

**Melinda Somasekhar, PhD.**

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**Professional Education Support  
Wyeth Pharmaceuticals**

# Disclosure

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**The views and opinions that I am going to present are solely my own and do not represent those of Wyeth**

# Definition of CME

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**“CME is a process of lifelong learning that serves to maintain, develop, or increase the knowledge, skills, professional performance, and relationships that physicians use in the care of patients.”**

# Who were the Players in CE Activities?

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- **Commercial supporter**
- **Medical education company**
- **Accredited provider**
- **Faculty**
- **Audience**

# History of CME

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**CME was not learner oriented**

**CME was activity oriented**

- **How many program one did**
- **How much they cost**
- **How many people attended them**

# Sources Impacting Commercial Support

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- **Government and state agencies (i.e. FDA, OIG)**
- **ACCME guidelines and CME providers**
- **Medical agencies/societies (i.e. AMA, AAFP, AOA, ACPE, and ANCC)**
- **Industry Standards (PhRMA)**

# Primary Regulatory Bodies

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- **FDA – Food and Drug Administration**
  - Regulates industry support of CME
  - “Final Guidance on Industry-supported Scientific and Educational Activities” 1997
- **OIG - Office of Inspector General**
  - “OIG Compliance Program Guidance for Pharmaceutical Manufacturers” 2003
  - Anti-kickback statute
  - False claim act

# **FDA Final Guidance - 12 Factors for Independence (continued)**

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- **Identified by FDA in Final Guidance communication in December 1997**
- **As the number of factors violated increases so does the company's risk/liability**



# FDA Final Guidance - 12 Factors for Independence (continued)

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- **Provider's failure to meet standards - independent, balanced, objective or scientific rigor**
- **Restrictions on multiple programs**
- **Influence on audience selection or invitation by company sales or marketing**
- **Opportunity for meaningful audience discussion**

# **FDA Final Guidance - 12 Factors for Independence (continued)**

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- **Product-related information from CE activity is to be disseminated only on unsolicited request or through independent provider**
- **No promotional activities by the commercial supporter in CE program meeting room**
- **Absence of complaints by provider, presenters, attendees**

# **FDA Final Guidance - 12 Factors for Independence (continued)**

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- **Provider (not company) controls content, planning, and speaker selection**
- **Full disclosures**
  - **Company funding of program**
  - **Relationships between company, provider, speakers, and moderators**
  - **Discussion of unapproved uses of products**

# **FDA Final Guidance - 12 Factors for Independence (continued)**

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- **Program focus - independent, non-promotional, educational**
- **Relationship between company and CE provider does not influence CE activity**
- **Involvement between provider and company sales/marketing**

# OIG Provided Guidance in 2003

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- CME has now come under scrutiny
- Commercial support in the form of grants to HCP have elevated anti-kickback concerns
- Commercial influence over programs, including the selection of presenters/faculty, is not an appropriate marketing practice

In essence, following the dollar and determining if it was used to influence a CE activity to promote use of a product

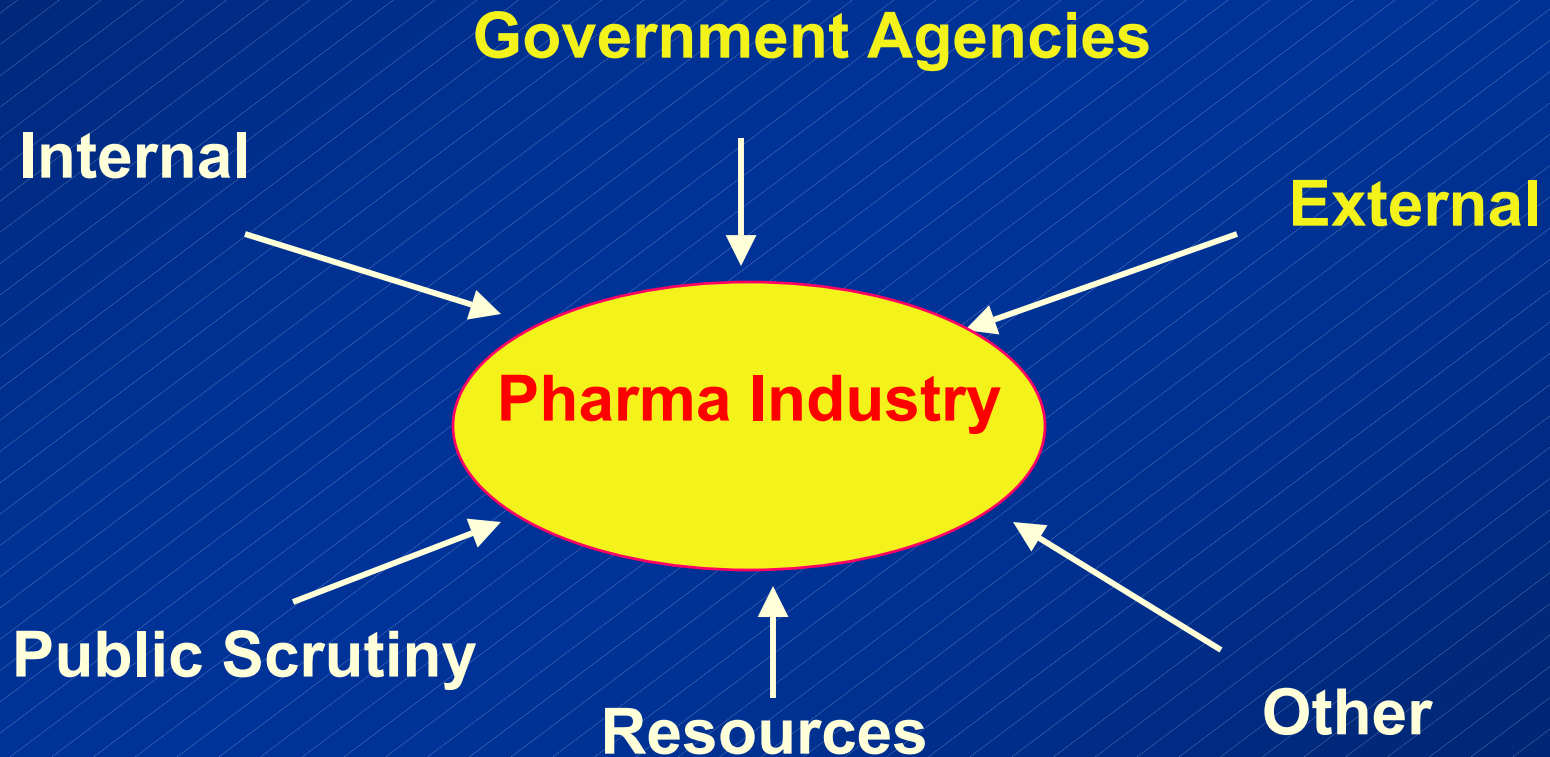
# Recent Fines and Penalties

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	<u>Est. Cost (in millions \$)</u>
• TAP	875
• Abbott	622
• Warner-Lambert(Pfizer)	430
• AstraZeneca	355
• Bayer	271
• GSK	88
• Pfizer	50
• Genentech	30

# Sources Impacting Commercial Support of CE

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# Sources Impacting Commercial Support

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- **Government and state agencies (i.e. FDA, OIG)**
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- **Industry Standards (PhRMA)**
- **News agencies (WSJ, NY Times, CNN)**
- **Lawsuits**
- **Clinical data (current and emerging)**
- **Treatment Guidelines**
- **Company Policies and Guidelines**
- **Budgets**



# What Does Pharma do to Reconcile the Rules

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- Separate grant fulfillment functions from Sales & Marketing
- Move education to Global Medical affairs
- Hire educators
- Creation of Grant Review committees

# What Does Pharma do to Reconcile the Rules

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- Developing Compliance programs
- Developing Policies for Promotion and Independent Education
- Developing Training to Support Policies

# What Does Pharma do to Reconcile the Rules

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- Requiring firewalls when dealing with medical education companies
- Developing procedures to ensure “Independence”
- Seeking advice from meetings focused on the current environment as well as seeking outside counsel

# Who are the Players in CE Activities?

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- Accredited provider
  - Medical education company
  - Faculty
  - Audience
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- Commercial supporter

# Early Reactions of Marketers to Proposed Changes

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- CME has become too risky
- We're not doing anything wrong
- Why should we support CME
- If we cannot have input we will not support it
- This does not make sense
- Why have a committee approach to funding CME
- Our Medical Affairs Group handles it now
- We will not change our approach – will wait and see

# **When is it Appropriate for Industry to Support Independent Medical Education?**

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- **Educational program would benefit patient care**
- **Issues or topics are of interest and of need to the medical community**
- **New data or information has become available that benefits patient care**

# **When is it Appropriate for Industry to Support Independent Medical Education?**

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- **Good business to support the communication or valuable information to healthcare providers**
- **Policies and guidelines governing independent education can be adhered to and followed**

# When is it NOT Appropriate for Industry to Support Independent Medical Education?

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- A medical education need does not exist
- Program or educational activity is focused on only a single product



# When is it NOT Appropriate for Industry to Support Independent Medical Education?

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- Education that serves only commercial interests without improving patient care
- Policies and guidelines governing independent education cannot be met

# How Can We Design the Most Effective Independent Education and Stay Compliant?

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- **Appreciation for laws, guidelines, policies and how they drive each stakeholder's behavior**
- **Learn how to engage and work together to better serve HCP needs and improve patient care**
- **Understand all stakeholder's roles**

# Marketer Realization: We Cannot Stop Supporting CME

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**CME is a powerful tool to improve the patient outcome**

# **Need to Institute Basic Principles of Adult Education**

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- **Physician's self-assessment of their competencies**
- **Understanding how physicians learn**
- **Understand why physicians learn**
- **The environment physicians practice in**
- **Practice-based issues**
- **The improved patient outcome**

# Most Crucial Elements of Education

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- **Designing activities for physicians that would allow them to learn from their clinical experience**
- **Improving patient outcome**

# Need to Institute Basic Principles of Adult Education

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## Gap in the education

- Needs assessment
- Learning objectives
- Designing the activity to meet the learning objectives
- The cost of doing the program

# **Commercial Focus – Moving Forward**

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- **Compliant within policies and guidelines**
- **Strategic with business objectives**
- **Fiscally accountable and responsible**

# **New World of Clinically Based CME**

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**Strong Relationship Between all parts of Educational Community**

- **CME provider**
- **Physicians**
- **Educators**



# Summary

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**Designing CME programs that include educational strategies how physicians learn, influence physicians knowledge, and improve health care outcome is more critical than ever.**