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- *AudioConference on HHS OIG Guidance for*
- *Pharmaceutical Manufacturers*
- *September 18, 2003*
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**Operationalizing the Guidance:
Sales and Marketing Practices**



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Summary of Presentation

- How companies are reviewing practices in response to guidance
- Separation of sales and marketing from various functions (education and research funding, training, market research)
- Other potential safeguards
- Other practices
 - Off-label promotion
 - Reimbursement counseling and support

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What Companies Are Doing to Review Sales/Marketing Practices

- Most major pharma companies have initiated some type of comprehensive review of their sales and marketing practices in response to the HHS OIG guidance.
- In some cases, the review was prompted by the Legal Department or the Compliance Officer. In at least a small number of others, the Board and/or Senior Management called for the review.
- Some Compliance Officers have used a survey-style approach, asking relevant business units (or the lawyers supporting sales and marketing) to review their practices and to provide some assurance as to the appropriateness of such practices.

Review of the Guidance (cont'd)

- Other companies have established task forces or working groups to review the “risk areas” outlined in the guidance.
- The guidance has prompted only modest changes in sales and marketing activities that are the subject of the PhRMA Code, since most companies have adopted -- and the guidance is generally positive about -- the Code.
- The areas that have been the most difficult to address include:
 - Relationships with PBMs and managed care organizations
 - Separation of sales and marketing functions
 - Discounts
 - Compensation of sales agents

Separating Certain Practices from Sales/Marketing Function

- OIG suggestion to separate educational and research funding from sales/marketing should be read as a specific application of a broader point: Activities that can be justified only for non-sales and marketing purposes should be divorced from sales and marketing function.
Examples:
 - Educational and research grants
 - Preceptorships and other training programs
 - Market research
- Separation of educational and research funding (examples):
 - Objective criteria established in advance
 - Procedures to bypass the field sales force (e.g., web-based application procedure)
 - Final decision-making by non-sales/marketing personnel
 - But -- identifying legitimate mechanisms to obtain knowledge and expertise from sales/marketing personnel

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Separating Sales and Marketing -- Training

- Preceptorships (and related activities) are justified based on their ability to assist in training the field sales force (or even HQ sales/marketing personnel).
- If the legitimate purpose is training, however, companies should consider whether the responsibility for oversight and operation of these programs should be transferred to the sales training operation.
- Oversight and operation should include:
 - Determining when consultants are needed (and, if so, the number of consultants)
 - Ensuring compliance with the PhRMA Code's provisions on consultants
 - Transferring the budget for such programs to the training function

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Separating Sales and Marketing -- Market Research

- Some companies use a variety of market research strategies -- *e.g.*, data purchases from customers, use of consultants -- that raise a “red flag” in the eyes of the HHS OIG.
- In companies that have stand-alone market research units, such companies may want to require market research projects to be overseen and operated by that unit.
- Oversight and operation could include (examples):
 - Determining the most cost-effective means of obtaining the relevant market research data
 - If consultants are needed, ensuring compliance with the PhRMA Code
 - If data needs to be purchased from a customer, the market research unit should be responsible for the transaction

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Taking A Fresh Look at Regulatory Safe Harbors

- A number of pharma companies are taking a much closer look at the statutory and regulatory safe harbors under the Anti-Kickback Statute
- The most relevant safe harbors include:
 - Discount safe harbor
 - Consulting relationships and the personal services safe harbor
 - PBMs and the GPO safe harbor

Other Potential Safeguards

- Budgeting and accounting
 - Companies should re-consider whether to allocate funding for a variety of activities to the sales/marketing function
 - Examples of such activities include:
 - Educational and research funding
 - Preceptorships and related sales training programs
- Fair market value analysis
 - The guidance emphasizes the importance of FMV with respect transactions/activities in identified “risk areas”
 - A growing number of companies are turning to third parties for independent FMV analysis

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Fine Print

- The slides and presentation discuss a variety of options and strategies for responding to the HHS OIG's guidance. The guidance is voluntary, and none of the suggestions contained herein are required to ensure compliance with applicable law.
- These slides and the views expressed during the presentation are my own, and do not necessarily represent the views of my clients or Arnold & Porter.
- Slides and comments summarize issues arising under the HHS OIG guidance and related laws and regulations -- they do not represent, nor should they be relied upon, as legal advice.

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Questions?

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