

**Medical Device Fraud and Abuse
Hypothetical Case Studies**

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**Fraud and Abuse Compliance
Objectives**

- All company personnel have interest in advancing business objectives through compliant activities
 - Achieve business objective without legal/compliance exposure for company
- Lessons Learned
 - Effective business/legal/compliance partnership requires proactive disclosure of proposed activities
 - Most activities with compliance concerns can be modified to achieve compliance and business objectives
 - Problems arise when disclosure occurs too late for appropriate modification
 - Activity denied
 - Company exposure

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Fraud and Abuse Current Concerns

- Free equipment
 - Trial evaluations
 - Capital with disposables
- Use of consultants
 - Current trends in fair market value
- Activities at conferences, tradeshow and exhibits
- Distinguishing between medical education and promotional activities
 - Company provided education and training
 - Sponsorship of third party educational events
- Educational items
- Funding of travel expenses for product training or site visits
- Meals
 - Recurring issues
 - Complications from state laws
- Charitable contributions
 - Ensuring appropriate separation from sales and marketing on decisions
- Oversight for distributor/third party dealer activity
- New product/new technology issues
- Physician-owned medical device companies

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Case Study #1

At Medical Gadgets, Inc., Sales has opportunity to convert Community Hospital from competition for key capital and disposable product line. The account manager has proposed placing capital equipment at hospital for trial evaluation for one year and supplying free disposables for use during trial period. At end of year, if hospital decides to purchase company products, the account manager would like to provide 100 units of capital equipment per year if the hospital agrees to purchase 10 cases of disposables in the same period.

Legal has been asked to prepare the necessary agreements because company policy requires written agreements for these arrangements. In following up with the account manager, Legal discovers that the hospital has already had capital equipment from demo inventory and received disposables from sample stock for six months and has been using the equipment regularly during the period.

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Issues

- Reasonable necessity of trial evaluation
- Lack of advance documentation
- Description and disclosure of capital equipment/disposables

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Resolution

- Written trial evaluation agreement memorialize prior understanding
- End trial evaluation absent compelling circumstances for additional evaluation
- Written capital placement/disposable purchase agreement
 - Capital reasonable and necessary for needs
 - Disposable commitment not encourage over-utilization
 - Disposition of capital/modification of agreement if terms not met or agreement terminated
 - Discount on products disclosed
 - Anti-kickback notice/disclosure language included
- Employee corrective action for policy violation (e.g., education or impact on commission)

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Case Study #2

American Association of Specialists has asked Medical Widgets, Inc. (Company) to be gold sponsor for its annual national convention in Boston, Massachusetts

Sponsorship covers:

- One continuing medical education event
- Exhibit booth in prime location
- Tote bags distributed to membership
- Named sponsor of one after-hours reception

Marketing has approved sponsorship and has developed plan to optimize sponsorship:

- Distribution of educational materials on USB sticks at exhibit booth
- Raffle for iPod to first 100 visitors at exhibit booth
- Suite in convention hotel with additional product displays, educational sessions and refreshments
- Scheduled meals with attendees

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Issues

- Requirements for approval
 - Grant versus fair market value payment
- Prohibition on gifts excluding educational items
- Prohibition on entertainment
- Restrictions on meals

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Resolution

- Bifurcation of conference sponsorship/educational grant for approval or revise sponsorship package
- Clarity on sponsorship of convention versus provision of gifts/meals
- Modification of educational materials/items
- Guidelines for meals
 - State law issues

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Case Study #3

- ❑ ABC Device Co routinely engages key opinion leaders from across the country (including Massachusetts) who use ABC's products to provide feedback on product use and enhancements. Consultants receive a yearly fee under a written agreement.
- ❑ New compliance officer raises questions about the routine use of KOLs.
- ❑ Needs assessment, yearly fee (FMV?), selection of consultants, use of information by the company
- ❑ Use of information
- ❑ Selection of Doctors to participate in the KOL Program

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Resolution

- ❑ Company needs to perform a needs assessment
- ❑ Use only qualified consultants and reasonable number of KOLs
- ❑ Fee based on actual services performed
- ❑ FMV – develop fee schedules based on accepted FMV methodology
- ❑ Monitor the info provided by consultants

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