

*The Pharma, Biotech and Device Colloquium
Compliance Pre-Conference Workshop
Monday, June 6, 2005*

A Primer on Compliance Programs for Pharmaceutical and Medical Device Companies



Louise Mehrotra
VP WW Health Care Compliance
Johnson & Johnson

Kathy Lundberg
SVP/Chief Compliance Officer
Guidant Corporation

Johnson & Johnson

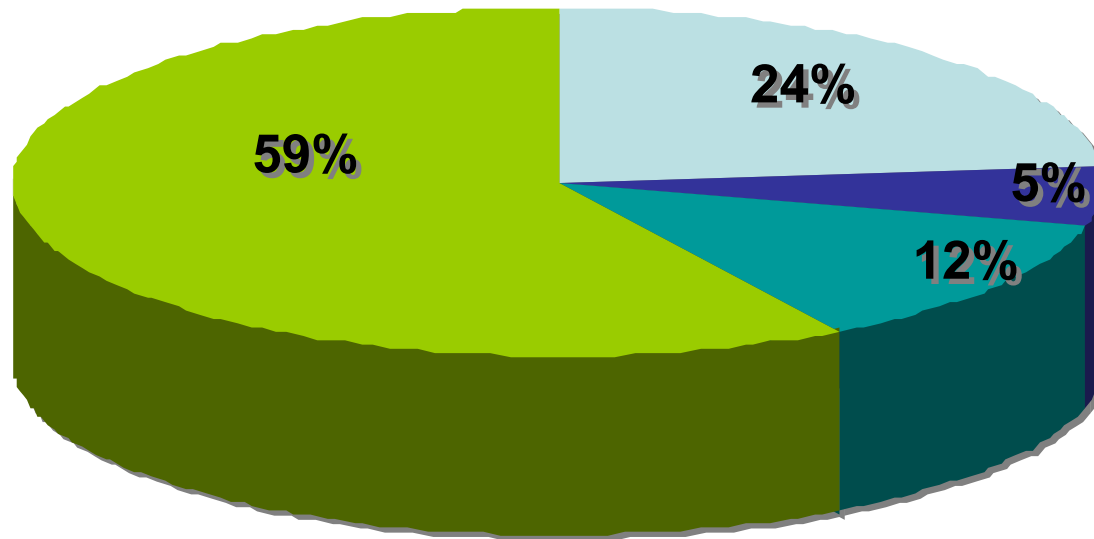
World's Most Comprehensive and Broadly Based Health Care Company

- **2004 Sales of \$47.3 Billion**
- **Over 200 operating companies in 57 countries around the world**
- **Leadership positions in ethical and OTC pharmaceuticals, medical/surgical supplies, diagnostics and a variety of consumer products**
- **Broad based, diverse portfolio of products**



Worldwide Net Trade Sales By Geographic Area

2004



U.S.



**Asia Pacific &
Africa**

\$47.3 Billion



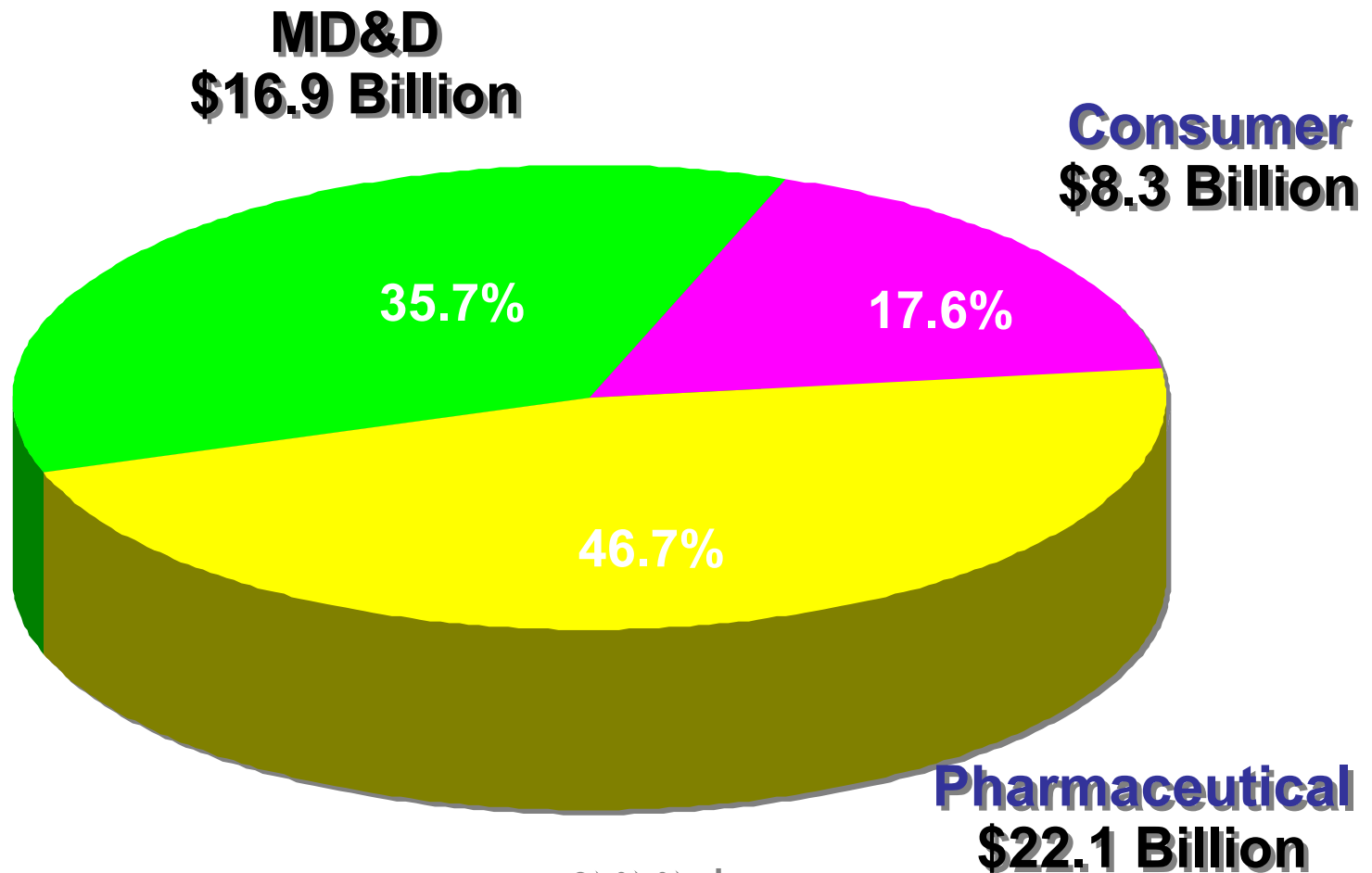
W. Hem (ex. US)



Europe



Sales by Segment



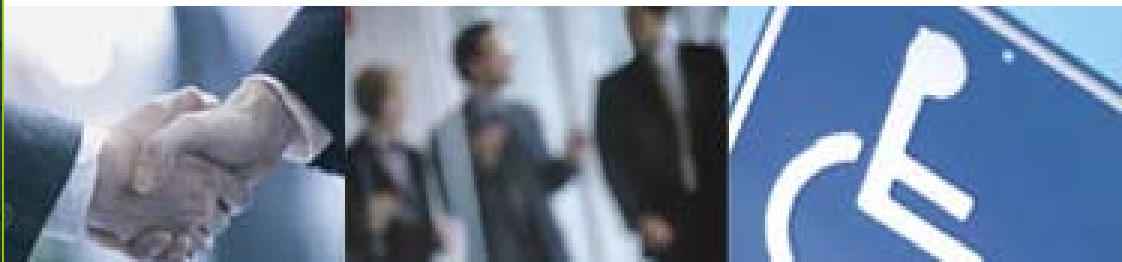
2004





Guidant Corporate Profile

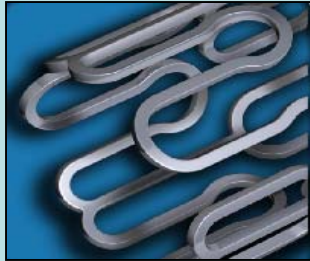
- **Indiana-based company selling products in 100 countries around the world**
- **Leader in design and manufacture of cardiac and vascular devices and therapies**
- **Business units with up to 30 years experience in key markets**
- **Over 12,000 employees worldwide**
- **GDT traded on the NYSE and PCX**



Guidant Corporation Structure

Geographic Operations

VI



**VASCULAR
INTERVENTION**

ES



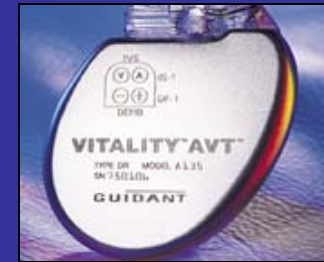
**ENDOVASCULAR
SOLUTIONS**

CS



**CARDIAC
SURGERY**

CRM



**CARDIAC RHYTHM
MANAGEMENT**

COMPASS

Headquarters



Overview

- Why are Compliance Programs Important?
- History and Basics of the U.S. Sentencing Commission Guidelines
- HHS OIG Compliance Program Guidelines
- Compliance Program Basics
 - Written Standards of Conduct
 - Leadership and Infrastructure
 - Education and Training
 - Internal Communications and Reporting
 - Monitoring and Auditing
 - Enforcement of Disciplinary Standards
 - Responding to Detected Offenses
- Concluding Thoughts



Why Are Compliance Programs Important? (Or ... Who Cares?)

- Effective programs can prevent wrongdoing and lessen the damage when violations do occur.
- A credible compliance program can be influential at key stages of the investigative and enforcement processes:
 - Whether to continue or expand an investigation
 - Whether to turn investigatory results over to prosecutors
 - Whether to charge a company with wrongdoing
 - Whether to pursue criminal or civil charges
 - Whether to settle a case and, if so, on what terms
 - Whether to pursue exclusion or debarment of a company



U.S. Sentencing Commission Guidelines

- The 1984 Sentencing Reform Act created the U.S. Sentencing Commission and directed it to develop guidelines for sentencing of individuals and entities convicted of Federal crimes.
- Sentencing guidelines for individuals were issued in 1987. The Guidelines for Organizations (including corporations convicted of Federal crimes) were issued in 1991.
- Effect under the Guidelines:
 - An effective compliance and ethics program is one of mitigating factors that can reduce a company's fine
 - Absence may be a reason to place a corporation on probation
 - Implementation of a program may be condition of probation



USSC Guidelines (cont'd)

- The original guidelines defined an “effective compliance program” as having seven “elements”
 1. Standards and procedures for employees
 2. Specific high-level individual(s) must be assigned overall responsibility for compliance program
 3. Exercise of due care not to delegate substantial authority to individuals
 4. Training and communication of standards to employees and agents
 5. Reasonable steps to achieve compliance – both through auditing and monitoring programs and internal reporting systems
 6. Consistent enforcement of disciplinary standards
 7. Steps to respond to reported misconduct and prevent future violations



USSC Guidelines (cont'd)

- Recent amendments (effective November 1, 2004) strengthened each of the seven elements (and arguably added a new element).
- Among the major changes:
 - Compliance programs should be designed to reasonably prevent and detect all violations of law (not just crimes)
 - Significantly expands responsibility of “governing authority,” including a requirement to “otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance ...”
 - Requires “high-level personnel” to have ultimate responsibility for program
 - Requires adequate resources to implement the program
 - Extends training requirement to all levels of the organization
 - Requires periodic evaluation of program effectiveness
 - Adds duty to promote program conduct through incentive to existing requirement to ensure enforcement of discipline for wrongdoing



USSC Guidelines (cont'd)

- Arguably adds new “element” – a requirement to implement an on-going process to assess the risk of violations and to take steps to address such risks
- Bolsters provisions relating to “small organizations” (defined as those with less than 200 employees)
- States that waiver of attorney-client privilege and work-product protections “is not a prerequisite to a reduction in culpability score ... unless such waiver is necessary in order to prove timely and thorough disclosure of all pertinent information known to the organization.”



Introduction to HHS OIG Guidelines

- The OIG has issued “Compliance Program Guidances” for 11 health care industry sectors – most recently for pharmaceutical manufacturers (May 5, 2003, 68 Fed. Reg. 23731-43).
- The Pharmaceutical Guidance states that it “may have application to manufacturers of other products ... such as medical devices”
- Each Guidance is voluntary and “represents the OIG’s suggestions” on how to implement a compliance program. The Pharmaceutical Guidance states:
 - “The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers.”
 - “This guide is not a compliance program. Rather, it is a set of guidelines that ... manufacturers should consider when developing and implementing a compliance program”



HHS OIG Guidelines (cont'd)

- Each OIG Guidance is organized around “seven elements that have been widely recognized as fundamental to an effective compliance program.”
- These “seven elements” are:
 1. Implementing written policies and procedures
 2. Designating a compliance officer and committee
 3. Conducting effective training and education
 4. Developing effective lines of communication
 5. Conducting internal monitoring and auditing
 6. Enforcing disciplinary standards for wrongdoing
 7. Responding promptly to detect programs and undertaking corrective action



Policies and Procedures

- Written policies and procedures should be developed under direction of Compliance Officer and distributed to all relevant employees
- Policies and procedures should include:
 - *Code of Conduct*: A high-level document that details the fundamental principles, values, and framework for action within a company. It should be brief, understandable, and cover principles applicable to all employees.
 - *Detailed policies in specific risk areas*: These policies should address risk areas specific to a company's business activities, organizational structure, and regulatory requirements.
- While policies – alone – do not constitute an effective program, much of an effective program flows from written standards of conduct



Compliance Officer and Committee

- Every company should designate a high-level official to serve as the Compliance Officer. May be full- or part-time.
- Should have access and regularly report to the Board of Directors and Senior Management.
- Should have authority to effectuate change within the organization, to exercise independent judgment, and to have access to all documents and information relevant to compliance activities.



Compliance Officer and Committee

- The Compliance Officer's primary duties should include:
 - Overseeing implementation of the compliance program
 - Reporting on regular basis to the Board, CEO, and others
 - Periodically revising the program to address changing needs/activities
 - Implementing a multi-faceted education and training program
 - Ensuring that independent contractors are aware of the company's program
 - Coordinating personnel issues with Human Resources
 - Assisting the company's internal auditors in compliance reviews
 - Reviewing and responding to reports of non-compliance
 - Independently investigating and acting on matters related to compliance
 - Participating with counsel in self-reporting to government agencies
 - Continuing the momentum after the initial years of implementation



Johnson & Johnson Health Care Compliance Framework

- **Each operating company must build on the foundation of the Johnson & Johnson Health Care Compliance Framework and operationalize it by implementing detailed policies and procedures.**
- **A robust Health Care Compliance program will assist each operating company in fulfilling their commitment to responsible corporate conduct.**



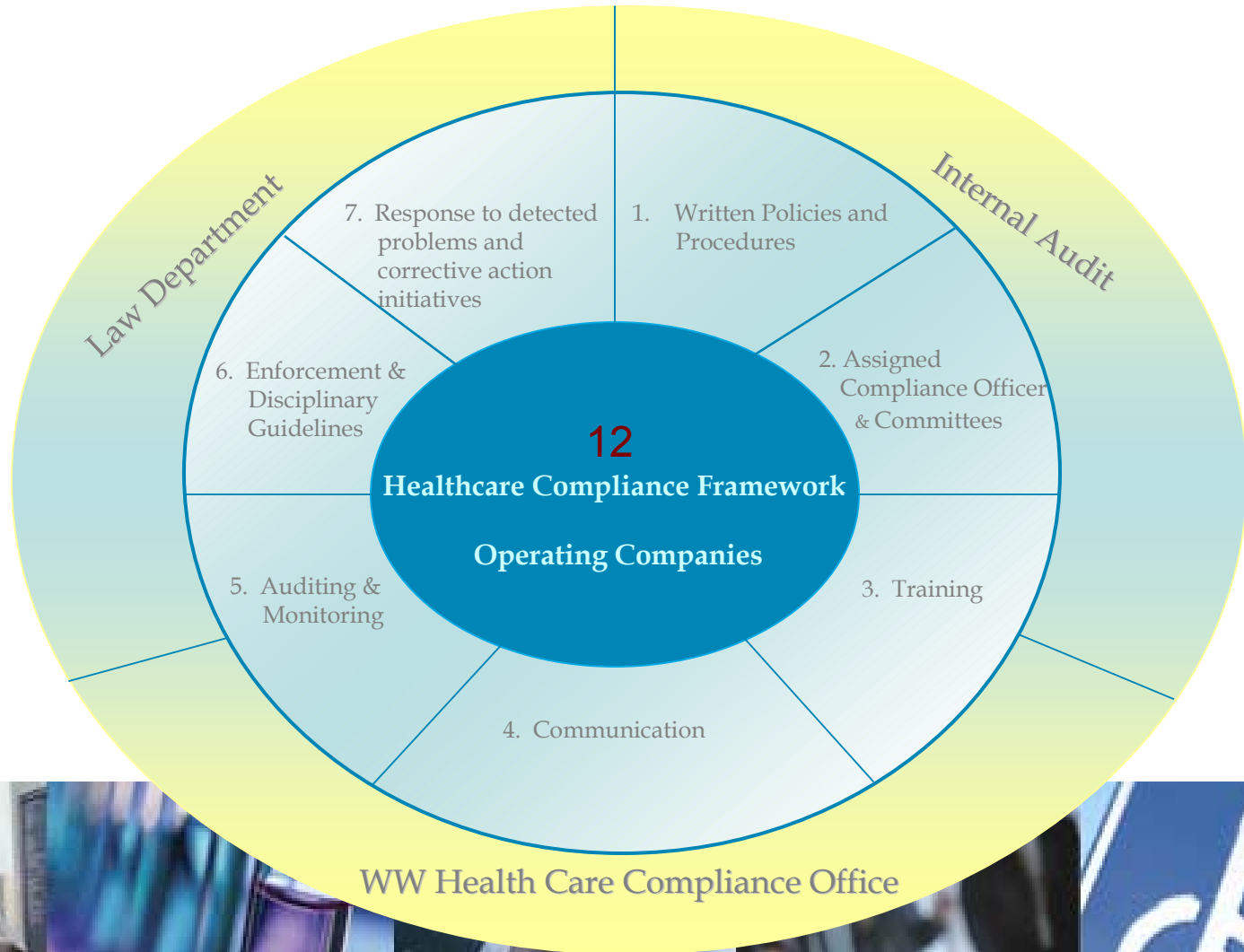
Johnson & Johnson Health Care Compliance Program

- **Framework**
 - US
 - International
- **Health Care Compliance Guidance**
 - US
 - International



Johnson & Johnson Health Care Compliance

Common Mission: Protect and grow the business.



Johnson & Johnson Health Care Compliance Program

Written Policies and Procedures

- **Framework**

- **Based on the “Seven Elements of an Effective Compliance Program”**

- **Guidance**

- **US - Safe Harbors and other applicable laws / regulations / standards**
- **International – Guidance on key interactions with Health Care Professionals**



Johnson & Johnson Health Care Compliance Program

Assigned Compliance Officer and Committees

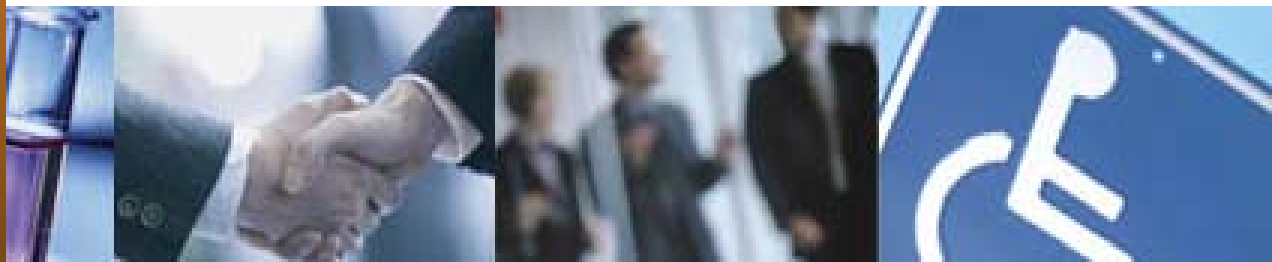
- **Chief Compliance Officer**
- **Corporate Compliance Officer**
- **VP of Worldwide Health Care Compliance**
- **Health Care Compliance Steering Committee**
- **HCC Officer at each Operating Company – Worldwide**
- **HCC Committee at each Operating Company**



Governance at Guidant

Long-term Commitment to Board Best Practices

- Board committees
 - Audit Committee
 - Management Development & Compensation
 - Corporate Governance
 - Science & Technology
 - Compliance



Governance at Guidant

Long-term Commitment to Board Best Practices

Guidant Board Compliance Committee

Ronald W. Dollens
President, Chief Executive
Officer



James M. Cornelius
Chairman of the Board
(non-executive) /
Guidant Corporation



Nancy-Ann Min DeParle
Senior Advisor / J.P.
Morgan Partners, LLC,
Adjunct Professor / The
Wharton School,
University of
Pennsylvania



Mark Novitch, M.D.
Retired Vice
Chairman / The
Upjohn Company



**Ruedi E.
Wäger, Ph.D.**
President,
Chief Executive
Officer /
Aventis
Behring LLC

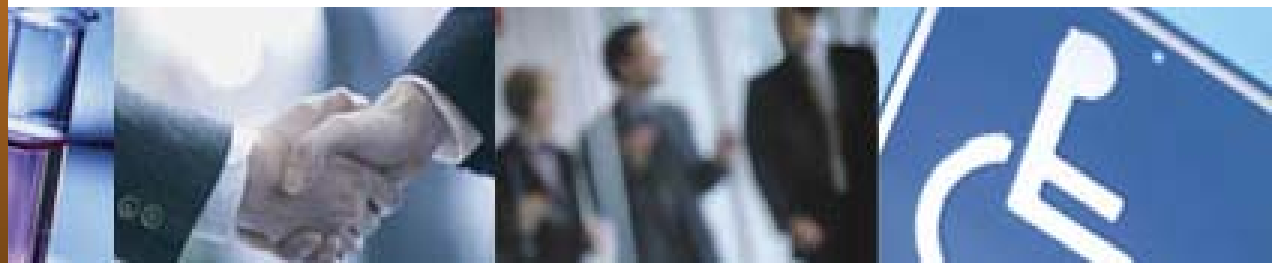


Kristina Johnson, PhD
Department Chair,
School of Engineering
Duke University



J. Kevin Moore
Senior Vice
President,
Strategic Planning
/ Advanced
Medical
Productions

Compliance Committee Chairman



Governance at Guidant

Corporate Controls Discipline

- Corporate Compliance
 - Chief Compliance Officer (since 1995)
 - CCO reports directly to the CEO and the Compliance Committee of the Board of Directors
 - Robust audit and oversight
 - Quarterly updates to board committee



Guidant Compliance Committee Charter

- Code of Business Conduct and Customer Relationship Policies – oversee implementation and future revisions
- Provide oversight for development and implementation of compliance program as a leader in the industry
- Review status and significant compliance issues
- Periodically verify leading edge of compliance program
- With CEO, assess performance of compliance organization/office
- Review management/resource commitment to compliance office
- Coordinate with the Audit Committee on compliance matters that may be significant from a financial perspective, and on matters brought to the Compliance Committee's attention related to auditing or accounting issues and compliance with related laws/regs



Education and Training

- Companies should implement programs to educate and train employees and agents on compliance issues.
- Training should include communicating a company's standards of conduct to all relevant employees and agents.
- General training should focus on the company's compliance program, written standards of conduct, and applicable regulatory requirements.
- Specialized training should be provided to employees and agents in appropriate areas (e.g., sales and marketing, etc.)



Education and Training (cont'd)

- New employees should receive training promptly.
- The Compliance Officer should document training programs and retain attendance logs, descriptions of the compliance program, and copies of materials distributed.
- Successful completion of training should be made a condition of employment and adherence to training requirements should be a factor in the annual evaluation of each employee.



Johnson & Johnson Health Care Compliance Program

Training

- Testing and annual certification
- Targeted to job responsibilities
- New Employee Program
- Training on failure to comply



Code of Business Conduct Training

Selected topics



Message on Corporate Responsibility

Screen 3 of 4



Continued honest and ethical business conduct will earn Guidant the trust of customers, patients, suppliers, investors, regulators, and fellow employees, while sustaining our long-term commitment to our shareholders.

Personal integrity, upheld on a day-to-day basis, is the unshakable foundation for corporate integrity. This Code of Business Conduct, which has been approved by a committee of Guidant's board of directors, is provided to outline appropriate business conduct and the mechanisms available for addressing issues and questions. It is essential that you take time to read and understand it. Your dedication to these principles will enhance our corporate reputation for excellence and quality, and allow you to feel a sense of pride at the end of each day for what we have accomplished together. Guidant thanks you for your cooperation and support.

Sincerely,

James M. Cornelius
Chairman of the Board

Ronald W. Dollens

You must read and scroll down to the end of this text before continuing.

GUIDANT

CODE OF BUSINESS CONDUCT

Introduction:
Corporate Responsibility



Exit



Menu



Submit



Back



Next

Knowledge Check 1

Screen 4 of 4

Answer the question below by clicking on the correct answer(s), (Select as many from the list that are appropriate, you can de-select your choice by clicking on it a second time). When you are satisfied with your answer(s), click the "Submit" button.

You have a responsibility to uphold Guidant's dedication to corporate ethics and compliance on a daily basis. You are expected to:

- A. Know and follow the Code of Business Conduct and take responsibility for your own conduct.**
- B. Know and comply with the requirements and expectations that apply to your job.**
- C. Cooperate with any investigation of an alleged violation of the Code of Business Conduct.**
- D. Report suspected violations of the Code of Business Conduct to the global compliance office or otherwise as set forth in the Code.**

GUIDANT

CODE OF BUSINESS CONDUCT

**Introduction:
Corporate Responsibility**



Exit



Menu



Submit



Back



Next

Individual and Corporate Responsibility

Screen 3 of 9



In addition to emphasizing Guidant's shared values, this Code of Business Conduct is designed to define individual and corporate responsibility. You must understand that you are responsible for your own conduct. No one has the authority to make another person violate Guidant's Code of Business Conduct, and any attempt to direct or otherwise influence someone else to commit a violation is a violation in itself. Alleged violations will be investigated and appropriate action taken.

People in management positions, in particular, set an example for other workers and are often responsible for directing the actions of their subordinates. Guidant requires you to know and understand the Code of Business Conduct.

GUIDANT

CODE OF BUSINESS CONDUCT

Topic 1:
Purpose of the Code and Its Use



Exit



Menu



Submit



Back



Next

Medical Device Laws and Regulations

Screen 3 of 13



Because the laws and regulations that affect the design, manufacture and sale of medical devices are quite broad and complex, each employee must be aware of laws and regulations that affect his or her specific responsibilities.

Because the laws and regulations that affect the design, manufacture and sale of medical devices are quite broad and complex, you must be aware of the laws and regulations that affect your specific responsibilities. For example, manufacturing employees must know and comply with industry quality regulations and standards; research employees must know and adhere to standards of laboratory practices; sales and marketing employees must know and comply with regulatory limitations on the promotion of products, privacy of protected health information, complaint reporting procedures and so on. Also, medical device laws require accurate and complete recordkeeping from numerous departments and business units. It is your responsibility to understand and comply with these requirements as they apply to your specific job and to ensure that documentation regarding training and compliance with internal procedures and processes is complete and accurate.

You must read and scroll down to the end of this text before continuing.

GUIDANT

CODE OF BUSINESS CONDUCT

Topic 2:
Legal/Compliance Obligations



Exit



Menu



Submit



Back



Next

Code Certificate

Screen 4 of 5

Please answer the following questions:

I have read the current Code of Business Conduct ("Code") and I understand and will abide by its contents. Yes ☒ No ☐

As a supervisor, the employees for whom I have supervisory responsibility have knowledge of, and access to the Code.

Yes ☒ No ☐ Not Applicable ☐

As a supervisor, I acknowledge that I have the responsibility to implement and maintain adequate internal controls to ensure compliance with the Code within the area for which I am responsible, and I certify that such controls are in place.

Yes ☒ No ☐ Not Applicable ☐

I am not aware of past or current activities that may violate the Code, that have not already been reported to management.

True ☒ False ☐

I will promptly report any situations that may be violations of the Code.

Yes ☒ No ☐

GUIDANT

CODE OF BUSINESS CONDUCT

Topic 9:
Summary & Certification



Exit



Menu



Submit



Back



Next

Main Menu

U.S. Customer Relationship Policy

GP1169

Select a Section:



I General Guidelines



II Continuing Education and Product Training



III Business Conducted in Association with Meals



*IV Gifts, Promotions, and Contributions to
Healthcare providers*



V Grants and Contributions Guidelines



VI Consulting and Honoraria



VII Free Product



VIII Support and Ancillary Equipment and Services

GUIDANT

Screen 7 of 7



Exit



Menu



Back



Forward

TRAINING TOOLS

- **On-line Training Management System**
 - Integrated with HR system
 - Matches people in current job category to required training
 - Email message to take training
 - Follow-up message to 'the boss'
 - Maintains the record of training taken and date
- Assessment test for understanding. Must pass with 80% correct.



Internal Reporting & Communications

- Employees should have access to access to supervisors and/or the Compliance Officer.
- Companies should implement an internal “hotline” or similar mechanism to allow employees and others to ask questions or report potential violations of policy or law.
- Reporting mechanisms should allow for the anonymous reporting of violations and company policy should prohibit retaliation for good faith reporting.
 - Sarbanes-Oxley added new prohibitions on retaliation in some situations



Auditing and Monitoring

- Compliance programs should include mechanisms to monitor and audit compliance.
- Compliance Officers should document on-going monitoring and auditing programs.
- Extent and frequency of compliance audits may vary according to:
 - Available resources
 - Prior history of non-compliance
 - Risk factors particular to the company
- Can include prospective systemic review or a retrospective review of actual practices



Johnson & Johnson Health Care Compliance Program

Auditing and Monitoring

- **Self Assessments – web based tool**
- **Testing**
- **Monitoring**
- **Internal Audits**
- **“Deep dives”**
- **Third party assessments**



Johnson & Johnson Health Care Compliance Program

Communications

- Open door policy
- Hotline
 - Investigation protocol
 - Case management system
- “Tone at Top”



Guidant Reporting Process:



HELPLINE CALL PRIORITIZATION

- Priority A

An “A” priority report involves an emergency or urgent situation. Company is called, report delivered immediately.

- Priority B

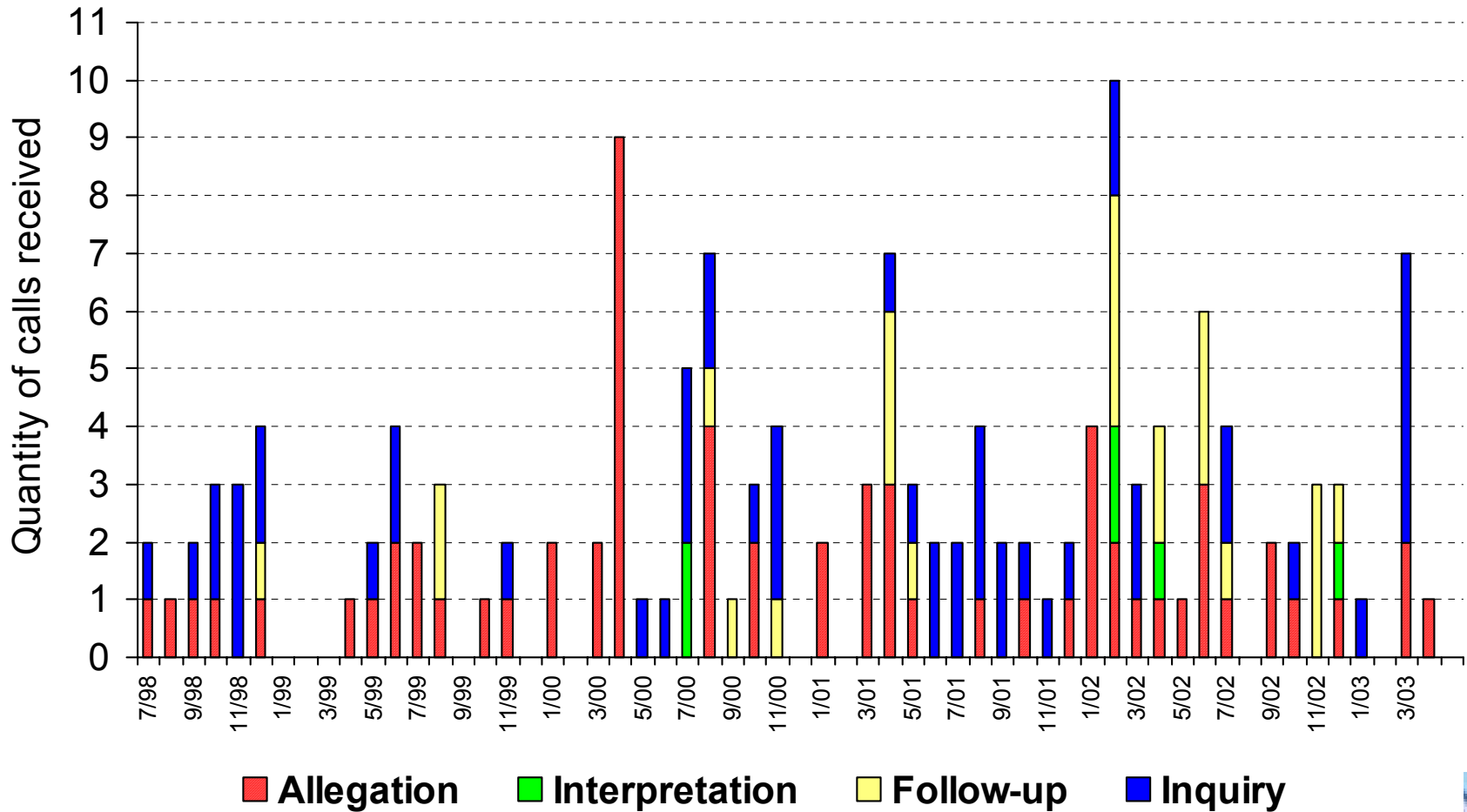
A priority “B” report involves a serious or time-sensitive issue that does not rise to the level of an emergency. A completed written report is delivered within a few hours of the call’s completion.

- Priority C

A “C” priority report involves routine sorts of issues that are not time-sensitive and do not require immediate response by the client. Report is delivered within 24 hours.



Guidant 'HelpLine' Call Volume by Type

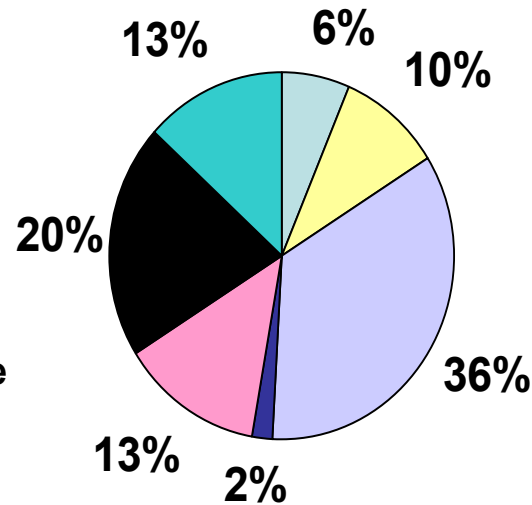


'HelpLine'

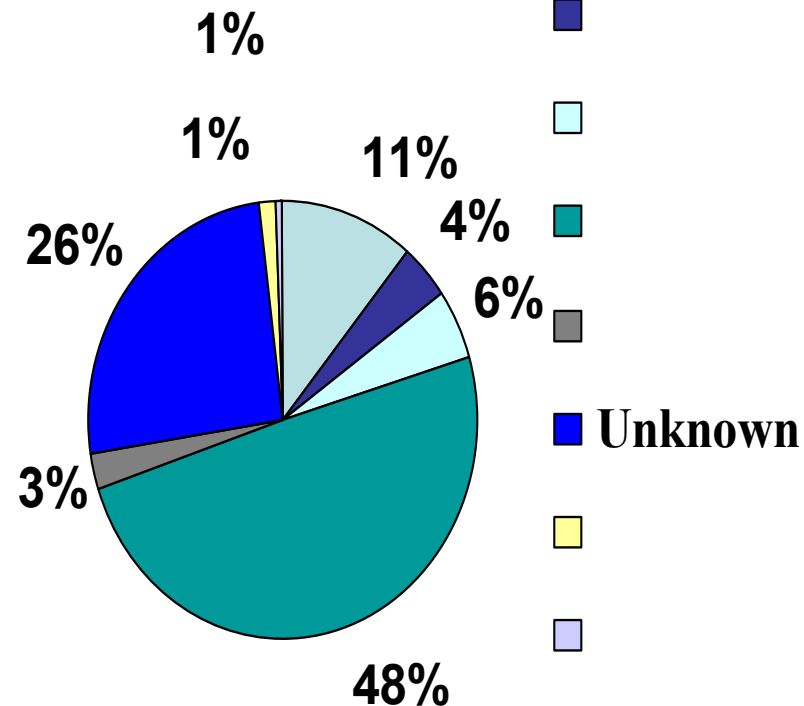
Observations – Sample Cumulative Statistics

CATEGORIES

- Policy interpretation
- Helpline Operation
- Unfair Treatment
- Safety Hazard
- Violation/Non-compliance
- Request for Information
- Follow-up



SOURCE



Current Follow up Process and Communication

- All Calls investigated – all documentation of investigation, conclusions and closure date maintained by compliance office
- Quarterly Review with Ethical Issues Review Group (HR/Legal/Financial Audit/Compliance senior management)
 - **Evaluate Issues**
 - **Look for trends**
 - **Identify communications needed**
- Board Compliance Committee Review



Enforcement of Disciplinary Standards

- An effective program should include clear and specific disciplinary policies that set out the consequences for violations of company policy or law.
- Companies should adopt processes to ensure consistent enforcement of disciplinary standards.
- Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct.



Responding to Detected Offenses

- Upon receipt of a reasonable indication of non-compliance, the Compliance Officer or other management official should immediately investigate the allegation.
- The review should be sufficiently detailed to identify the “root cause” of the problem.
- As appropriate, the investigation should “include a corrective action plan, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.”
- Credible evidence of an administrative, civil or criminal law should be promptly reported (*i.e.*, within 60 days) to appropriate federal and state authorities.



Johnson & Johnson Health Care Compliance Program

Enforcement and Disciplinary Action

- Documented
- Standards of conduct
- Debarment/exclusion checks



Johnson & Johnson Health Care Compliance Program

**Response to detected problems and actions to
correct issues**

- **Management Action Plan**
- **HCC Committee review process**



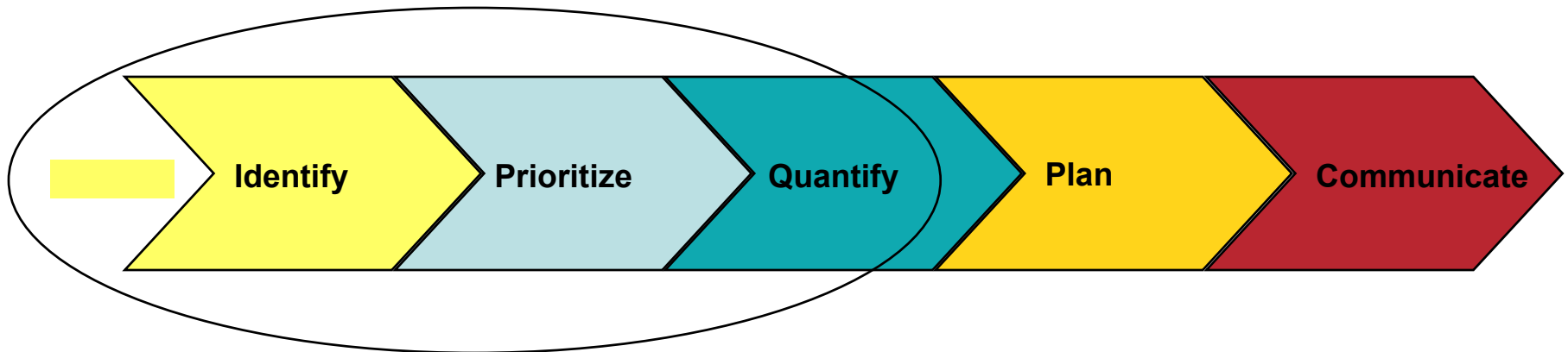
Risk Assessment

- USSC requirement for risk assessment:
 - a requirement to implement an on-going process to assess the risk of violations and to take steps to address such risks
- Guidant Example



Process

Guidant wide, comprehensive risk assessment



Risk = Potential to Interfere with Achievement of Strategy or Business Objectives



Risk Assessment Process

- Cross-functional/BU team of 11 Domain Experts and 3 VP's
- Support
 - Best practices from Marsh & McLennan
 - Global Compliance, Treasury and GC&R



Risk Summit Participants

EXECUTIVE SPONSORS

- VPs representing Global Control, Treasury, Global Compliance

DOMAIN EXPERTS

Director or Manager

- GC&R
- Treasury
- SOx Core Team
- Global Compliance, GSC Legal
- Sales
- IS
- Legal
- Manufacturing
- HR

Marsh Risk Consulting



Best Practice Process

- 1. Identify the “vital few” business risks to the corporation**
- 2. Assess the state of preparedness to manage those risks**
- 3. Take corrective action on priorities**
- 4. Gain assurance that confidence in the state of preparedness is justified**
- 5. Report the results and sustain the process**
- 6. Continuously improve**



Guidant Business Risk Inventory (BRI)

EXTERNAL RISKS

Capital Availability Competitor Customer Needs	Distribution Infrastructure Economy Financial Markets	Industry Legal Natural Hazard	Regulatory Environment Shareholder Relations Social Responsibility	Political Terrorism
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INTERNAL RISKS

Strategic

Business Model
Business Portfolio
Image/Reputation
Intellectual Property Protection
Location
Market Intelligence
Organizational Structure
Planning
Product Relevance
Resource Allocation

Operational

Process

Acquisition Integration Business Interruption Change Response Compliance/Reg. Rpt Contract Commitment Customer Satisfaction Cycle Time Delivery Channel	Distribution Efficiency Sales Practices Environmental Health and Safety Inventory Mgmt Knowledge Mgmt Mfg. Capacity	Measurement Partnering Patent Infringement Physical Security Product Svc Liability Product/Svc Failure Product/Svc Pricing Project Execution	Real Estate Relationship Mgmt (vendor/customer) Sourcing Supply Chain Strategy Implementation Transaction Processing Product Development
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Process

Management Information

Budgeting & Forecasting
Completeness/Accuracy
Financial Reporting
Investment Evaluation
Pension Fund
Taxation

Human Capital

Accountability
Change Readiness
Communications (Internal)
Competencies/Skills
Cultural Shift
Culture
Employee Concentration
Employment Law Practices
Employment Law Violation
Empowerment
Hiring/Retention
Epidemic/Pandemic Exposure
Leadership
Performance Incentives
Succession Planning
Temporary Workforce
Training/Development
Workplace Violence

Integrity

Conflict of Interest
Employee Fraud
Ethical Decision Making
Illegal Employee Acts
Management Fraud
3rd Party Fraud
Unauthorized Acts

Technology

Access
Availability
Capacity/Infrastructure
Data Integrity
E-Commerce
Information Security
Infrastructure
Relevance
Reliability
Technological Innovation

Financial

Cash Flow
Collateral
Commodities
Concentration
Credit
Default
Equity
Financial Instruments
Foreign Exchange
Interest Rate
Liquidity
Modeling
Opportunity Cost

Guidant Key BRI

EXTERNAL RISKS

Competitor
Shareholder Relations
Industry
Natural Hazard

Regulatory Environment
Political

INTERNAL RISKS

Strategic

Business Portfolio
Intellectual
Property
Product
Relevance

Operational

Process

Compliance/Regulatory Reporting
Inventory Management
Knowledge Management
Manufacturing Capacity
Product Development Process

Product/Service Failure
Sales Practices
Sourcing

Management Information

Financial
Reporting

Human Resource

Competencies/Skills
Cultural Shift
Culture
Employment Law
Practices
Hiring/Retention
Succession Planning
Training/Development

Integrity

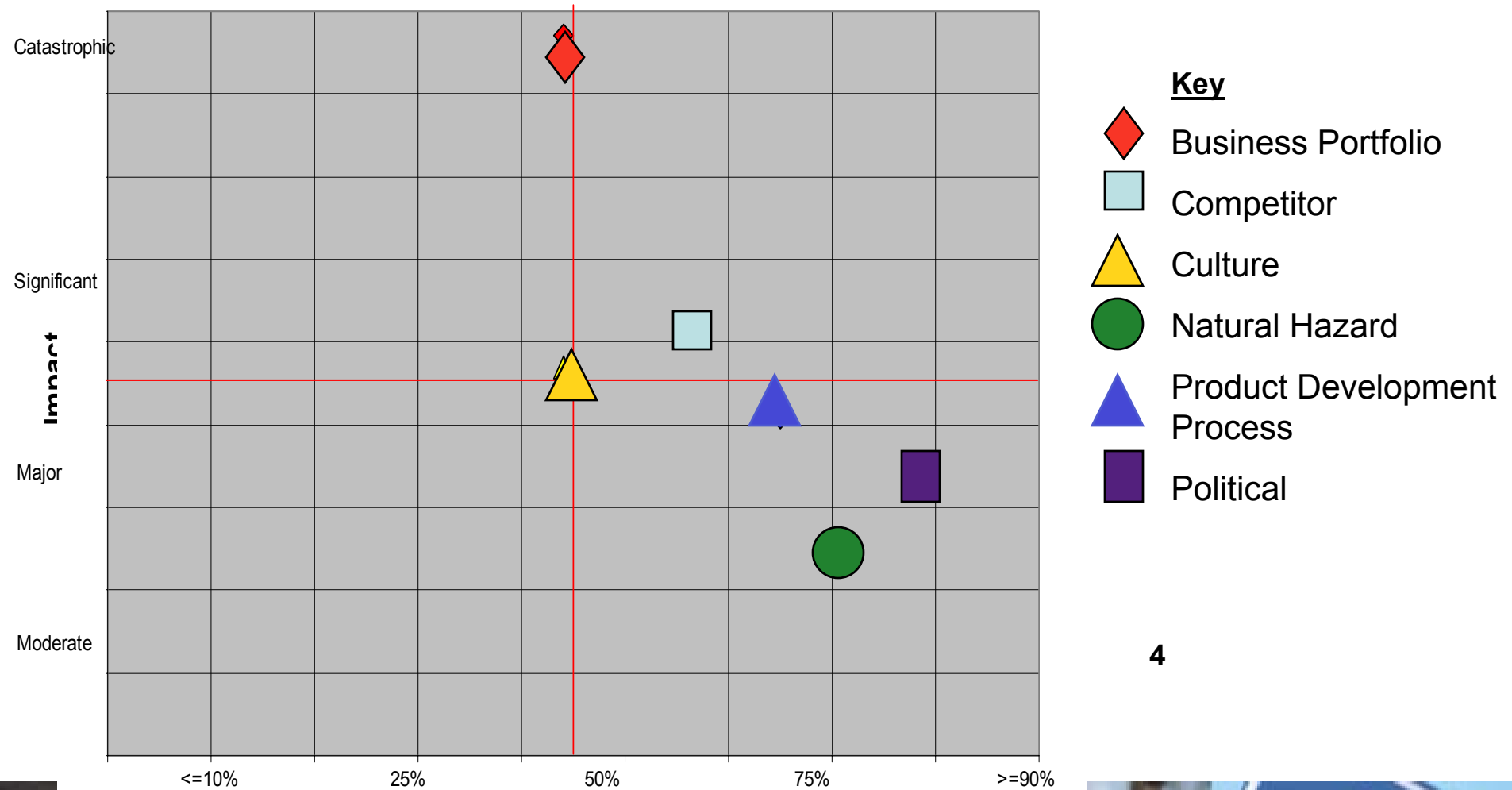
Conflict of
Interest
Illegal
Employee
Acts

Technology

Data Integrity
Information
Security
Reliability

Financial

Risk Assessment Priorities



4



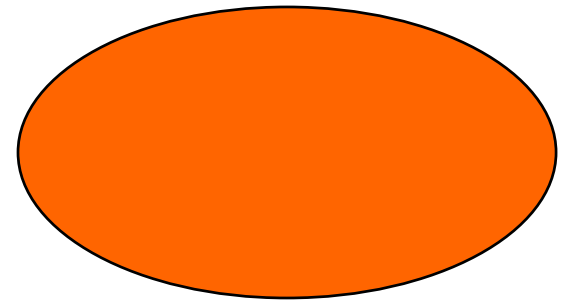
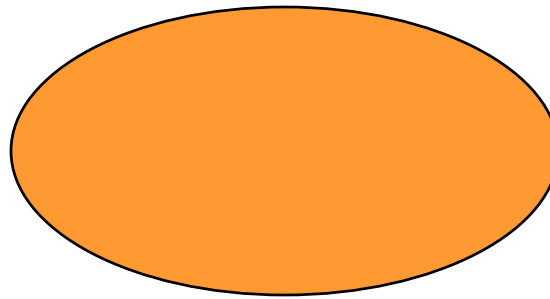
Risk Management Process



Guidant Wide Compliance Coverage

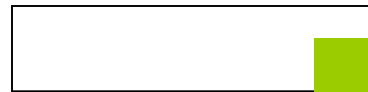
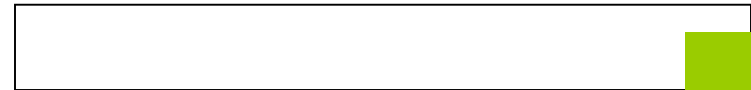


**External
GMC**

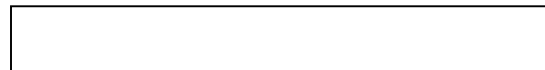


Regulatory Environment

**Strategic and Financial
GMC**



**Operational
BU's/HQ**



Practical Considerations

- Even the most impressive written compliance programs may do little to prevent and detect violations of law. Effective programs are dynamic, enjoy the support of senior management, and are tailored to a company's culture, organization, and activities.
- Numerous agencies are involved in the investigative and enforcement process, and each has varying standards and expectations with respect to compliance programs.
- Government investigators and prosecutors are knowledgeable about compliance programs – paper programs will not have an influence on their decision making.





END OF PRESENTATION ONE



Health Care Compliance Program





International Health Care Compliance Program



World's Most Comprehensive and Broadly Based Health Care Company

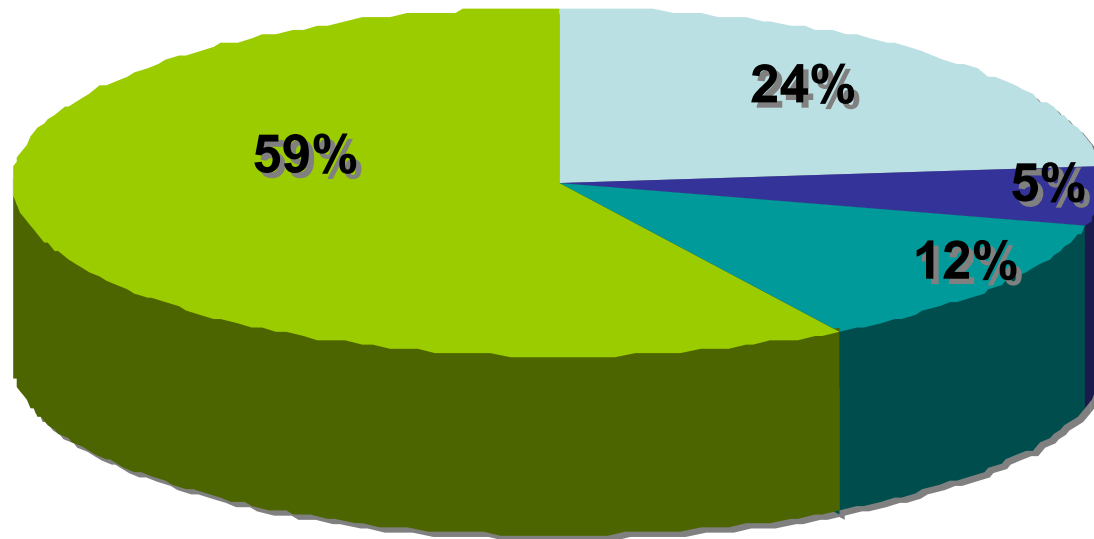
- **2004 Sales of \$47.3 Billion**
- **Over 200 operating companies in 57 countries around the world**
- **Leadership positions in ethical and OTC pharmaceuticals, medical/surgical supplies, diagnostics and a variety of consumer products**
- **Broad based, diverse portfolio of products**



Worldwide Net Trade Sales

By Geographic Area

2004



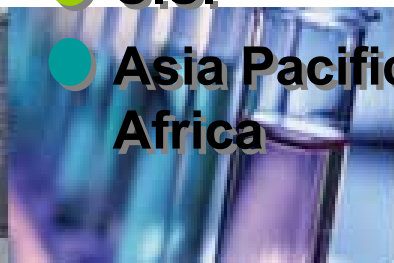
\$47.3 Billion

● U.S.

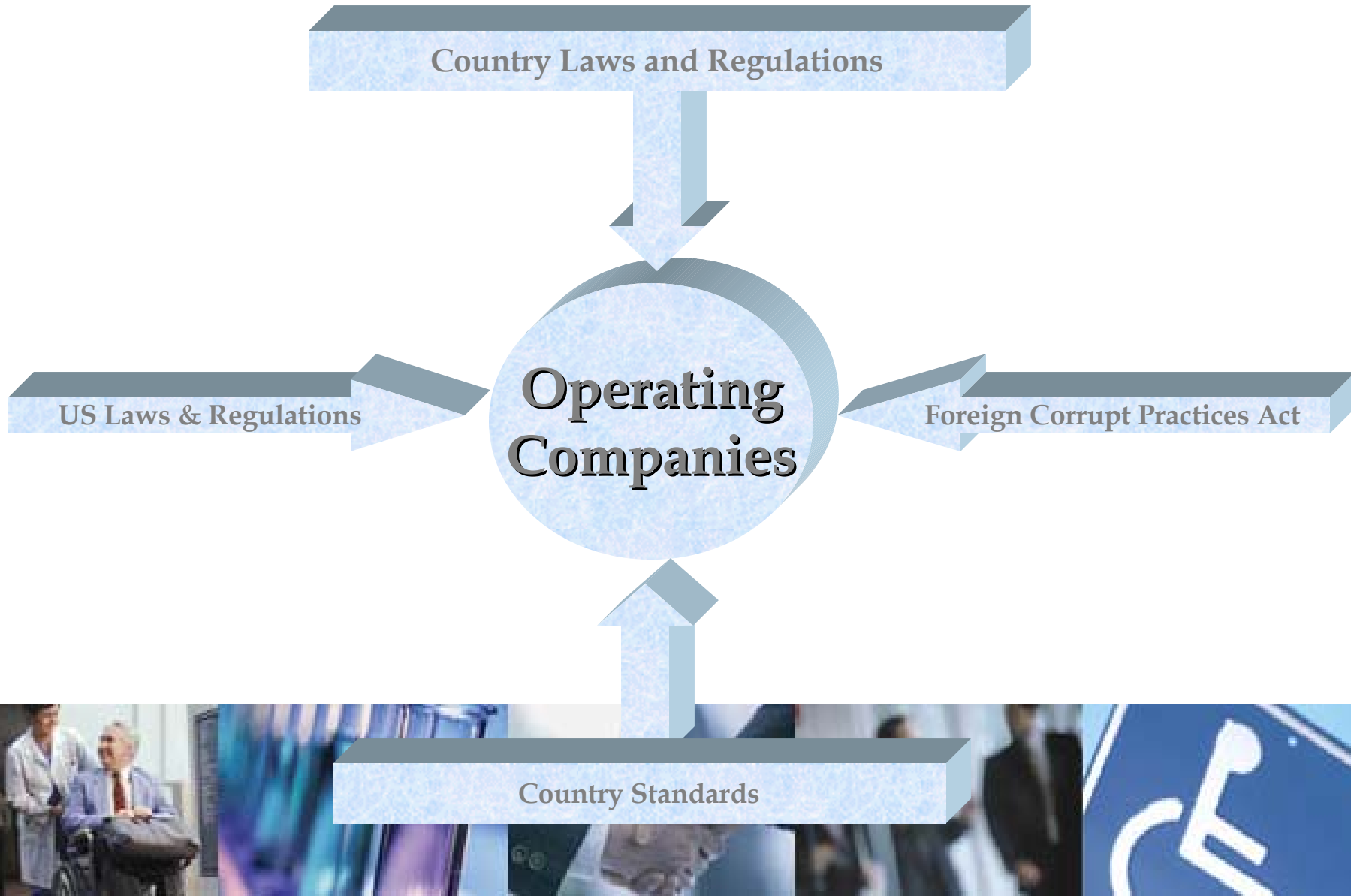
● Asia Pacific & Africa

● W. Hem (ex. US)

● Europe



The Global Health Care Environment



Johnson & Johnson Health Care Compliance Program - International

Elements

- **Policy on Business Conduct - Global**
- **International Health Care Compliance Framework**
- **International Health Care Compliance Guidance**
- **Local laws, regulations and industry standards**
- **FCPA training**
- **Consistent approach globally**



International Program Roll-Out

Q1 2005 Q2 2005 Q3 2005 Q4 2005

Law Dept.

Finalize Guides

COHCC & Law Dept.

Finalize Framework

Approved Implementation
Plan

Communication Plan

Training

Core Best Practices Developed

Develop & Roll-out Self-Assessment

MAARS Training

OpCo w/Guidance from Law Dept & COHCC

Staff HCC

Coordinate w/Law Dept. on need for
identification of local counsel

Implement Framework including organizational redesign

OpCo Process & Document Development

Employee Training

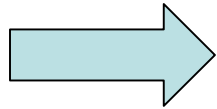
Testing & Monitoring

Complete Self-Assessment



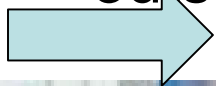
International HCC Guide

Objective: set of common - required - standards
for interactions with HCP



if more restrictive, local laws,
regulations and codes of conduct take
precedence

binding for all J&J companies operating
outside the US



Major Sections of the Guide

- Definition of Health Care Professionals
- Interactions with Health Care Professional
 - Arrangements to obtain consulting and other services from HCPs
 - Interactions with HCPs relating to conferences, hospitality and gifts
 - HCP Initiated Research Grants
 - J&J Company Initiated Studies
 - Educational Grants
 - Charitable Contributions
 - Promotional materials
 - Samples
 - Capital Equipment Evaluations
 - Competent medical representatives and behavior in operating rooms
 - Reimbursement information
- Cross-border Interactions with HCPs
- Certifying Compliance with the Guide



Foreign Corrupt Practices Act



Current Enforcement Environment

- Increasing Foreign Corrupt Practices Act (“FCPA”) enforcement by U.S. authorities
- FCPA-type laws implemented by OUS governments
 - Organization of Economic Development and Cooperation (“OECD”) anti-bribery convention



Foreign Corrupt Practices Act Overview

- Anti-bribery provision (no bribes)
- Accounting provision (no secret or disguised accounts)



Elements of FCPA Violation

- A “covered” person
- Must offer or give something of “value”
- Directly or indirectly to a government official
- For the purpose of retaining business or securing an improper advantage (i.e., with “corrupt intent”)



FCPA

Who is a “Foreign Official”?

- Foreign officials at all levels very broadly defined
- Private persons acting in official capacity
 - Includes ceremonial advisors, consultants, etc.



FCPA Penalties

- Criminal and civil penalties
- Applies to companies and individuals



OECD Anti-bribery Convention

- Establishes standard to be met by all parties in defining offense of bribery of foreign officials
- Parties must take all necessary measures to establish bribery of foreign officials as a criminal offense



Ratification of OECD Convention

Other OECD Countries

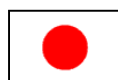
Non-OECD Countries



Australia



France



Japan



Portugal



Austria



Germany



Korea



Slovak Republic



Belgium



Greece



Luxembourg



Spain



Canada



Hungary



Mexico



Sweden



Czech Republic



Iceland



The Netherlands



Switzerland



Denmark



Ireland



New Zealand



Turkey



Finland



Italy



Norway



United Kingdom



Poland



United States

▪ Argentina

▪ Brazil

▪ Bulgaria

▪ Chile

▪ Slovenia



Current Enforcement Environment

U.S. v. Titan Corp. (March 2005) -- \$28.5 million

SEC v. GE Invision (February 2005)

SEC v. Schering-Plough (2004)

U.S. v. ABB, Ltd. (2004) -- \$16 million

U.S. v. David Kay (2004)

GlaxoSmithKline – under investigation (Italy)

Bristol-Myers – under investigation (Germany)

U.S. v. Syncor Taiwan, Inc. (2002)

U.S. v. Lockheed Corp. (1994)

Titan to Pay Fine And Plead Guilty In Bribery Probe

By JONATHAN KARP
And ANDY PASZTOR

Defense contractor Titan Corp. tentatively agreed to plead guilty to criminal charges and pay less than \$30 million to resolve a yearlong overseas-bribery investigation, people familiar with the situation say.

That probe scuttled Lockheed Martin Corp.'s proposed \$1.6 billion acquisition of Titan in June and rocked investor confidence in the San Diego company. Under the current deal to end investigations by the Justice Department and Securities and Exchange Commission, Titan will admit that payments by its overseas consultants violated the Foreign Corrupt Practices Act, these people say.

Titan has set aside \$28.5 million to cover possible fines and penalties to settle the case, and the people briefed on the agreement said the total would be "less than \$30 million." Though it is expected to be one of the biggest penalties ever imposed under the antibribery law, a settlement would clear the way for Titan to find another merger partner.

The settlement could be announced by the end of the month, but the details are subject to change. The Justice Department, the SEC and Titan declined to comment. The company has said it is cooperating with government authorities.

**\$28.5
Million**

March 2005

Largest

FCPA

Settlement

In History

