

# 2007 Medical Technology Industry Benchmarking Survey

Discussion of Survey Results

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# Presenters

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# Survey Background

As a follow up to its 2006 benchmarking survey on industry compliance practices, PwC, King & Spalding and Compliance-Alliance, conducted the 2007 Medical Technology Industry Benchmarking Survey.

## The Survey was designed to examine:

- The effect of the AdvaMed Code of Ethics on Interactions with Health Care Professional on firms' internal operations
- The challenges that companies were experiencing in administering their compliance programs
- What various stakeholders can do to encourage more robust and effective compliance measures in the medical device industry

# Implementation of the AdvaMed Code

The Code continues to play an important role in driving sales and marketing compliance efforts within the medical device and diagnostics sectors.

- As of February 2007, more than 500 medical device companies and/or subsidiaries have designated a compliance officer to oversee their company's compliance with fraud and abuse laws and implementation of AdvaMed Code

# Implementation of the AdvaMed Code

Companies are continuing to enhance their sales and marketing compliance functions through activities such as training, monitoring and auditing.

- 72% of respondents said their companies audit for compliance with the AdvaMed Code. Most often, these audits are handled by internal personnel (more than 75%) and
- 47% of respondents said their companies had added headcount to implement the AdvaMed Code, with 25% reporting that their company added two or more FTEs to support the Code's implementation
- 92% of respondents said implementing the AdvaMed had no negative impact on (82%) or actually improved (10%) their companies' financial results

# Implementation of the AdvaMed Code

A strong commitment to improve compliance was observed in the companies surveyed

The expansion of the Code's adoption, and increased compliance of the Code's suggested sales and marketing practices will require efforts by three important stakeholders:

- Medical technology manufacturers,
- Regulatory and enforcement agencies, and
- Physician professional societies

# Challenges in Adopting the Code

One of the primary goals of the Survey was to gain a better understanding of the challenges companies are experiencing when adopting the Code and other sales and marketing compliance safeguards

The Survey found that the three most significant challenges are:

- Lack of clear industry-specific regulatory guidance on what sales and marketing practices are and are not unlawful,
- Lack of awareness of (or disregard for) laws and industry codes of conduct among physicians and other customers,
- Insufficient management time and resources

# Challenges in Adopting the Code

## Challenge: Lack of Clear Industry-Specific Regulatory Guidance

- 66% of respondents rated lack of governmental guidance as among the top three challenges to implementing a comprehensive commercial compliance program
- 56% of respondents said lack of regulatory guidance was a barrier to implementing the AdvaMed Code
- 41% of respondents said lack of clarity from government (as to what conduct is unlawful) was the first or second biggest challenge to implementing a comprehensive compliance program
- Almost 60% of respondents disagreed or strongly disagreed that government enforcement agencies have public clear guidance as to what types of sales/marketing activities are and are not unlawful

# Challenges in Adopting the Code

Challenge: Competitors continue to engage in improper behavior and Customers continue to expect it

- The need to match sales and marketing practices of competitors was rated as the most significant challenge towards implementing a compliance program (64%)
- Customer expectations was the second most significant challenge (44%)
- 75% of respondents said their companies had received some (62%) or substantial (15%) resistance from customers in striving to comply with the AdvaMed Code

***The “demand” side of the equation is a major challenge for companies in the implementation of effective compliance programs***

# Challenges in Adopting the Code

## Challenge: Insufficient management time and resources

- 35% of companies reported they did not have a cross-functional compliance committee composed of senior management personnel
- 29% of respondents said getting management to make time was the most significant challenge in training personnel on sales and marketing compliance policies
- Lack of resources or time was one of the most common complaints

# So what do these challenges mean?

The challenges can be summed up in three major themes:

- Government can help the industry succeed
- Compliance is not just for the manufacturers
- Companies need to invest for success

# Government can help the industry succeed

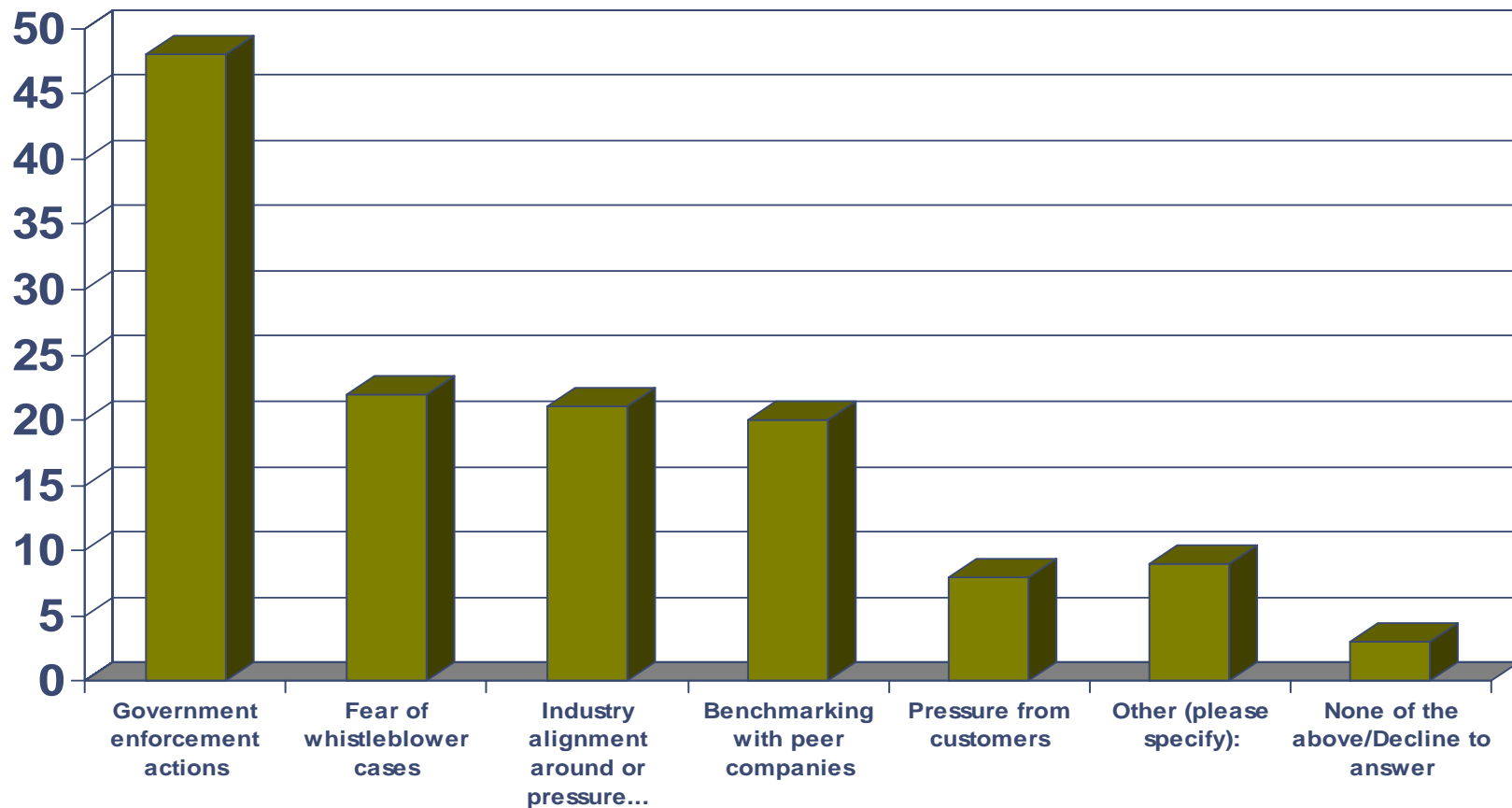
The government could level the playing field through better guidance for Medical Device specific activities and visible enforcement on HCPs who receive or solicit improper acts (equal enforcement)

## Survey Commentary

- 59% believe that government enforcement agencies have not published clear guidance on lawfulness of medical device-specific sales/marketing activities
- 75% indicated that government enforcement action is the most effective way of convincing senior management of the importance of compliance
- 64% of survey respondents agree or strongly agree that Government officials should prosecute those who receive inappropriate payments from medical device firms

# Government can help the industry succeed

*Government enforcement actions have been among the most effective means of convincing senior management of the importance of compliance*



# Government can help the industry succeed

Companies are seeking clear credit for self-disclosure and compliance program quality and disclosure protection for internal compliance audits

## Survey Commentary

- The major barriers for self-disclosing included:
  - No certainty or guidance as to how the Government will respond,
  - Disclosure might waive privileges as to material and info that could be used by 3rd parties against the company,
  - Belief that it offers little or no credit in an investigation
- 75% indicated that the DOJ and OIG do not give adequate credit to companies that self-disclose potential violations of laws

# Government can help the industry succeed

## Recommendations

- Engage the industry to provide clear guidance around medical device industry-specific topics and issues
- Communicate the exposures that counterparties face for soliciting or accepting improper incentives through visible, equal enforcement of the counterparty
- Provide demonstrable examples of the benefits to a company of self-disclosure and a high quality compliance program
- Encourage self-audits by providing third-party disclosure protections for the results

# Compliance is not just for the manufacturers:

Survey results indicate continued pressure on manufacturers from customers and competitors to act unethically

## Survey Commentary

- Market and customer expectations need to be adjusted to reflect the new reality
- Customer “demand” can be outside of regulatory guidelines
- HCP education should begin “at the medical school level”
- Companies expressed a need for:
  - Customers to better understand allowable interactions, and
  - Greater enforcement on HCPs who drive or benefit from improper transactions

# Compliance is not just for the manufacturers:

All parties should recognize their role in promoting ethical business behavior

- Customer societies should include Code of Conduct training and interaction limits at annual meetings, CME programs and publications
- Highlight the guidelines of accepting gifts, requesting funding and engagement with the industry

# Compliance is not just for the manufacturers:

## Recommendations

Customers and Physician Societies should help compliance environment by reducing pressure on medical device companies

- Communicate to members that the environment has changed
- Reinforce that compliance is good for patient health and outcomes
- Include Ethics and Compliance training at all levels: medical schools, CME programs, industry organizations, etc to manage customer expectations

## Companies need to invest for success:

Investment in and commitment of resources surrounding training, technology, time, and staff are the beginning steps to achieving success in compliance.

### Survey Results:

- 40% face challenges with obtaining the necessary time for training
- Main challenges in implementing a compliance committee and monitoring compliance activities:
  - Lack of resources,
  - Unclear roles,
  - Company size and bandwidth
  - Inadequate systems for capturing the necessary data.

# Companies need to invest for success:

Senior management leadership necessary to drive compliant behavior through the organization

## Survey Results:

- Key success factor listed is senior management involvement in, and commitment to, the compliance program
- 35% don't have compliance committee comprised of senior cross-functional management due to lack of resources or time
- On the positive side,
  - 64% of respondents said compliance personnel periodically provide reports to the CEO (82%) and Board of Directors
  - 72 percent of respondents said their companies audit for compliance with the AdvaMed Code. More than 75 percent said internal personnel handle these audits

# Companies need to invest for success:

## Recommendations:

- **Policies:** Expand their sales and marketing policies to address risks beyond those currently in the AdvaMed Code
- **Controls:** Develop effective controls around consultants, speaker programs, and educational and research funding
- **Incentive Compensation:** Ensure that sales compensation and performance evaluations strike the proper balance between sales performance and compliance requirements
- **Education:** Make time for more sophisticated training, moving beyond “basic” fraud/abuse
- **Compliance Auditing:** Continue to implement or expand compliance monitoring and auditing

# **Selected Benchmarking Results**

# We asked...you answered

## Compliance Training Techniques

- Use of in-person instructors in interactive training with real-life examples. Individuals should have gravity in the organization (senior management, High-performing Sales Reps who “walk the walk”)
- Web based training and testing – most recommended were LRN and EduNeering
- Reinforced training annually during regional and national sales meetings
- Corporate white papers distributed to all personnel

# We asked...you answered

## Forming a Compliance committee

- CEO support and involvement
- Message: “Compliance is not an option”

## Continuous communication

- Quarterly Ethics bulletin
- Include compliance discussions during routine conference calls

# We asked...you answered

## Fair Market Value

- Use of MGMA Physician Comp Survey

## Off-Label Promotion Controls

- Training, training, training
- Review of copy by legal/regulatory

Questions?

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