

# Current Topics at the Intersection of Medical and Marketing

November 16, 2004



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# TODAY'S PANEL

## Panelist

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# TODAY'S TOPICS

## **Disclosure of clinical trial activity and results**

Publications and ghost writing

Continuing Medical Education (CME)

# **DISCLOSURE OF CLINICAL TRIAL ACTIVITY AND RESULTS – A GROWING TIDE**

- Spitzer lawsuit against GSK for allegedly concealing negative information on Paxil (June 2004)**
- Endorsement of comprehensive registry by the American Medical Association (June 2004)**
- Proposal by International Committee of Medical Journal Editors (ICMJE) that trials to be registered at inception as a condition for later publication**
- PhRMA's plan to establish voluntary on-line database of clinical trial results (September 2004)**
- Perceived increase in number of products pulled from the market (Rezulin, diet drugs, Baycol, Vioxx) and continued public distrust of pharmaceutical companies**
- Potential for creation of a new drug safety organization as outcome of new IOM study**

# SOME COMPANIES HAVE TAKEN THEIR OWN STEPS



**September 2004** – Agreed to publish summary results of all GSK-sponsored tests since December 2000 on the internet



**August 2004** -- Announced it will disclose on a public registry all clinical results for the company's Phase I through Phase IV clinical trials



**August 2004** – announced it would post certain test data on a website run by the NIH



**September 2004** – as part of agreement with NY SAG, agreed to establish an online clinical trials registry similar to GSK

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# GHOSTWRITING IN THE SPOTLIGHT

**Pharma Ghostwriting Revealed:  
How Drug Firms “Hoodwink”  
Medical Journals**

– *London Observer,*  
December 2003

**“Estimates suggest that up to  
half of all articles published in  
medical journals are written by  
ghost writers”**

– *London Observer*

**Spitzer Sues a Drug Maker, Saying It Hid Negative Data**  
Glaxo Challenged in the Use of Pooled Data  
By GARDNER BUCKER  
The suit, which filed in Manhattan federal court, is the latest in a series of legal actions by the state attorney general against GlaxoSmithKline, the company that has been accused of concealing negative information about its popular antidepressant, Zoloft.

**Your Doctor's Drug Problem**  
By Arnold S. Reisman  
The rising costs of prescription drugs are driving the current debate about Medicare reform. Yet Republicans and Democrats alike may be unaware of a primary reason for this inflation: doctors are taught about drugs by agents of the pharmaceutical industry, which works hard to persuade them to select the newest and most expensive medications — even in the absence of scientific evidence that they are safe, effective,

**Pharmaceutical firms are corrupting medical education.**  
... are corrupting medical education...  
... engaged in persistent fraud...  
Half the articles appearing in medical journals about new drugs are "ghost written" by the pharmaceutical companies which produce them, RPL heard yesterday.

**Drugs companies 'writing reviews of own products in medical press'**  
JOHN DAVES  
The Commons health committee heard that articles in journals such as The Lancet, names of distinguished doctors and academics, even though the supposed "author" scientific data behind them.

**Biovail Is Paying Doctors Prescribing New Heart Drug**  
By GREGORY ZUCKERMAN  
DIOVAIL CORP., a large Canadian drug

**MARKETPLACE**  
Technology & Health + Media + Marketing

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# CME – WHAT A DIFFERENCE 2 YEARS MAKES

## **What's ROI Got to Do with CME?**

*Medical Marketing and Media, August 2002*

- “Companies are beginning to develop comprehensive approaches to measure return on CME investments to compare effectiveness with other budgeted activities.”
- “Prescribing patterns can be measured by comparing pre-event prescription writing with post-event use of . . . the specific drug involved.”

# CME – SELECTED REGULATORY GUIDANCE

- OIG
- PhRMA Code
- ACCME Code

# INTERPRETING THE 2004 ACCME GUIDANCE – SELECT EXAMPLES

## Guidance

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- Presentation **must** give a balanced view of therapeutic options
  
- Conflicts of interest must be **resolved**, not just disclosed

## Interpretation

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- “No single product or service (may be) overrepresented in the education activity when competing products are available for the inclusion.”
  
- “If a speaker has a conflict of interest related to conflict, choose someone else,” or
  
- “Change the focus of the activity so that the content is not about the products . . . that are the basis of the conflict of interest.”
  
- “ACCME does not accept disclosures or disclaimers as mechanisms that resolve conflict of interest.”
  
- “Recommendations . . . should (only) be offered by individuals who do not have a personal conflict of interest.”

# ACCME GUIDANCE

## Challenges

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- More than 55% of CME funding is now supported by industry. What is the sustainable future model for CME funding as guidelines grow increasingly challenging?
- How will CME departments successfully determine the presence of, and resolve, conflicts of interest?
- Is the *purpose* for supporting CME clear within your organization?
- Are your policies and procedures supportive of that *purpose*?
- Are your organizational structure(s) and your funding decision-mechanisms supportive of that *purpose*?

## Opportunities

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- New maintenance of certification efforts provide CME with increased relevance and traction, both in terms of "learning" and in terms of "providing high quality health care"
- New technologies and innovation in the eCME space are making CME more interactive, asynchronous and cost-effective/scaleable
- New CME guidelines may make CME program content more evidence-based