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- *Pharmaceutical, Biotech and Device Colloquium*
- *Princeton, New Jersey*
- *June 6-9, 2004*
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Medical Device Compliance Roundtable



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Overview

- Fraud & Abuse: Potential Risks for Device Companies
- Risk Areas: Practical Advice and Insight from Compliance Professionals
- Compliance Programs: Reducing Your Risk By Implementing An Effective Compliance Program



Fraud & Abuse: The Risks

- Criminal prosecution of companies and individuals (up to 5 years imprisonment)
 - Fines (up to \$250,000 for individuals, up to \$500,000 for companies or multiple of fraud/loss)
- Civil penalties (under FCA or OIG's CMP authority)
- Exclusion/CIAs
- Lawsuits by private third-parties
- Increasing interest of PL plaintiffs' lawyers
- Reputational harm, management distraction

Fraud & Abuse: The Risks

- Recent cases include criminal charges against senior executives and lawyers:
 - Chief Executive Officer
 - VP, Sales and Marketing
 - VP, Regulatory Affairs
 - General Counsel
- July 2003 -- Supplier of enteral nutrition products/pumps
 - Settles criminal/civil charges involving sales/marketing practices
 - Agrees to pay \$600 million, enter into five-year CIA
- June 2003 -- Global medical device company
 - Plea to criminal/civil charges, agrees to pay \$94 million, 5-year CIA
 - Company failed to file MDRs, made false statements to FDA

Fraud & Abuse: The Risks (cont'd)

- February 2003 -- Manufacturer of sterilizer system
 - 19-count indictment* against CEO, VP Regulatory Affairs, VP Sales
 - Charges include off-label promotion of system for unapproved use, false statements, mail/wire fraud
- January 2003 -- Manufacturer of wound care products
 - Indictment* of company and three individuals on charges of fraud relating to reimbursement, billing practices
- July 2002 -- Manufacturer of oxygen and patient monitors
 - Paid \$7 million to settle case involving sale of defective monitors to DOD/VA
- November 2001 -- Device company
 - Pays \$15 million for overcharging government under VA contracts
 - Settlement was result of company's voluntary disclosure

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Specific Sales and Marketing Activities (“Risk Areas”)

- Member-Sponsored Product Training/Education
- Sales & Promotional Meetings
- Arrangements with Consultants
- Third Party Educational Conferences
- Gifts & Meals
- Reimbursement & Other Economic Information
- Grants & Charitable Donations
- Emerging Risk Areas

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Member-Sponsored Product Training and Education

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Sales and Promotional Meetings



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Training / Sales Meetings

- Device companies have a responsibility to educate and train HCPs in the safe and effective use of products
- Modest meals and hospitality
- Venue conducive to effective communication
- Reasonable travel and lodging
- No grazing spouses

Training/Sales Meetings -- Challenges

- Competitive disadvantage?
- Grazing spouses
- Venues --
 - What venues are conducive to educational, clinical information exchange
 - What is a “lavish” venue
- Personal relationships
- The “modest” limitation on meals, receptions
- Sales/promotional meetings -- how to determine when travel/lodging is “necessary”

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Consultants

Consultants

- Device companies have need to engage HCPs as consultants for a variety of legitimate purposes
- Under the AdvaMed Code, companies may:
 - Pay reasonable compensation for *bona fide* consulting services
 - Pay reasonable and actual expenses incurred
- Factors indicative of *bona fide* consulting arrangements:
 - Agreement must be in writing, signed, specify services
 - Compensation consistent with fair market value
 - Legitimate purpose & need for services identified in advance
 - Selection based on consultant's qualifications and expertise
 - Venue & circumstances of meetings - appropriate, hospitality - modest, subordinate to meeting purpose
 - Written protocol for research services

Consultants -- Challenges

- Setting FMV compensation
 - Market for services tainted?
 - Gross or net revenue?
 - Stark as a model?
- Limiting expenses incurred
 - Clear, prospective guidelines
 - Audit and controls
- Limits on number of consultants
 - Limits at District, Regional level
 - Some companies have adopted limits based on specialty area

Consultants -- Challenges (cont'd)

- Establishing need
 - Prospective forecast of need
 - Right people in decision making capacities
 - Excluding sales & marketing per the OIG Guidance
 - Is anyone left
 - Practical concerns
 - Using the results
- Controlling venue selection
 - Lists and approval mechanisms

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Third Party Educational Meetings

Third-Party Educational Meetings

- Bona fide educational, scientific conferences
- Under the AdvaMed Code, companies can:
 - Provide funds to conference sponsor to reduce cost of meeting
 - Conference sponsor must select attendees
 - Provide funds to conference sponsor or academic institution for scholarships for HCPs in training
 - Conference sponsor or institution must select attendees
 - Provide modest hospitality for attendees if consistent with sponsor's guidelines

3rd Party Meetings -- Challenges

- When is a conference a conference?
 - Special considerations for customer sponsored conferences?
 - Look at location, subsidizing profitability, subsidizing marketing etc.
 - When is a subsidy actually the purchase of advertising?
 - Are there different rules for the purchase of advertising?
- Sponsor's may not be set up to pick and pay speakers, particularly in Europe
- When is an academic institution an academic institution?
 - Require accreditation or is an academic affiliation sufficient?
- Sponsor selected venues may not be modest
 - Even off-agenda locations may be controlled by sponsors

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Gifts & Meals

Gifts & Meals

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- Long-accepted that modest gifts can be provided to HCPs in a manner that is not intended as an inducement
- Under the AdvaMed Code, companies may give to HCPs:
 - Textbooks and anatomical models
 - Branded promotional items
 - Related to HCP's work or for benefit of patients
 - Of minimal value (e.g., pens, note pads)
 - Other gifts if:
 - Gift benefits patients or serves genuine educational function, and
 - Gift has Fair Market Value of less than \$100
 - Modest
 - Occasional
 - No cash or cash equivalents
 - Does not preclude legitimate practice of providing samples and opportunities for product evaluation

Gifts & Meals -- Challenges

- Type of Gift
 - No golf balls, T-shirts, flowers, gift baskets, meals, snacks, wine, other refreshments to HCP or HCP's office staff
 - Company mascots
- Value of Gift
 - Aggregate
 - Include tax?
 - Volume discounts?
 - Group practices
 - No dollar limit for textbooks and anatomical models
- Frequency of Gifts
 - No limit under Code -- what is "occasional"?
- Circumstances Surrounding Gift
 - As part of charitable event
 - Significant life events (e.g., birth, death of family member)

Gifts & Meals -- Challenges (cont'd)

- Government Employees
 - Follow federal, state and municipal laws
 - Tracking limits
- Creative Thinking
 - Splitting the cost with an HCP to stay within limit?
 - Creating patient benefit/educational/HCP-related items
 - Raffles?
 - Customer Appreciation items?
 - Detailing items?
- Sweepstakes
- Cash
 - Gift certificates
 - Coupons
 - Develop product evaluation agreements
 - Ensure no double-dipping



Gifts & Meals -- Challenges (cont'd)

- Samples
 - Establish and enforce rules
- Product evaluation
 - Set parameters
 - Set limits—number and time



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Reimbursement Advice and Support



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Reimbursement Advice and Support

- Appropriate for companies to provide accurate and responsible billing, coverage, coding, and reimbursement information to customers to support their products
- Companies may:
 - Provide economic efficiency and reimbursement info to HCPs and third party payors regarding their own products
 - Information limited to:
 - Identifying appropriate coverage, coding or billing of products or for procedures using these products, or
 - Costs, savings and revenues associated with the product.
 - Technical or other support for use or installation of Member's products
 - Company's own products
 - Inappropriate to provide services for the purpose of unlawfully inducing HCPs to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of products

Reimbursement -- Challenges (cont'd)

- Information on other companies' products
- General Practice Management Information
- Marketing the "Spread"
- Homegrown pieces
- Accuracy
- Dated information

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Grants and Charitable Donations

Grants and Charitable Donations

- Device company support for bona fide charitable activities is a public good
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- Under the AdvaMed Code, companies may:
 - Make donations:
 - to a charitable institution and to individuals engaged in a genuine charitable mission
 - for a charitable purpose, such as:
 - Indigent care
 - Patient education and public education
 - Sponsorship of events if proceeds are charitable
 - Advancement of education for HCPs-in-training
 - Support of research with scientific merit
 - Public education about health topics
 - All donations must be documented

Grants / Charities -- Challenges

- Assuring that the recipient is a charity & funds will be applied for a charitable purpose
- Distinguishing charitable grants to support research from contracted research
- Distinguishing the purchase of advertising from a charitable donation
- Establishing award processes and procedures that preclude involvement of sales and marketing
 - Is anyone left?
 - Information may reside in sales or marketing
- Can the desire to be seen as a good corporate citizen become the intent to inappropriately influence sales?
 - What about endowed chairs or events that honor customers?
- What to do with tickets to charitable events?

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Miscellaneous Risk Areas and Challenges

Other Risk Areas

- Discounts, Arrangements with GPOs/Wholesalers
- Compensation of sales representatives
 - Employees
 - Contract sales personnel
- FDA Regulatory Violations
- Evolving Theories of False Claims Act Liability
 - Implied certification theory
 - Examples of existing qui tam cases:
 - GMP violations
 - Patent/antitrust
- Intersection of FCA and Product Liability

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Other Challenges

- Hybrid Companies
- Competition with non-members
- Non-compliance by member-competitors

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Implementing and Effective Compliance Program:

How Does Your Company Measure Up?

Compliance Program Test

1. **Compliance Officer.** Does your company have a dedicated, senior-level Compliance Officer? (10 points)
2. **Code of Conduct.** Does your company have a Code of Conduct that requires officers and employees to comply with applicable laws, regulations and company policies? (5 points)
3. **Policies and Procedures – AdvaMed Code.** Has your company adopted written policies and procedures to implement the AdvaMed Code? (Up to 10 points)

Policies and Procedures – Other. Has your company adopted written policies or procedures to ensure compliance relating to discounts and pricing, off-label promotion, and product/office support? (Up to 10 points)

Compliance Program Test (cont'd)

4. **Training**. Does your company have written policies or procedures requiring officers and employees to receive periodic (at least annual) compliance training tailored to job responsibility and function? (10 points)

Training. Does your company require all officers and sales and marketing personnel to receive annual training on the Code of Conduct and the policies and procedures in Question 3, above? (10 points)

5. **Hotline**. Does your company operate a hotline that allows employees to report anonymously possible violations of law or company policy and protects employees against retaliation? (10 points)
6. **Investigation Procedures**. Does your company have a written policy or procedure for investigating allegations of non-compliance and preventing future violations? (5 points)

Compliance Program Test (cont'd)

7. **Compliance Audits**. Does your company conduct (at least) annual audits of compliance with law or company policy in the sales and marketing areas listed in Question 3, above? (10 points)
8. **Discipline**. Does your company have a written policy or procedure that requires the imposition of discipline for violations of law or company policy? (5 points)
9. **Supervision**. Does your company have a written policy or procedure that requires supervisors to take reasonable steps to ensure that employees within their span of control comply with applicable laws and company policy? (5 points)
10. **Reporting to the Board**. Does the Compliance Officer report at least annually to the Board of Directors and/or a designated Board Committee on the company's Compliance Program? (10 points)

Compliance Program Test (cont'd)

- **Total Score:** Add the points for Questions 1-10 above. To evaluate your total score, use the guidelines below:

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|---------------|-----------|
| • 90-100 | Excellent |
| • 70-89 | Good |
| • 51-69 | Fair |
| • 50 or below | Poor |