

# Medical Device Compliance Survey

## Discussion of Survey Results



# Survey Background

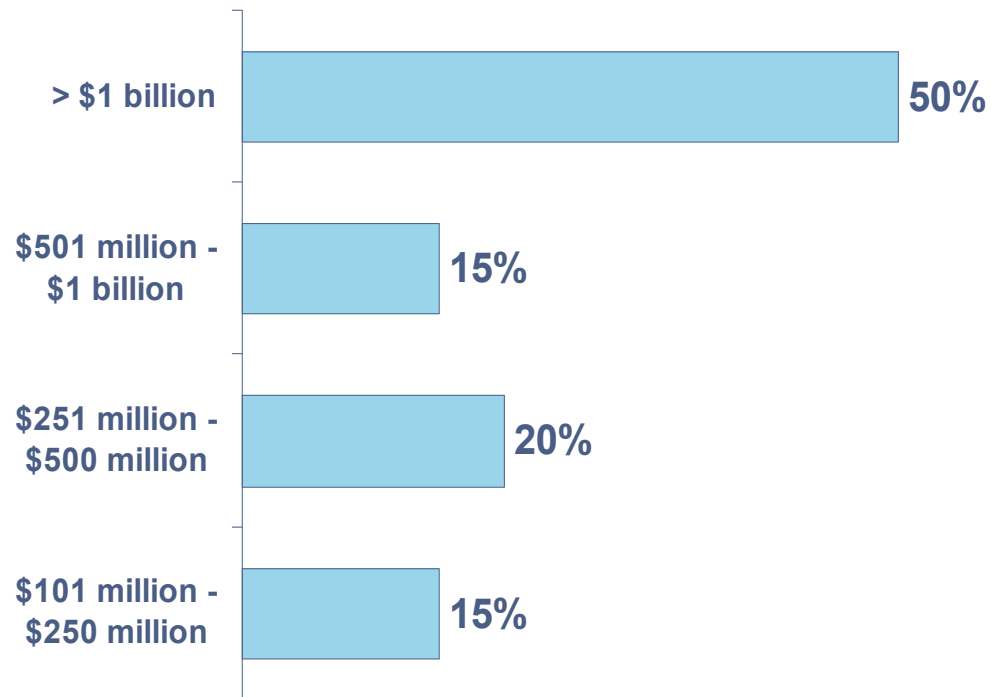
PwC conducted an in-depth benchmarking survey on medical device industry compliance practices

Together with King & Spalding and Compliance-Alliance, PwC:

- Worked with an advisory committee of device company compliance personnel to ensure survey questions were relevant
- Invited 30 medical device companies to participate in the 35-question survey; 20 agreed to participate
- Analyzed the data to identify the better practices in the industry

# Survey Demographics

Distribution of 2004 Global Sales for the twenty firms that participated in the survey:



# General Compliance Environment

The industry has overwhelmingly adopted the AdvaMed Code

About two-thirds of companies' presidents or CEOs have personally endorsed the AdvaMed Code in a written statement addressed to company employees and/or customers.

The general impression among the companies surveyed is that compliance with the AdvaMed Code varies depending on company size, market presence, and geography

# Gifts, Meals, and Entertainment

## Survey Results

Companies have implemented controls over gifts for HCPs to varying degrees

- Practices mixed as to whether pre-purchase approval occurs centrally or locally
- Value of individual gifts vs. frequency of gifts
- Restriction of the types of interactions in which gifts can be given
- Variability in definition of “reasonable”/“modest” meals and entertainment

## Better Practices

- List of pre-approved gifts from which reps can purchase, and gift-giving is only permitted for specified interactions
- Quantified measures of “reasonable”/“modest”
- Gift/meal/entertainment limitations are applied to all employees, regardless of title
- Gift/meal/entertainment expenses are tracked by HCP in aggregate spend analyses

# Engagement of Healthcare Professionals

## Survey Results

- Most companies have instituted robust controls over the engagement of healthcare professionals, including:
  - Approaches to determining Fair Market Value (FMV).
  - Ensuring value is received for engagement of HCPs.

## Better Practices

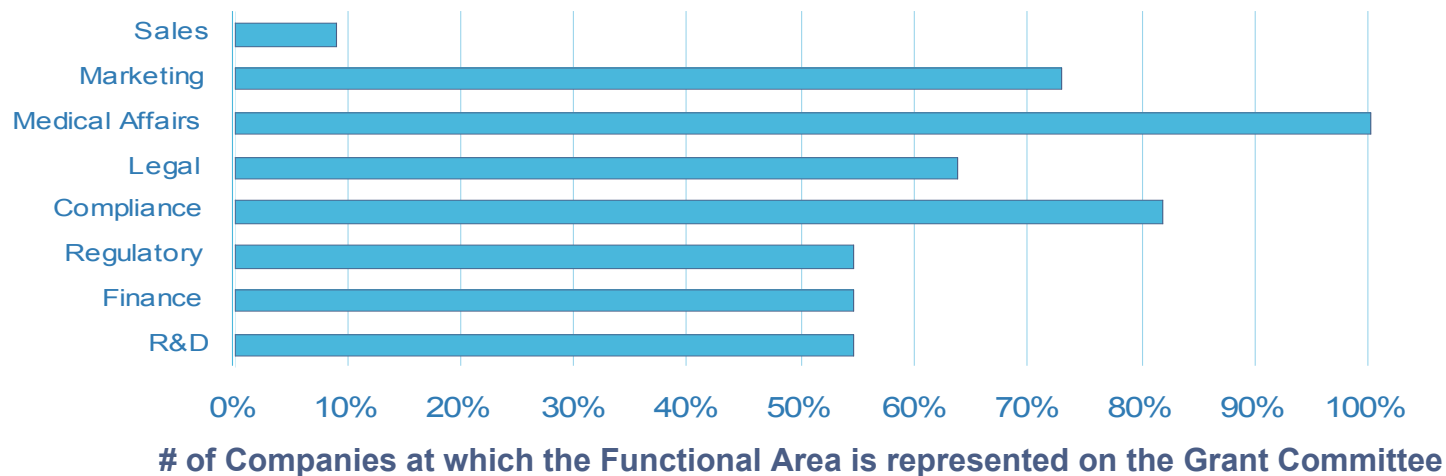
- Contracts for each engagement that include “anti-kickback” language
- Articulated standards for consistent determination of FMV
- Limits on frequency and value of engagements
- Domestic coach travel, International business travel
- Evidence obtained of services received and used
- Establish annual limits on total value of compensation paid to HCPs
- Reduce involvement of sales force in selecting participants

# Educational and Research Grants

## Survey Results

Companies continue to place restrictions around the involvement of the sales force for the distribution, receipt, processing, and approval of grant requests

There is growing use of grants committees for approval of educational/charitable grants and research grants. While sales is decreasingly owning budgets, sales and marketing are major participants on the committees:



# Educational and Research Grants, continued

## Survey Results, continued

### Charitable Contributions

- Most companies have established controls over charitable grants, with articulated selection and giving criteria.
- The sales force is excluded from the decision making process.
- Many companies have monitoring processes in place to ensure that denied educational or research grant requests are not resubmitted as charitable grant requests.

# Educational and Research Grants, continued

## Better Practices

- Involvement of sales force is limited to guiding requestors on how to initiate a request
- Requests are supported by a request letter, and business purpose is documented
- Requests are reviewed by a grants committee (or separate committees for research and non-research grants) or Compliance/Legal
- Proof of performance is required, and payments are made directly to the recipient

# Speaker Programs

## Survey Results

Most companies track and obtain detailed information on attendees

Sales Force commonly involved in identification/selection of HCPs for speaker bureaus

Most companies review and/or approve speaker program content prior to event:

- Review by Legal, Regulatory, Medical/Scientific, and/or Compliance functions

## Better Practices

- Speakers and speaker content pre-trained and pre-qualified, with honoraria determined through FMV calculation
- Policies on meals and entertainment applicable to speaker program events
- Tracking of attendance of HCPs at events
- On-site compliance monitoring of speaker programs

Questions?

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