Sales and Marketing Compliance Lessons from Recent Developments

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Disclaimer

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Agenda

- Recent Settlements and CIAs
- Compliance Challenges in Implementing the Revised PhRMA Code
- FDA Draft Guidance on “Good Reprint Practices”
- Industry Funding of Medical Education
- Access Issues

Recent Settlements and CIAs: Settlement Types

- Federal/State
- Criminal
  - Plea Agreement
  - Deferred or Non Prosecution
- Civil
  - Qui Tam Relators
  - State AGs, Medicaid Fraud Units
- Corporate Integrity Agreement (HHS OIG)
  - Typical model: substantive provisions can incorporate pricing, anti-kickback, FDCA compliance
  - Alternative model: FDA consent decree incorporating CIA-like supervision and reporting requirements

Recent Settlements and CIAs

Pharma Misbranding and Anti-Kickback Settlements

2004	2005	2006	2007	2008 (to date)
1 $430 million	2 $740 million	2 $471.9 million	6 $1.225 billion	2 $429 million

Recent Settlements and CIAs

- 2004
  - Neurontin ($430 million)
- 2005
  - Serono ($704 million)
  - Eli Lilly ($36 million)
- 2006
  - Schering II ($435 million)
  - Intermune ($36.9 million)
- 2007
  - Pharmacia ($34.8 million)
  - Cell Therapeutics ($10.5 million)
  - Purdue Frederick ($634.5 million)
  - Medicis ($9.8 million)
  - Jazz Pharmaceuticals ($20 million)
  - BMS ($515 million)
- 2008
  - Otsuka ($4 million)
  - Cephalon ($425 million)

Recent Settlements and CIAs

- Otsuka (3/2008)
- Cephalon (9/2008)

Otsuka Settlement

- Follow on from 2007 BMS settlement
- Settlement with U.S. subsidiary only
- Alleged off-label promotion of Abilify® for pediatric use and dementia-related psychosis
- Government focused on call plans that included pediatric specialists and long-term care sales force

Otsuka CIA

- Applies only to Otsuka America, Inc.
- Acknowledges company's existing compliance program and requires its continuation
- Requires policies and procedures covering: responding to off-label inquiries; call plan development; use of consultants; grants; CME; research funding; compensation incentives
- Mandatory reporting of "reportable events"
- Requires field force monitoring
- 5 year term

Cephalon Settlement

- Alleged off-label promotion of three drugs, including by
  - Targeting and sampling off-label specialists
  - Training sales reps to use visual aids to promote off-label based on unproven mechanism of action
  - Making dosing recommendations for unapproved use
  - Using small case study to promote off-label
  - Directing sales reps to disguise off-label marketing
  - Evaluating sales rep negatively based on lack of off-label promotional efforts
- Cephalon entered a guilty plea to a misdemeanor violation of the FDCA for off-label promotion
- $425 million criminal fines/forfeiture and civil penalties
- Five-year CIA

Cephalon CIA

- On a quarterly basis, Board must review and oversee compliance program, and adopt resolution that program is effective
- Each Board member must sign statement indicating it agrees to resolution
- Compliance certifications by a broad number of executives, including sales VPs and directors, marketing VPs and directors, Medical Affairs VP, MSLs, etc.

Cephalon CIA (cont.)

- Specific policies covering wide range of sales/marketing activities, including call plan development, incentive comp, funding research and grants, etc.
- Independent entity to perform message recall surveys
- Field force monitoring program
- Notice to all healthcare providers
- Public disclosure of payments to physicians on Cephalon's website

Questions on Recent Settlements

1. The Cephalon settlement requires that senior management complete signed certifications that their business activities are in compliance with law and policies. Is the following statement true or false: “My company currently requires that senior management complete signed compliance certifications.”

    A. True
    B. False

Questions on Recent Settlements

2. The Cephalon CIA requires the posting of all payments to HCPs on the company's website. At my company:

   A. We post all payments to HCPs on our website

   B. We are considering posting all payments to HCPs on our website but have not made a decision

   C. We considered posting all payments to HCPs on our website and have decided not to post such information, at least for now.

   D. We don't post all payments to HCPs on our website.

Questions on Recent Settlements

3. How many of the top 10 pharmaceutical companies (by sales) do NOT have CIAs?
    A. More than two
    B. Two
    C. One
    D. Are you serious? They all have them.

Revised PhRMA Code on Interactions with Healthcare Professionals

- PhRMA Board unanimously adopted modifications to PhRMA Code on Interactions with Healthcare Professionals in July, 2008
- Effective January, 2009
- Reaffirms that interactions between company representatives and healthcare professionals “should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education”

Highlights of Revised PhRMA Code

- Sales representatives and their immediate managers may only provide occasional, modest meals, in connection with an informational/educational presentation, in HCPs' offices or hospitals
- Restaurant meals with sales representatives or their immediate managers are prohibited
- For consultants meetings, resort locations are not appropriate
- Recreational benefits/events or entertainment should not be provided to HCPs
- Non-educational items (e.g., pens, note pads, mugs), even if practice related and of minimal value, should not be offered to HCPs or their staff
- Educational items that are not of substantial value (i.e., $100 or less), designed primarily for the education of patients or HCPs (e.g., text books, anatomical models, educational brochures), may be occasionally distributed
- Appropriate educational items do not include, however, items such as a stethoscope which is not primarily designed for patient education but rather patient treatment.

Highlights of Revised PhRMA Code (cont.)

- An annual cap on the amount of compensation to be paid to speakers should be set
- Consultants/speakers who are also members of formulary or clinical guideline development committees should disclose that to the committee
- Company certification (by the CEO and Compliance Officer) that the company has processes in place to comply with the Code
- Sufficient training of sales representatives on the laws, regulations and the Code that govern their interactions with HCPs should be provided
- Requirement that CME should support education on a range of treatment options, not a specific product
- A set of principles for the use of non-patient identified prescriber data should be developed

Revised PhRMA Code: Signatory Companies

- As of September 10, 35 companies have announced their intention to abide by the Code when it takes effect
- State law requirements (e.g., California, Nevada)

Questions on Revised PhRMA Code

1. Has your company adopted the revised PhRMA Code on Interactions with Healthcare Professionals?
    A. Yes
    B. No
    C. Under consideration

Questions on Revised PhRMA Code

2. Does your company have compliance policies and procedures that address the requirements of the revised PhRMA Code on Interactions with Healthcare Professionals?

    A. Yes
    B. No
    C. Under consideration

Questions on Revised PhRMA Code

3. Does your company have a definition of “occasional” in the context of appropriate business meals and/or distribution of educational items?
    A. Yes
    B. No
    C. Under consideration

Questions on Revised PhRMA Code

4. Has your company set an annual cap for the amount of compensation to be paid to speakers?
    A. Yes
    B. No
    C. Under consideration

Questions on Revised PhRMA Code

5. Does your company have a set of principles for the use of non-patient identified prescriber data?
    A. Yes
    B. No
    C. Under consideration

FDA Draft Guidance on “Good Reprint Practices”

- Feb 15, 2008, FDA issues draft guidance on "Good Reprint Practices“
- FDA tried to strike a balance between fact that "Articles that discuss unapproved uses … can contribute to the practice of medicine” and FDA’s stated desire to "safeguard() against off-label promotion.“
- Evoked criticism even before it was issued – Waxman suggest that it would create a “large loophole” in current off-label law

Types of Reprints/Articles/Reference Publications

- Journal article that is distributed should be:
  - published by an organization that has an editorial board that uses independent experts and has full disclosure of any conflict of interest or biases
  - peer-reviewed
  - not a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers
- Publication should not be primarily distributed, written or edited by manufacturer or any individuals having a financial relationship
- Journal should address adequate and well-controlled clinical investigations that are considered scientifically sound
- The information must not be false or misleading, and should not be inconsistent with the weight of credible evidence derived from adequate and well-controlled clinical investigations

Manner in Which to Disseminate Scientific and Medical Information

Any articles disseminated:

- should be in the form of an unabridged reprint or copy
- should not be marked, highlighted, summarized, or characterized by the manufacturer in any way
- should be accompanied by approved labeling
- should be accompanied by a comprehensive bibliography; include copies of any articles that specifically call into question the publication (if such exist)
- should be distributed separately from information that is promotional in nature
- should be accompanied by a prominently displayed and permanently affixed statement detailed in the Guidance

Practical Considerations

- Principles amount to factors that FDA will use when evaluating whether distribution is promotional and therefore subject to FDA's prohibition on off-label promotion, or exchange of scientific information
- Companies should continue to focus on internal processes and policies on distributions

Questions on FDA Draft Guidance

1. Does your company permit sales representatives to distribute journal articles, approved by the company, that discuss off-label information?

    A. Yes, without any other conditions
    B. Yes, but not during a promotional detail
    C. Yes, but only upon request of the health care provider
    D. No

Questions on FDA Draft Guidance

2. Under our policies, if a sales representative is asked during a detail to a health care provider about a journal article that discusses off-label uses, the representative may:

   A. Obtain a copy of the article and provide it to the doctor

   B. Make a request to someone else in the company (medical affairs, sales operations, etc.) for that person(s) to provide the article to the doctor

   C. Provide the HCP with information that would enable the HCP to request the article from someone else at the company

   D. My company prohibits providing the article to the doctor.

Medical Education

- IOM Consensus Report Project
  - Hearings began November 2007
  - Report due 4Q 2009
- AAMC Report (June 2008)
- Proposed Revisions to ACCME Standards (June 2008)
- ACCME Letter of Inquiry (July 2008)
- Pfizer Announcement (July 2008)

Medical Education

- AAMC Report (June 2008)
  - For industry-supported CME, AMCs should offer only ACCME-accredited programs
  - AMCs should prohibit their faculty, students, and trainees from:
    - Attending non-ACCME accredited industry “CME” events
    - Accepting payment for attending industry-sponsored meetings
    - Accepting personal gifts from industry at such events

Medical Education

- AAMC Report (June 2008)
  - To the extent that AMCs allow faculty and staff to participate in CME, they should require
    - Full transparency and disclosure by their personnel to the AMC and when participating in such programs
    - Payments to academic personnel be at fair market value
  - AMCs should “strongly discourage participation by their faculty in industry-sponsored speakers’ bureaus” except when academic investigators are presenting results of their industry-sponsored studies to peers

Medical Education

- New ACCME Q&A (October 2007)
  - Providers may not ask commercial interests for suggestions relating to CME topics or speakers
  - Commercial supporters should not comment on factual accuracy
- Proposed Revisions (June 2008)
  - No communications from commercial interests announcing preferred content or topic (e.g., therapeutic area, product line, patho-physiology)
  - No communications regarding commercial interest's "internal criteria" for providing support
  - Consider eliminating commercial support of CME or continuing commercial support under a "new paradigm"
    - "New paradigm" proposed to include needs assessment verification by third parties (e.g., government agencies), curriculum specified by organizations such as the AMA, and verification of no commercial bias
    - Could include distribution from pooled industry funds

Medical Education

- ACCME Letter of Inquiry
  - Sent to 82 CME providers that receive 75% of commercial support
  - "ACCME is examining practices … to ensure compliance with ACCME's requirements for independence. ACCME seeks to understand the processes employed in obtaining and managing commercial support that meet the requirements set forth in the ACCME's … Standards for Commercial Support℠."
  - "ACCME believes that our system has an effective set of internal controls, based on the ACCME Standards for Commercial Support℠, that ensure learners and the public of the high quality, the independence and the scientific integrity of accredited continuing medical education. We believe the results of this Inquiry are going to verify the effectiveness of the safeguards in place in the CME programs that account for the vast majority of the commercial support of ACCME accredited CME."

Medical Education

- Pfizer Announcement (July 2008)
  - Immediately eliminating all direct funding for CME programs provided by medical education and communication companies (MECCs)
  - Continuing to support CME at AMCs and teaching hospitals, and programs sponsored by associations, medical societies, and community hospitals; these institutions may contract with MECCs
  - Initiating competitive grant review period to encourage more high-quality applications
  - Establishing financial caps on grant support
  - Requiring all major grant applicants to meet ACCME-equivalent criteria
  - Continuing disclosure of all CME grants on website

Access Issues, Industry Responses

- Hospitals have implemented restrictions on facility access
  - Required registration prior to access
    - Payment of fees
  - Registration has required such specific information as:
    - Documentation of HIPAA Training
    - Documentation of product training
    - Immunization records
    - Certificates of Insurance

Access Issues, Industry Responses

- Restrictions on Company/Representative Activities
  - Bans on gifts
  - Restrictions on consulting arrangements
  - Restrictions on educational programs

Questions?