Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Pre-Conference III: Auditing, Monitoring and Effective Internal Investigations

October 27, 2008

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Implementing a Compliance Monitoring Program

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Agenda

- **Introductions**

- **Implementing a Compliance Monitoring Program**

  - ✓ **Understanding the differences between monitoring and auditing**

  - ✓ **Establishing an effective compliance monitoring program**

  - ✓ **Case Study: Use of monitoring tools**

- **Q & A**

Presenters

- **Christopher Santarcangelo,** Assistant Director of Corporate Compliance, Purdue Pharma L.P.

- **Jonathan Williams,** Associate Director, Healthcare Compliance Office, Genentech, Inc.

- **Tracy Mastro,** Director, Huron Consulting Group

Compliance Monitoring and Auditing

Implementing a Compliance Monitoring Program

Compliance Monitoring and Auditing

- One of the seven key elements of an effective Corporate Compliance program (HHS Office of Inspector General)

- Facilitates the identification and mitigation of compliance risks and improvement of internal controls

- Should be used to:

  – Measure and benchmark a Compliance program's effectiveness and impact on business activities

  – Document Company's compliance with internal written controls

Compliance Monitoring and Auditing

- May be used to test the execution and effectiveness of functions at the core of a Compliance program, such as:

  – Compliance training

  – Employee and vendor screening

  – Disciplinary actions

- Should be used to measure a Compliance program's progress in attaining higher levels of compliance as the program matures

Key Objectives of Monitoring and Auditing

	Auditing	Monitoring
1. Purpose	• Retrospective • Processes and procedures comply with laws, regulations, policies	• Retrospective or prospective (live) • Daily activities to assess achievement of objectives
2. Scope/ Focus	• Internal controls and processes related to general business standards/policies	• Activities and transactions related to specific function/process/dept • Internal and external focus
3. Activities	• Periodic, structured reviews • Conducted by independent staff	• Validate/measure performance • Business units self-monitor
4. Frequency	• Determined by risk-based audit plan • "Snapshot" in time	• Determined by frequency of transactions • Ongoing process
5. Reporting	• Formal audit report with findings and recommendations	• Variance analysis, exception reporting, performance metrics

The Monitoring and Auditing Cycle

Establish/Revise Policy ①

⑦ **Revise Processes, Training, Systems**

Develop Processes (system and non-system) ②

⑥ **Assess and Report Results/Findings**

Train on Policies and Processes ③

⑤ **Monitor Processes and Conduct Audits**

④ **Develop Auditing and Monitoring Programs**

Implementing a Compliance Monitoring Program

Establishing an Effective Compliance Monitoring Program

Establishing a Monitoring Program

Establish Foundation	Design and Execution	Assess and Report

Establish Foundation
- Tone from the Top
- Organization Structure
- Baseline Understanding of the Effectiveness of Internal Controls
- Additional Internal Controls Implemented (if necessary)

Design and Execution
- Prioritize Compliance Risks
- Identify Relevant Operating Controls
- Identify Individuals Responsible for Monitoring
- Design and Implement Monitoring Procedures

Assess and Report
- Prioritize and Report Results and Findings
- Identify Correction Action(s) and Follow-Up
- Assign Individuals Responsible for Corrective Action

Establishing a Monitoring Program

Design and Execution

- Monitoring should be based on:

  - A fundamental analysis of compliance and business risks, and

  - An understanding of how key controls may/may not manage or mitigate risks

- Monitoring procedures also should be based on a Company's unique compliance risk profile

  - Prioritization of risks helps identify which risks are meaningful enough to subject to compliance monitoring

  - Results of risk assessments will influence decisions regarding the type, timing, and extent of monitoring

Establishing a Monitoring Program
Assessing Compliance Risks

Gap Analysis and Monitoring Plan
Internal monitoring groups evaluate the level of risks for each process and establish the extent of the monitoring for each process

7

Risk Identification
Using SMEs identify key **compliance risks** or **risk areas** (events or issues that will impact outcome of company's objectives).

1

6

Process Risk Prioritization
Link risks and processes with an exercise that creates ownership by process owners and agreement with compliance groups

2

Risk Ranking
Develop ranking methodology to provide an objective transparent quantification of potential harm from non-compliance

5

Risk Stratification Matrix
Develop a transparent method to rank the risk of a process and its relative relationship with compliance risks

3

Risk Assessment
Prioritize risks based on Inherent nature (i.e. impact and likelihood)

Inherent Risk Prioritization

4
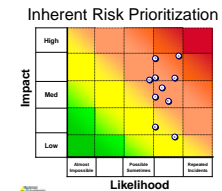
Business Processes and Owners
Identify business process and owner(s) that are exposed to each risk and the extent of their exposure
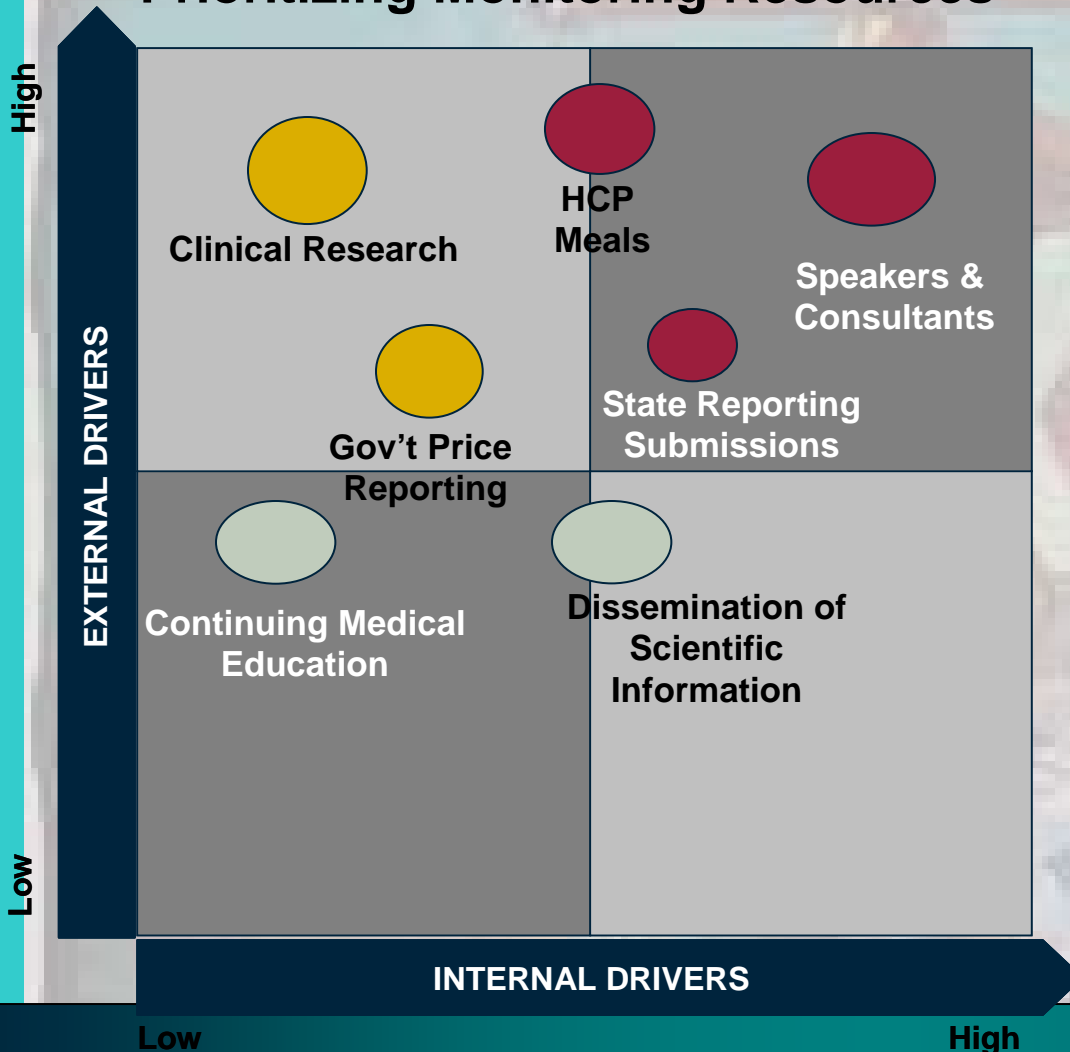
Establishing a Monitoring Program

Design and Execution (cont'd)

- Monitoring should reflect a Company's internal written controls and control structure

- Determine the key controls that are important in managing or mitigating identified compliance risks

    – Key controls are those that are most important to monitor

    – A focus on key controls helps ensure that the Company devotes monitoring resources efficiently and where they will provide the most value

Establishing a Monitoring Program
Prioritizing Monitoring Resources

High

EXTERNAL DRIVERS

Clinical Research

HCP Meals

Speakers & Consultants

Gov't Price Reporting

State Reporting Submissions

Continuing Medical Education

Dissemination of Scientific Information

Low

INTERNAL DRIVERS

Low — **High**

External Drivers

- CIA
- Regulatory
- Legal
- Enforcement Action
- Industry Standards
- Public Opinion
- Media/Press

Internal Drivers

- Organizational Structures
- Organizational Change
- Operational Exposure
  - Complexity
  - Automation
  - Committed Resources
  - Recent Changes
- Self-Assessment
- Historical Audit Results
- Technology Capabilities

Implementing a Compliance Monitoring Program

Establishing a Monitoring Program

Design and Execution (cont'd)

- Monitoring procedures should be developed to reflect a Company's unique risk profile. For example:

  - Older products may represent kickback issues

    - Not much clinical discussion with sales representatives

    - Services offered to customers could be used to influence prescribing (e.g., grants, promotional speaking)

  - New products may represent off-label promotion risks

    - Dosing

    - Product used in combination with other therapies

Establishing a Monitoring Program

Design and Execution (cont'd)

- There are different way to measure risk. For example:

  - Number of statutory/regulatory violations

    - Kickbacks (e.g., payments to HCPs, marketing the spread)

    - Off-Label activities (e.g., requests for off-label information)

  - Number of policy violations

    - Compliance issues with policies (e.g., promotional speaker programs)

    - Compliance issues with processes (e.g., state reporting requirements on Travel & Expense reports)

Establishing a Monitoring Program

Assess and Report

- Results of monitoring should either:

  - Confirm previously established expectations about the effectiveness of internal controls, or

  - Highlight identified deficiencies for possible corrective action

- Results should be compiled, analyzed and reported to appropriate personnel for information and/or action

Establishing a Monitoring Program
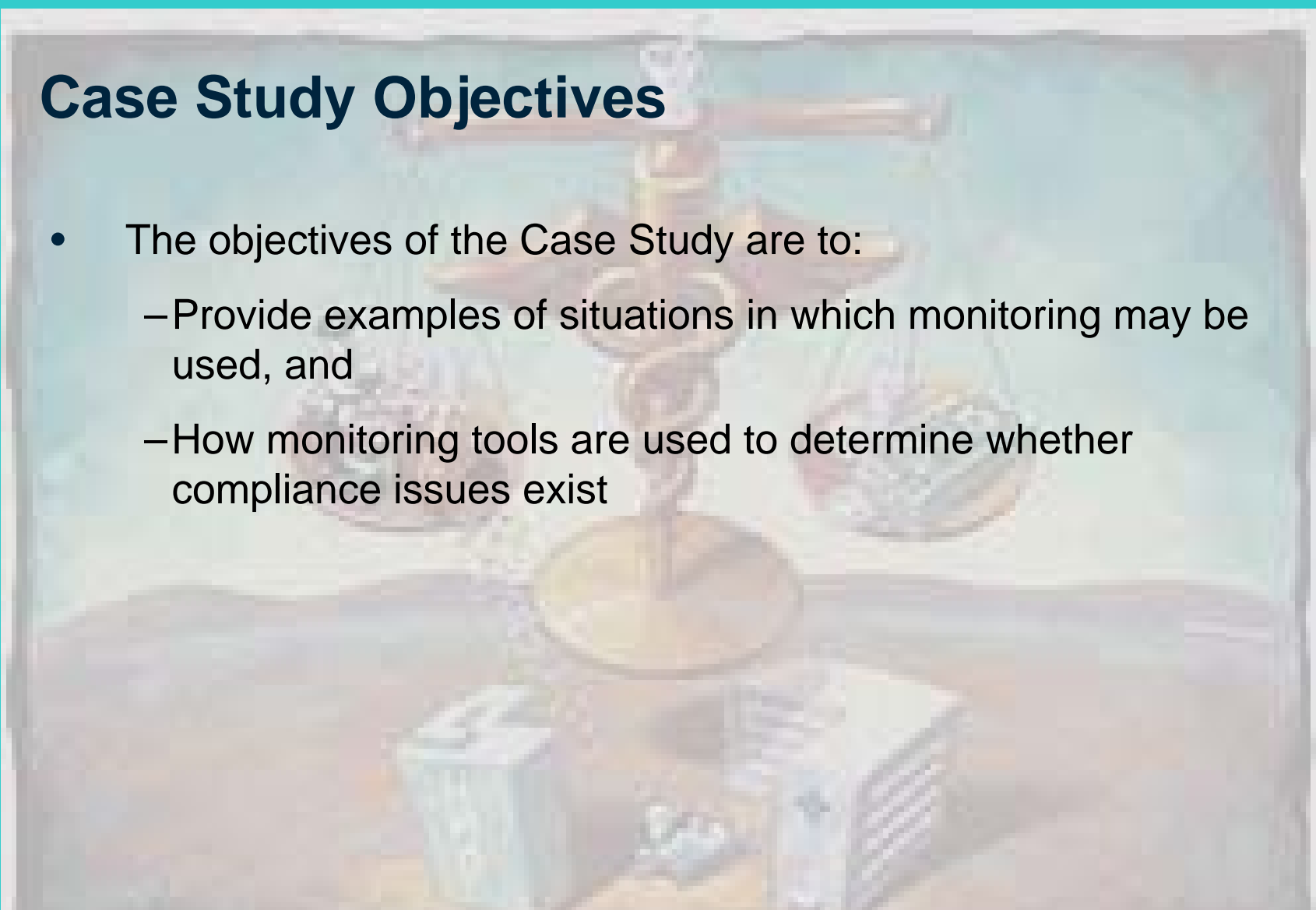
Effective Programs

- Properly designed and executed, effective monitoring programs:

  – Provide the right information to the right people (e.g., Compliance, business units) regarding effectiveness

    • Effectiveness defined through identification of criteria, measures, and metrics

  – Identify and communicate internal control deficiencies in a timely manner

  – Facilitate the correction of control deficiencies before they materially affect the achievement of a Company's objectives

Case Study: Use of Monitoring Tools

Case Study Objectives

- The objectives of the Case Study are to:

    – Provide examples of situations in which monitoring may be used, and

    – How monitoring tools are used to determine whether compliance issues exist

Case Study Scenario

- Company X recently a new Oncology product launch in January 2008

  – The new product was approved for Lung cancer

  – There are studies that show the product's potential effectiveness in Thoracic cancer, an off-label use

- The product's Brand Plan reflects that Company X has been using promotional speaker programs, Advisory Board meetings, and CME to inform physicians about its new product
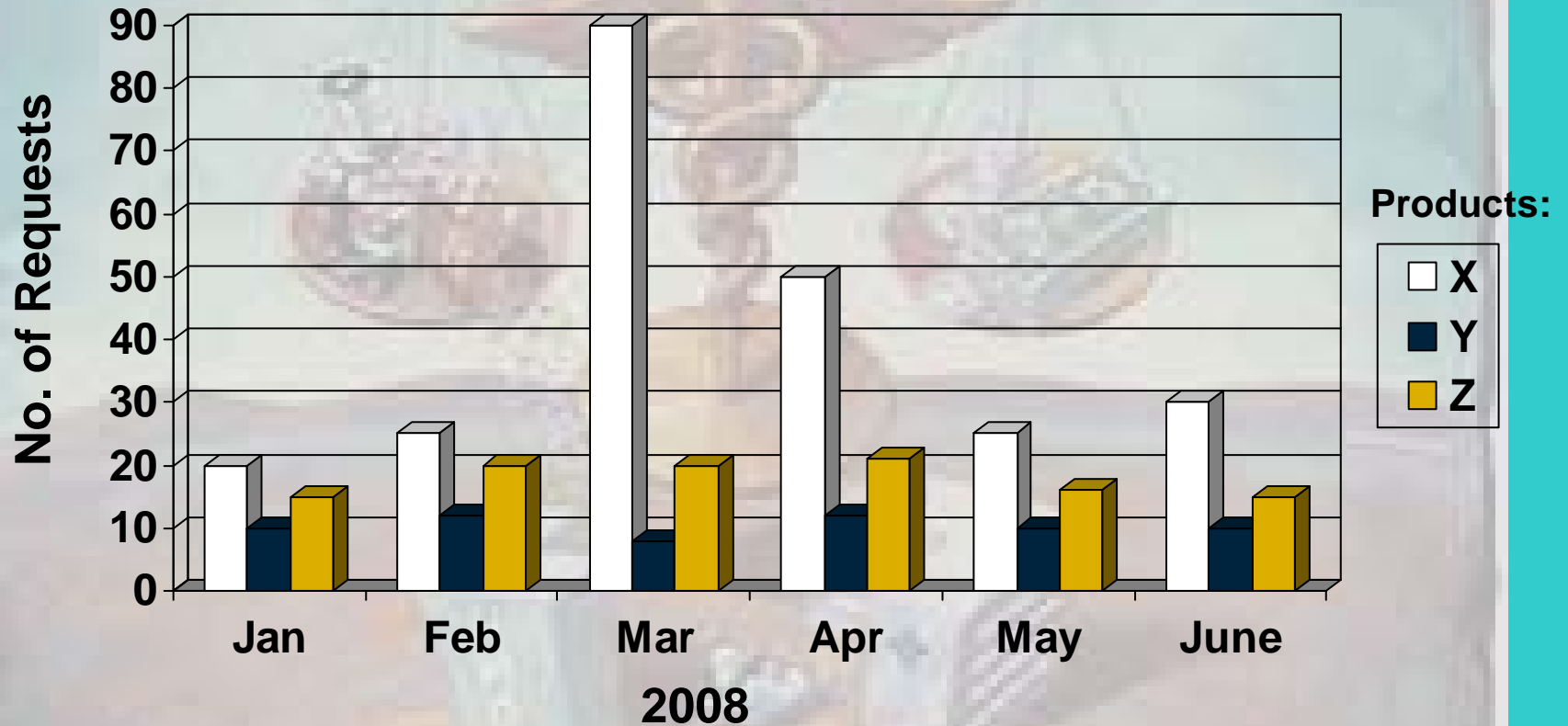
Case Study: Monitoring Activities

Medical Communications

- During the ongoing Medical Communications monitoring process, the Compliance unit discovered a spike in requests for off-label information for Product X in March of 2008

- Compliance looked at the monitoring data for requests coming in since January 2008 and identified the following trends
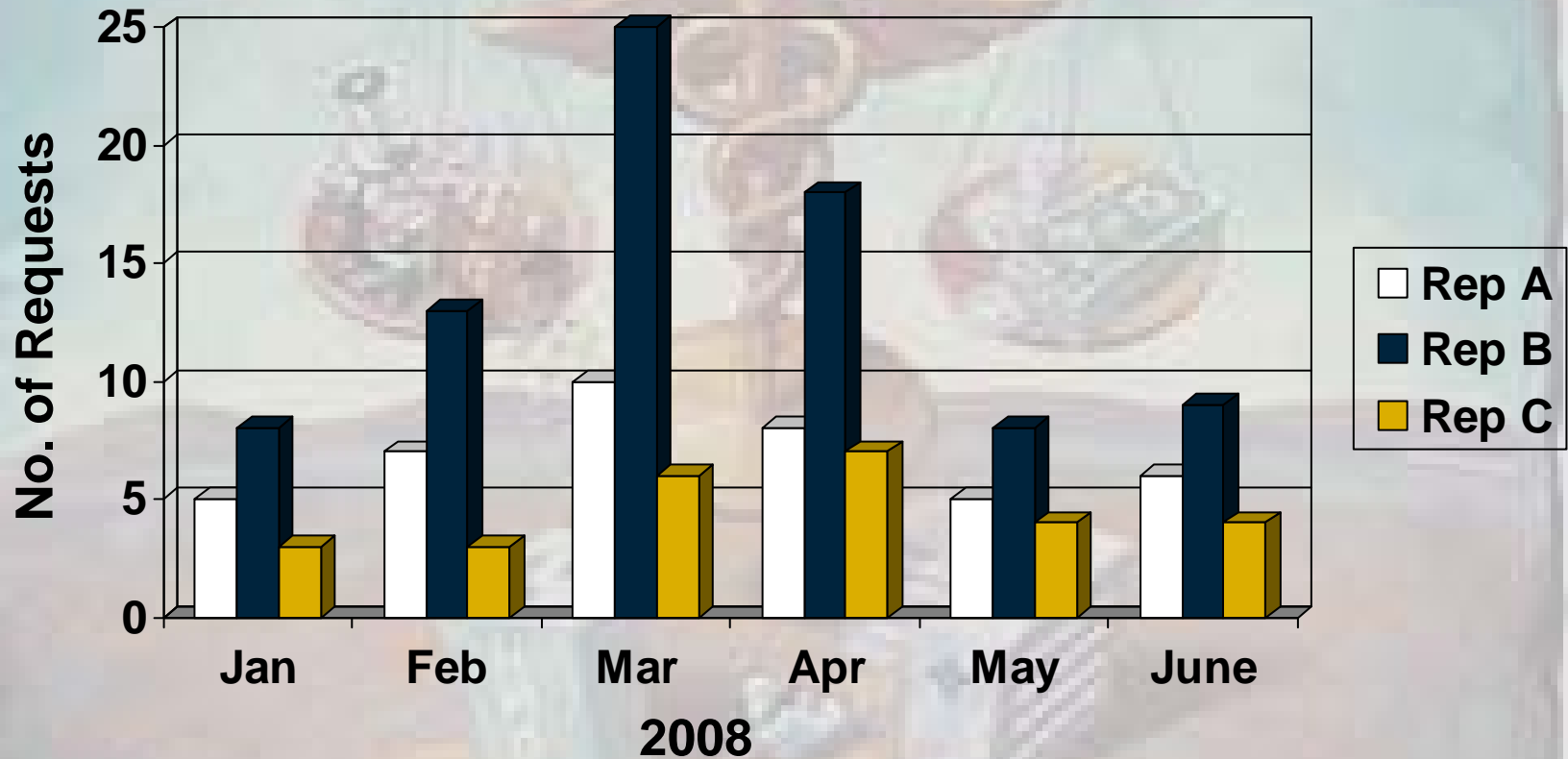
Case Study: Monitoring Activities

Medical Information Requests by Product

Case Study: Monitoring Activities

Requests by Product X Sales Rep

Case Study: Monitoring Activities

Important Data Reference Points

- Requests for off-label information
  - Dates of conferences/meetings
  - Trends in requests (e.g., by region, sales rep)
  - MSL activities
  - Other activities in region
  - Internal communications to sales force

- Advisory Board meetings

- Promotional Speaker programs

- Continuing Medical Education meetings

Case Study: Monitoring Activities

Sales Representative Ride-Along

- Inform Sales Rep and DM of ride-along

- Compliance monitor identified generically as being from "home office"

- Sales Rep behaviors monitored:
  - Conversations with DM
  - Interactions/discussions with physician(s), nurses and office staff
    - Discussions of grants, CME programs, sponsorships, other consulting opportunities
  - Comments made by physicians, nurses and/or office staff to sales rep
  - Use of reprints/other leave behind materials

Questions?

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