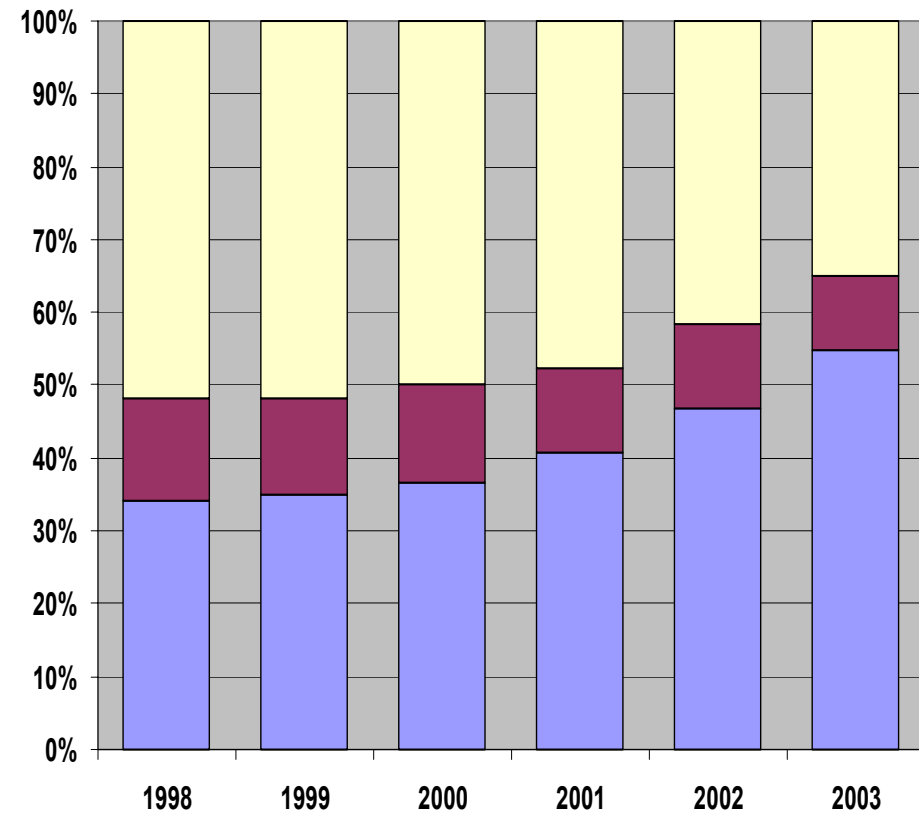
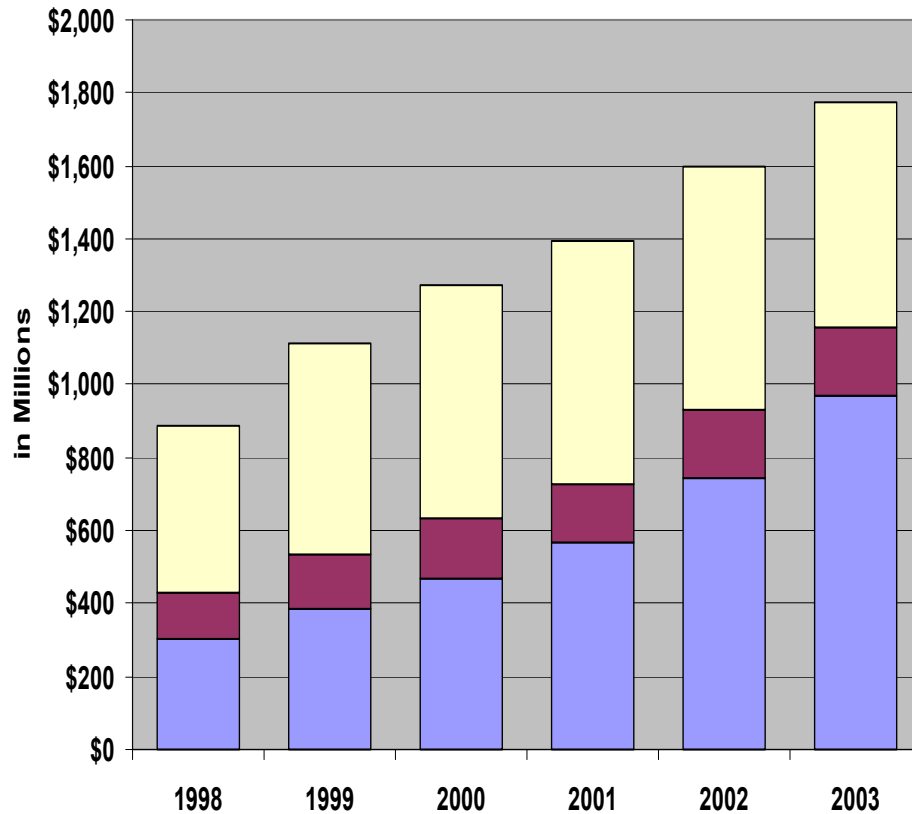
# Size of Enterprise - 2003



 ACCME  
Accredited

 State Medical  
Society Accredited

# Funding of CME



 **Commercial Support**

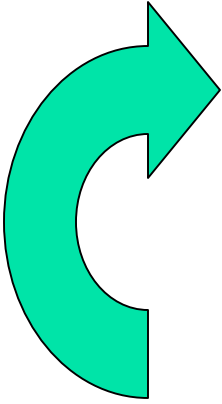
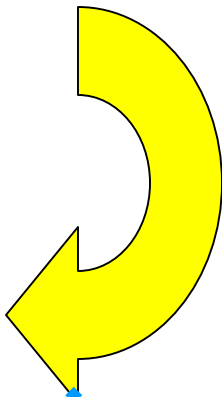
 **Advertising & Exhibits**

 **Other Income**

#1

Quality and Safety as  
an **OUTCOME**

**‘Mission critical’ that CME be...**

- 
- 
- Linked to quality and safety
  - Effective in improving practice
  - Based on valid content
  - Independent of commercial interests

Quality and Safety as  
a **NEED**

# **‘Mission critical’ that CME be...**

## **Linked to quality and safety**

- **Effective in improving practice**
- Based on valid content
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# **‘Mission critical’ that CME be...**

## **Linked to quality and safety**

- **Effective in improving practice**
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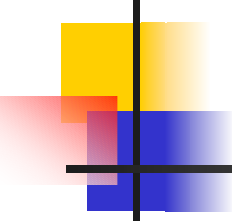
# The literature is clear...

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Continuing education is effective  
in assisting professionals to  
modify and improve their practice

Umble and Cervero, 1996

Robertson Umble Cervero 2003



Our challenge is  
to overcome...

- Overuse
- Under use
- Misuse

...in clinical care

Grol, JAMA, 286,20,2001

Via interventions  
that are ...

- Predisposing  
(Prepare for change)
- Enabling  
(Link new to what learner  
already doing, in practice)
- Reinforcing  
(Via reminders and feedback)

Cantillon and Jones, BMJ, 318:127, 1999

# **‘Mission critical’ that CME be...**

## **Linked to quality and safety**

- Effective in improving practice
- **Based on valid content**
- Independent of commercial interests



# Validity of CME

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## **Content Validity**

- True
- New or Important
- Free of commercial bias

## **Credibility or Face Validity**

- Credentials
- Independent
- Transparency



2002  
ACCME Action

# Validation of the Clinical Content of CME

## Content & Quality

All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

## Scientific Integrity

All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

# **‘Mission critical’ that CME be...**

## **Linked to quality and safety**

- Effective in improving practice
- Based on valid content
- **Independent of commercial interests**

***Standards for Commercial Support*** are a key part of ACCME's overall strategy to ensure validity of CME...

## **Content Validity**

- True
- New or Important
- Free of commercial bias

## **Credibility or Face Validity**

- Credentials
- Independent
- Transparency





FDA  
Draft #1 and #2

ACCME  
Guidelines on  
Commercial Support  
of CME

Congressional  
Hearings

CEJA x 2

TF

**ACCME STANDARDS for  
COMMERCIAL SUPPORT of  
CME**

Subpoenas

1/87

1/88

1/89

1/90

1/91

1/92

1/93

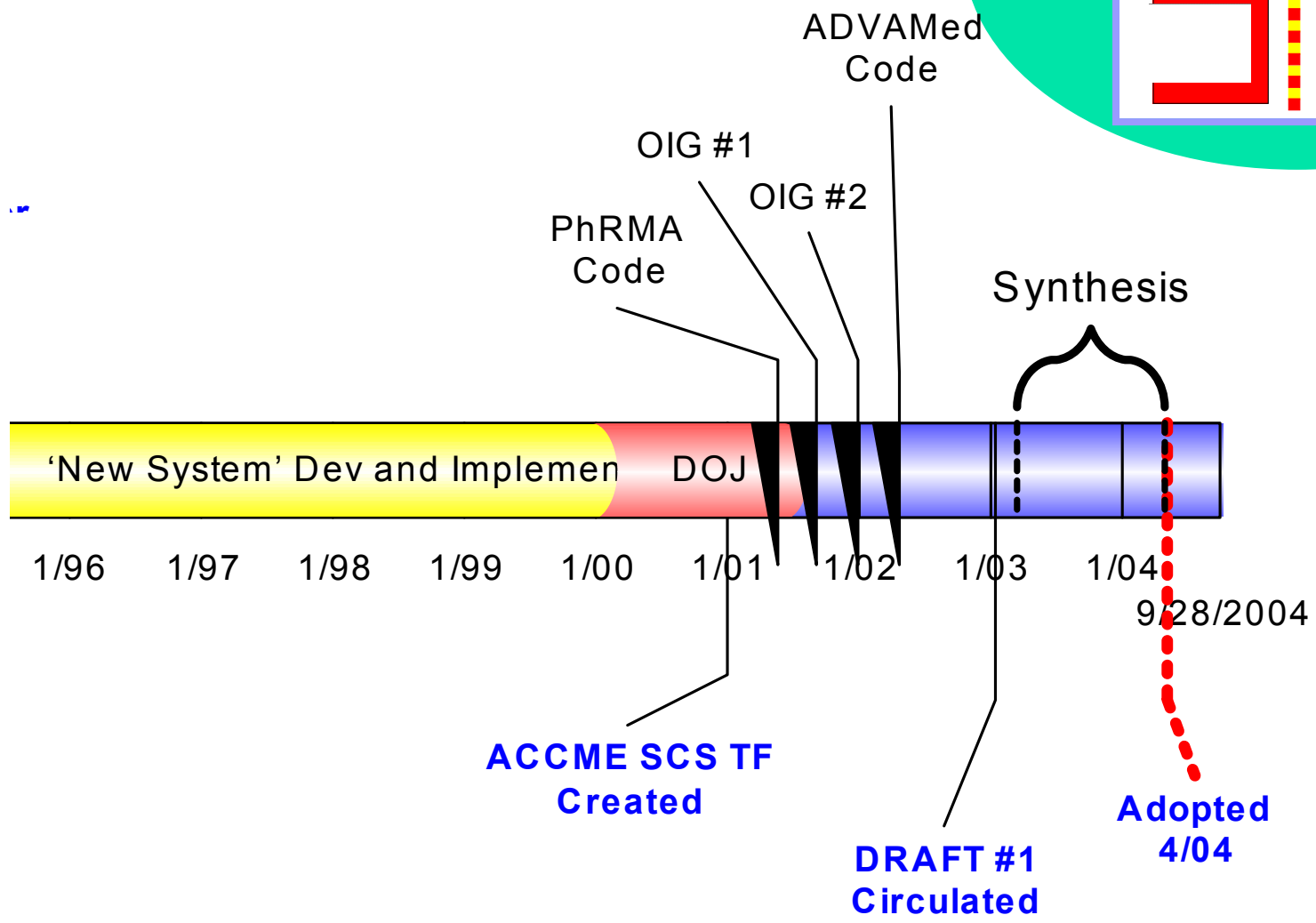
1/94

1/95

1/1/1986

Adopted by all  
SMS Accreditors  
AAFP  
AOA

# “Second wave...”



“ In my view, the ACCME 2004 Updated Standards for Commercial Support were necessary to remind CME providers and commercial supporters alike, that **CME is to enhance physicians' ability to care for patients** and that accredited providers have sole responsibility / accountability for certifying that CME is independent from commercial interests.”

Fred Wilson  
Category Manager CME  
P&G Pharmaceuticals  
October 30, 2004

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Fred Wilson  
Category Manager CME  
P&G Pharmaceuticals  
October 30, 2004

## The Standards

Standards to En

New

### STANDARD 1: Independence

**1.1** A CME provider must ensure that the decisions were made free of the commercial interest. The ACCME defines "commercial interest" as any proprietary producing health care goods or services, the exemption of non-profit or government organizations and non-health care companies.

New

tion of CME needs; identification of educational objectives and presentation of content; of all persons and organizations that will be in a position to control content of the CME;

(e) Selection of educational methods; of the activity.

New

cial interest cannot take the ed partner in a joint sponsorship.

### STANDARD 2: Resolution of Personal Interest

New

vider must be able to show no is in a position to control education activity has disclosed relevant financial relationships with commercial interest to the provider. ACCME defines "relevant" as financial relationships occurring within the past 12 conflict of interest.

New

ual who refuses to disclose financial relationships will be disqualified being a planning committee member, teacher, or an author of CME, and cannot control of, or responsibility for management, presentation of the CME activity.

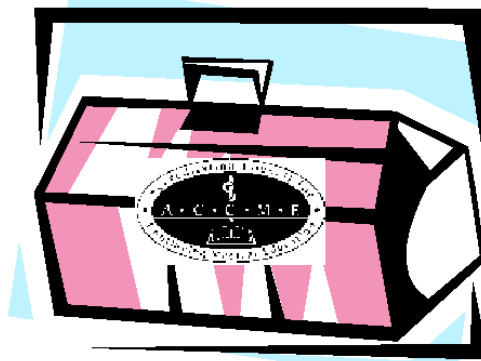
New

vider must have implemented to identify and resolve all of interest prior to the education activity delivered to learners.

### STANDARD 3: Appropriate Use of Commercial Support

**3.1** The provider must make all decisions regarding the disposition and disbursement of commercial support.

**3.2** A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other



# TOOLS TO SUPPORT IMPLEMENTATION OF ACCME'S UPDATED STANDARDS FOR COMMERCIAL SUPPORT

(ADOPTED SEPTEMBER 2004)

a product-group message.

**4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

provider cannot use a commercial interest as agent providing a CME activity to learners, distribution of self-study CME activities or arranging for electronic access to CME activities.

### STANDARD 5. Content and Format without Commercial Bias

the content or format of a CME activity or its materials must promote improvements in quality in healthcare and not a specific proprietary business interest of a commercial interest.

**5.2** Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

### STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

**6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

**6.2** For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

**6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

**6.4** 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

**6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.

# Standard 1: Independence



CME decisions  
free of the control  
of commercial  
interest











Commercial  
interest is not joint  
sponsor








- Identification of CME needs;
- Determination of educational objectives;
- Selection and presentation of content;
- Selection of all persons and organizations that will be in a position to control the content of the CME;
- Selection of educational methods;
- Evaluation of the activity.

# The Standards for Commercial Support

## Standards to Ensure Independence in CME Activities

...a checklist

<b>STANDARD 1: Independence</b>	
	A CME provider must ensure that the following decisions were made free of the control of a commercial interest. ...
<b>STANDARD 2: Resolution of Personal Conflicts of Interest</b>	
	The provider must be able to show that everyone who is in a position to control ...
	An individual who refuses to disclose .. will be disqualified ...
	The provider must have implemented a mechanism to identify and resolve ...
<b>STANDARD 3: Appropriate Use of Commercial Support</b>	
	Written agreement documenting terms of support
	Expenditures for an individual providing CME
	Expenditures for learners
	Accountability

<b>STANDARD 4. Appropriate Management of Associated Commercial Promotion</b>	
	Arrangements for commercial exhibits or advertisements ...
	A provider cannot use a commercial interest as the agent providing a CME activity to learners...
<b>STANDARD 5. Content and Format without Commercial Bias</b>	
	The content or format of a CME activity ... must promote improvements or quality in healthcare ...
	Presentations must give a balanced view of therapeutic options. ...
<b>STANDARD 6. Disclosures Relevant to Potential Commercial Bias</b>	
	Relevant financial relationships of those with control over CME content
	Commercial support for the CME activity.
	Timing of disclosure

“ Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements.”

DEPARTMENT OF HEALTH AND HUMAN SERVICES

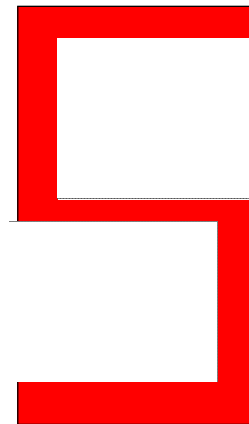
Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

Federal Register / Vol. 68, No. 86 / Monday, May 5, 2003

## Independence

Industry's



Profession's








# Standard 2: Resolution of Personal COI

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- Everyone discloses to Provider


 Continue with persons who disclose

 Implement a mechanism\*\*  
i.e. Manage COI by inserting safeguards  
against bias.



## Standard 1: Independence




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-  CME decisions free of the control of commercial interest
-  Commercial interest is not joint sponsor



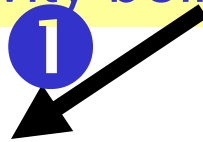
## Standard 2: Resolution of Personal COI

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-  Everyone discloses to Provider
-  Continue with persons who disclose
-  Implement a mechanism\*\*  
i.e. Manage COI by inserting safeguards against bias.

## STANDARD 2: Resolution of Personal Conflicts of interest

The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.



The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both

- A financial relationship with a commercial interest and
- The opportunity to affect the content of CME about the products or services of that commercial interest.

How do these circumstances create a conflict of interest?

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

## STANDARD 2: Resolution of Personal Conflicts of interest

The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

1

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both

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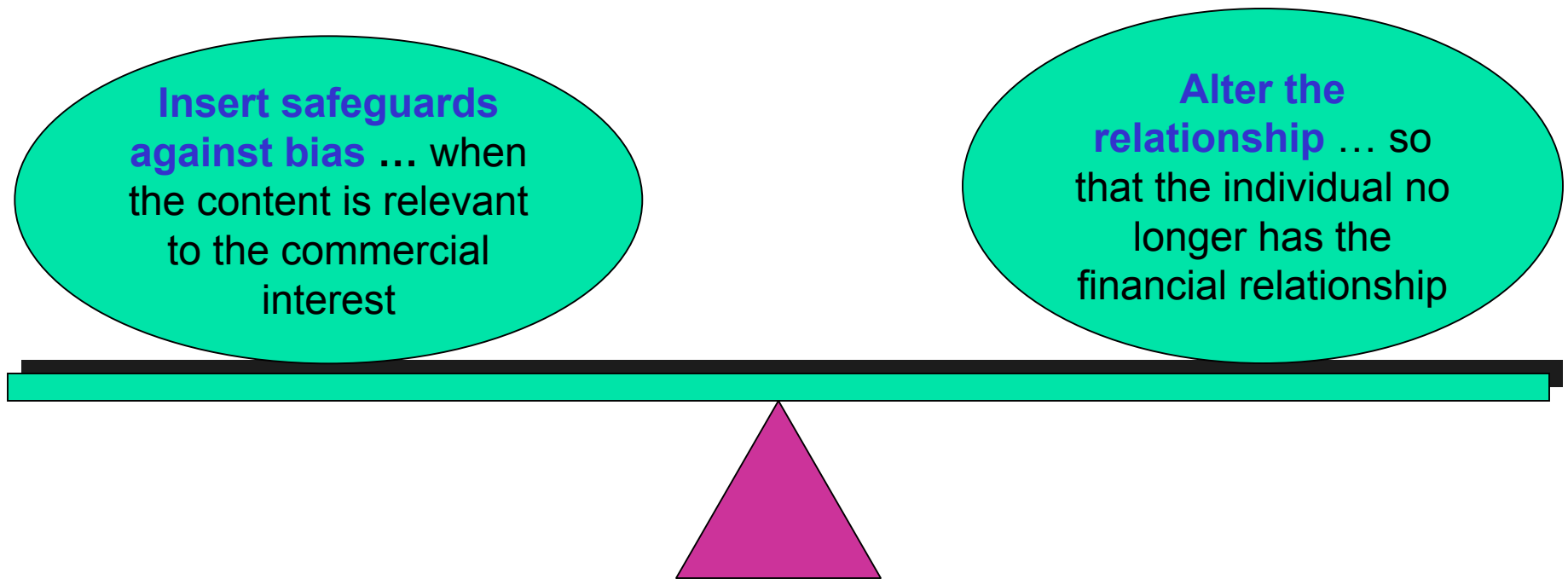
2

Any amount...within the past 12 months...

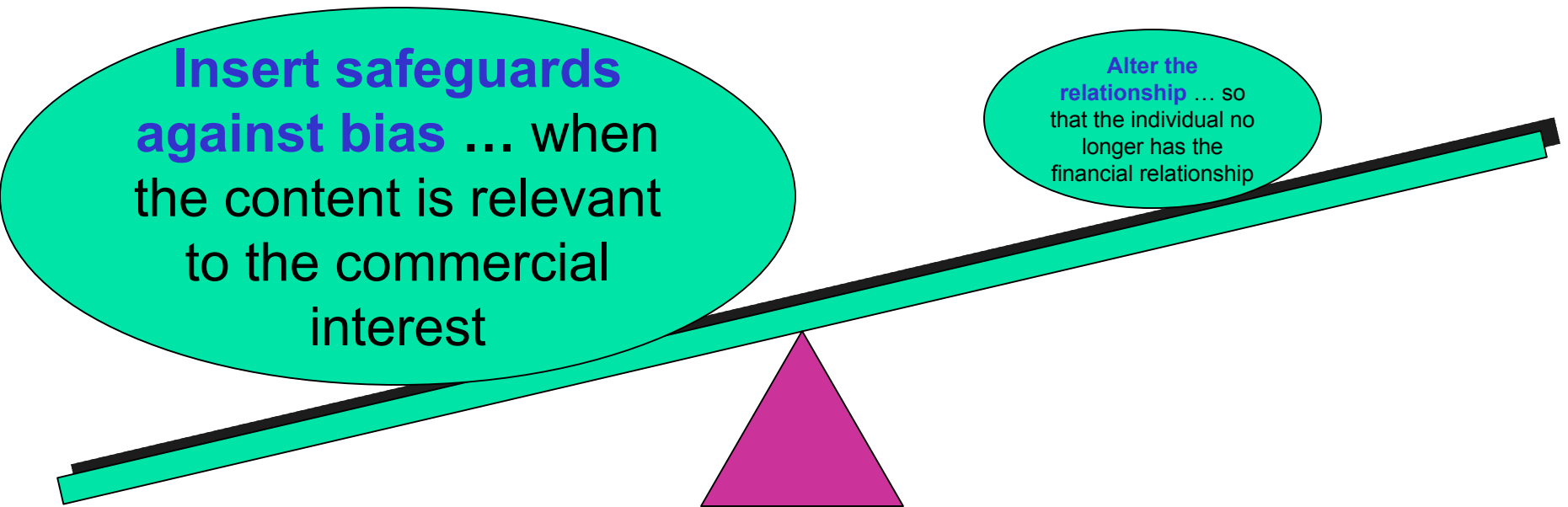
Types of Relationships

- Salary
- Royalty
- Intellectual property rights
- Consulting fee
- Honoraria
- Ownership interest (excluding diversified mutual funds)
- Other financial benefit

***Resolving* the conflict means making sure that the content of the activity is aligned with the interests of the public.**



***Resolving* the conflict means making sure that the content of the activity is aligned with the interests of the public.**



**“It is **not** the intent of the ACCME to**  
block participation in CME events by all  
physicians who receive any remuneration from  
a pharmaceutical or medical device company;  
and

**It is **not** the intent of the ACCME to**  
adopt a policy whereby conflicts of interest can  
only be addressed by excluding physicians  
from participating as planners or teachers in  
CME activities that might be related to their  
conflicts of interest.”

Murray Kopelow MD CEO ACCME  
Alliance for CME Annual Meeting  
January 2004

### Standard 3: Use of Commercial Support

- Decisions & Approval
- Written Agreements

#### *P & P on Honoraria/ Expenses*

- No payments outside of agreement
- Expenditures for learners
- Accountability

### Standard 4: Managing Commercial Promotion at the Activity

- Exhibit booths
- Commercial Advertising

-  Print
-  Computer-based
-  Audio and video
  - Live, face-to-face

-  Education materials: Agent providing CME (distribution)





## Standard 5: Content and Format without Commercial Bias

**New** ... must promote improvements or quality in healthcare ...

- ... balanced view ....

### ACCME Element **2.4**

Measuring Educational Effectiveness

#### **Criteria for Exemplary Compliance**

“ Educational activities are evaluated consistently for effectiveness in meeting identified educational needs, as measured by practice application and/or health status improvement.”



# Standard 6: Disclosure

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- Individuals' disclosure to learners (including no relationships) prior to activity
- Disclosure of commercial support



No use of trade names or product group message in disclosure



# In making decisions about implementing the SCS...

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**“CME providers must be guided by what is in the best interest of the public.”**

**“...always deferring to**

- **Independence**  
from commercial interests
- **Transparency** and
- CME **separate** from  
product promotion”

**...as basic and guiding principles.”**

Thank you

