Advanced Issues In Medical Affairs Compliance: A Panel Discussion

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- The opinions expressed on the panel are the participants' own and should not be imputed to any employer, past or present. The information given in this presentation should not be construed as legal advice, but is information provided for general informational purposes only
- This presentation has been updated for today's presentation by adding audience response questions

Agenda for our discussion

- Some initial questions to consider
- Medical Affairs generally
- Field Medical Affairs issues
- Independent Medical Education
- Publications
- Medical Affairs and Corporate Ethics

A question about Field Medical

My company uses field medical personnel (MSLs) :

- for activities that would be considered promotional by the FDA (e.g. speaking, advising doctors about new indications, new data)
- strictly for non-promotional activities (responding to unsolicited questions, addressing disease state issues, communicating REMs information)

A question about business and medical strategy

In my company:

- Medical Affairs and Marketing participate collaboratively in business planning for our products and in developing medical strategies
- Business and Medical Planning are conducted separately and fire-walled
- Other

A question about grants

My company's educational grants function (CME, IME and community education support):

- Is housed in Medical Affairs
- Is housed in Compliance
- Other

A question about Medical Information

My company's legal department:

- Reviews all medical information letters
- Reviews selected medical information letters (e.g., those deemed to be higher risk)
- Does not review any medical information letters

Medical Affairs : An Overview

- Regulatory basis for a Medical Affairs department is slender
  - Convention endorsed here and there by OIG and FDA in discrete areas
  - Embraced as a bulwark against intent based statutes
- Recent government enforcement focus
  - CIAs require rules for field medical interactions and unsolicited requests
  - Recent awareness of publication issues
- How Medical Affairs views itself: Medical Affairs and whistleblowers

Medical Affairs: HQ Function

- Can the separation of Medical Affairs and Marketing have adverse consequences?
  - Medical role in strategic planning: “medical needs”
  - Interactions with marketing in medical strategic planning: necessarily inappropriate?
  - Risks from siloed operations versus risks of Medical Affairs under pressure from Marketing
- Another issue for Medical Affairs HQ: safety information after Wyeth v. Levine

Medical Affairs: Promotion Review Function

- Government expectations and recent off-label promotion cases
- Are your medical reviewers cognizant of the regulatory framework of promotion?
- Do they view role as strictly addressing “medical appropriateness”?
- Are they aware of the pivotal role they play in promotion compliance
  - communicating strengths and limitations of studies to review team
  - standing up to marketing
- Importance of compliance training for medical reviewers

Medical Affairs: Medical Information

Medical letters: what is the appropriate oversight?

- Applicable standard
- Need to focus questions and responses: how handled
- Who reviews: the pros and cons of legal review, and a suggested compromise:
  - Letters making any comparative claims
  - Letters on agreed upon sensitive issues
- Utilization of Medical Information for other purposes

Medical Affairs: Medical Information (cont'd)

- State prosecutors and deceptive trade practices: inclusion of negative data in your medical information letters
- Auditing and monitoring: is anyone looking at the overall picture?
- A suggested methodology for a quick review

A question about pipeline presentations

My company's medical department:

- Makes pipeline presentations proactively to managed care organizations
- Makes pipeline presentations reactively to managed care organizations in response to unsolicited requests
- Does not make pipeline presentations to managed care organizations

A question about formulary presentations

During the course of a P&T presentation:

- Our medical personnel are permitted to proactively present about off-label uses of our products
- Our medical personnel can respond to questions about off-label uses of our products
- Our medical personnel may not discuss off-label information

Medical Directors

- Appropriate functions and protocols for a Company's medical directors
  - Clinical trials?
  - Formulary presentations?
  - Promotional speaking?

A question about the deployment of field medical personnel

Which best describes your company's use of MSLs:

- Proactive (visiting opinion leaders, making formulary presentations, carrying new safety information to doctors)
- Proactive and reactive (all the above, and responding to requests for information)
- Reactive only (deployed in response to requests for information only)

Field Medical Affairs Representatives

What is the value of your MSL/MSM deployment?

- Pro-active deployment v. in response to an "unsolicited request"
  - What does proactive really mean?
  - Use in "disease state" education
  - Is fulfilling a request that the company provide medical updates "proactive" and inappropriate?
  - What about the provision of safety information?
  - Promotional use: necessarily inappropriate?
  - Role in dissemination of reprints and other data; what about updating information already given?

Field Medical Affairs Representatives (cont'd)

- Is there a value in a reactive only model?
- Field Medical performance metrics:
  - Measuring activity versus value
  - The role of HCP surveys
- Field Medical and the corporate practice of medicine
  - Use of medical personnel to address side effects of treatment in certain classes of compounds

A question about profiling

Prior to launch of new products:

- My company's MSLs are deployed in physician profiling
- My company uses other field personnel to profile physicians
- My company does not profile physicians , but uses third party commercial services to obtain information about physicians, the populations they treat, and their specialties.

Other current compliance issues with Field Medical personnel

- Physician profiling pre-launch
- Treatment of field medical personnel under DC registration requirements and also institutional requirements
- Interactions with sales force: trend towards curtailing interactions between medical and sales
  - Introductions
  - Training
  - Promotional programs
- Appropriate description of field medical objectives with KOLs

Government Enforcement and Field Medical

- Concerns with field medical role expressed in recent CIAs
- Tracking of unsolicited questions and required monitoring of trends: how are companies complying?

A question about grants and RFPs

Which answer best reflects the frequency with which your company issues RFPs for IME programs?

- Often
- On occasion
- Never

Independent Medical Education

- Do RFPs continue to be appropriate?
- Lilly/Pfizer policy – use only Academic (not for profit) medical education providers
- REMS requirements – can they be incorporated into every IME, and if so, how to do so without controlling content: a practical suggestion to debate
- The advantages of IME supporters (manufacturers) conducting IME provider days
- Grants portals – necessary because of state law tracking requirements/Sunshine laws

Independent Medical Education

- How are we doing with the new paradigm of IME/CME (evolution from a model that included content review)?
- Any change in focus from product specific CME to CME that focuses on ranges of options, including non-pharmaceutical intervention?
- Recent academic recommendations: prospect for further change?

A question about publications

In developing a publications strategy in my company :

- Marketing is part of the process and has a vote
- Marketing is part of the discussion but has no vote; Medical Affairs has final responsibility for decisions
- Medical Affairs is solely responsible
- Other

Medical Affairs: Publications

- Government enforcement focus in recent CIAs
- New ghostwriting issues
- Who reviews and what level of input is permissible?
- Auditing of biostatistics and other data provided to authors

Medical Affairs and Corporate Ethics

- The importance of conveying to Medical Affairs its key role in corporate compliance and ethics
- Need for management buy-in to support Medical Affairs elevating its concerns: how is such buy-in best created?