Complying with FDA/OIG Rules

Wayne L. Pines
August 24, 2006
Wayne Pines

Consultant to pharma/ devices industries on advertising/promotion issues, crisis control

Former Associate Commissioner for Public Affairs, FDA

Author/ editor, FDA Advertising and Promotion Manual, 10 others books
Traditional Marketing Regulation

- FDA enforcement of advertising/promotion rules
- Dates to 1960’s
- Penalties are warning or untitled letters
- Tend to focus on print materials
  - Not dinner meetings, CME, non-traditional promotion
- Limited impact of penalties
The Industry’s New 800-Pound Gorilla(s)

- Fraud and abuse cases filed by OIG/DOJ
- Has cost industry $3 billion plus
- Much more to come

Plus:
- PhRMA rules
- OIG rules
- State restrictions on gifts etc.
- State AGs
- Liability cases
New Development

Psychiatrist arrested for promoting Xyrem off-label at dinner meetings

Shows seriousness of government against off-label promotion
Bottom Lines

- Pharma companies facing a new environment in terms of promoting their products
- HCPs will have less “off-label” information available, even when medically justified
- Will affect promotion, prescribing, reimbursement, general information flow
Big Five Regulators of Pharma Promotion

I. Inspector General of HHS (DOJ)
II. ACCME
III. PhRMA
IV. AMA
V. FDA
I. OIG Rules

- False Claims Act
  - Originally passed in 1863
  - Amended in 1986
  - Government using it as weapon against drug/device companies

- Anti-Kickback Statute
Underlying Concern

- Law prohibits payments by government when fraud is involved in the sale
- Government now pays for drugs under Medicare, Medicaid, VA, Defense Department etc.
OIG Legal Theory

Government theory:
- When a company promotes off-label, and
- Then a physician prescribes the product for the off-label use, and
- Then the government pays for the off-label use under one of its programs -
- Then that is fraud against the government
How Cases Develop

- Whistleblowers bring against their own companies (can bring against anyone)
  - “Qui tam”
- Whistleblowers get 15-30% of the settlement fine
- Significant inducement for internal whistleblowers, disgruntled employees
- Recent cases have changed HR practices in drug/device companies
The Future
For the Industry

Government now investigating more than 150 cases
This is why companies are so cautious
II. ACCME

- Sets rules on independence of Continuing Medical Education programs
- Follow FDA, OIG guidance and PhRMA and AMA guidelines
III. PhRMA Codes

Code created by PhRMA in 2002, but adopted by OIG, California

DTC Principles effective Jan. 1, 2006
PhRMA Code

- Rules on gift-giving, grants, use of consultants, general relationship between pharma companies and HCPs
- Effective 2002
- Has become standard in industry
- Reflected in OIG rules, CA statute
PhRMA Code

Occasional modest meals may still be offered, so long as educational venue. No spouses. No dine ‘n dash.

CME: Companies can sponsor medical conferences. Cannot control content or venue. Cannot pay doc’s expenses to attend.
PhRMA Code - Consultants

Consultants can be paid for their time
- Services must be legitimate
- Prohibits “token” consulting arrangements
  - Continued
Consultant Agreements

Six factors for a *bona fide* arrangement:

- Written contract
- Legitimate need for services, identified in advance
- Selection criteria related to service
- Number of consultants should not be more than necessary to achieve purpose
- Services actually provided and documented
- Venue and circumstances conducive to services
  - Social events “clearly subordinated”
  - No support for consultant spouses
PhRMA Code - Speakers Bureau

Speaker training OK, so long as speakers will actually be used and they meet criteria for consultants

- Reasonable payments
- Speakers receive “extensive training” on company’s products and FDA requirements
  - Training will result in participants providing a valuable service to company
  - Participants meet same criteria applicable to consultants
  - Number of trainees cannot significantly exceed number the company uses
PhRMA Code - Grants

Companies can support scholarships/ educational grants

- Selection must be made by independent/ academic institutions
- Process is independent of marketing
PhRMA Code - Gifts

Gifts
- Prohibited for personal benefit
- Appropriate gifts ($100 or less) primarily benefiting patients are OK on occasional basis, as are gifts of “nominal” value (e.g., pens, notepads)

Meals
- Modest meals during informational presentation are permitted in appropriate venue; spouses prohibited

Entertainment and recreational events
- Generally prohibited
- Exception: In context of meetings with parties providing bona fide services to the company

Samples: Permitted for patient use; prohibited for personal/family use
PhRMA DTC Principles

- Professional education should precede DTC
- No more TV “reminder ads”
- Ads should be appropriate for audience
- Submission of DTC ads to FDA for advance review
IV. AMA Guidelines on Gifts

Any gift should “primarily” entail a benefit to patient, and not be of “substantial value” ($100)

- Texts, modest meals are OK if they serve educational purpose
- Pens, diaries are OK if related to work

Gifts to support medical meetings OK BUT
- Cannot pay for travel, lodging, personal expenses, physician’s time
- Modest hospitality OK
AMA Guidelines

- Faculty at conferences and consultants may get honoraria and travel/ lodging reimbursement
- No gifts with “strings attached”
- Financial support for conferences should be disclosed
V. FDA Rules

- Promotion must
  - Be within labeling
  - Include fair balance of benefits/risks
  - Not be false and/ or misleading
FDA’s Expectations

- Compliance with FDA’s view of the rules
- Standard operating procedures
  - Internal review process
- Company-wide control by management
- Sales force
  - Distribute only approved materials
  - Refer off-label questions to Medical Affairs
Off-label Dissemination

- FDA prohibits promotion of off-label uses
- Washington Legal Foundation litigation:
  - Dealt only with peer-reviewed articles to health professionals
- Companies can disseminate peer-reviewed articles and texts under two processes:
  - Follow process in FDAMA 401
  - Do it without FDA approval
- FDA will bring action if material is “false and misleading” or if part of larger of-label campaign
Investigational Products/Uses

Regulation 312.7:

“A sponsor...shall not represent in a promotional context that an investigational new drug is safe or effective...

“This provision is not intended to restrict the full exchange of scientific information...including (in) the lay media...

“Rather, its intent is to restrict promotional claims of safety or effectiveness...and commercialization of a new drug before it is approved.”
Enforcement 2006

12 DDMAC enforcement letters thus far in 2006

Focus on:
- Lack of fair balance
- Risk minimization
- Unwarranted claims

DDMAC on same track as 2004-5
- But, no DTC letters
Tips for Overall Compliance

- Every company should have a culture of compliance
  - Too much at stake if there are lapses
  - Qui tam provides strong incentive for whistleblowers
Tips for Compliance

1. Every company should have an OIG-type compliance program:
   - Written policies & procedures
   - Designating a compliance officer
   - Effective training and education
   - Effective means of communication
   - Internal monitoring & auditing
   - Well-publicized disciplinary guidelines
   - Prompt detection of problems & corrective action
More Information

Wayne Pines

202 256 5455

wpines@apcoworldwide.com