

The Pharma, Biotech and Device Colloquium  
June 7, 2004

## **“Building the Compliance Program of the Future and its Role in Business Strategy”**

- Enhancing Reputation                      Lori Queisser, Lilly
- Risk Management                           Bert Weinstein, Purdue
- Measuring Effectiveness                Stephan Vincze, TAP
- Challenges of Biotechs                   Liz Lewis, Millennium
- Challenges of Devices                    Link Bonforte, ConvaTec
- Program of the Future                    Charles Brock, Abbott
- Moderator                                   Douglas Lankler, Pfizer

*“The views expressed by the panelists are their own and do not represent those of their companies.”*

“The Role of a Company’s  
Compliance Program in  
Enhancing the Reputation of  
the Enterprise.”

Lori Queisser

Vice President, Chief Compliance Officer

Eli Lilly and Company

# Would you take medicine manufactured by Enron if they were in the pharma business?

- Reputation is increasingly a differentiator
  - Shareholder
  - Payer
  - Prescriber
  - Consumer
- Reputation is measured in the court of public opinion
- AP/UPI help serve as reminder of who's good and who's bad

# Link of Reputation to Compliance Programs

- Compliance programs foster good compliance
- Good Compliance leads to reliability
- Cumulative experiences lead to a company's reputation

# Keys to Successful Linkages

- Compliance must be integrated into business to be leveraged
- Cannot exist in silos
- Video must match audio
- Iterative – not point in time
- Must be risk based

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“The Role of a Company’s  
Compliance Program in  
Implementing a Program of  
Enterprise Risk Management”

Bert Weinstein  
Vice President, Corporate Compliance  
Purdue Pharma L.P.

# Genesis of Internal Control Requirements

- Catalysts for change in corporate governance
  - Securities and Exchange Acts, 1933-1934
  - Foreign Corrupt Practices Act, 1977
  - Treadway Commission, 1987
  - US Federal Sentencing Guidelines
  - False Claims Act Cases
  - Sarbanes-Oxley, 2002
- Most of this legislation or guidance resulted from periodic public concern over illegal or unethical activities of certain corporations and the lack of transparency in financial reporting.

# Treadway Commission – 1987

## COSO – Generally-Accepted Internal Control Model

- Control Environment
  - *The control environment, together with integrity, ethical values and competence, sets the “tone at the top” of an organization*
- Risk Assessment
  - *Identification of external and internal risks, their significance, their likelihood of occurrence, and the costs and benefits of mitigation*
- Controls
  - *Actions taken within an entity to ensure adherence to policies and procedures established to address risks affecting achievement of the entity’s objectives*
- Monitor
  - *Combination of ongoing monitoring activities in the ordinary course of operations, and separate evaluations*
- Communicate
  - *Effective communication must occur throughout an organization, with a clear message that control responsibilities must be taken seriously*

# Categories of Risk

## Business Risk

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Risks impacting the accomplishment of business objectives.

## Compliance Risk

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Risks related to the failure to comply with laws, regulations and company policies.

## Financial Risk

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Risks related to maintaining accurate, financial statements, and the related timely and complete disclosures of financial information.

# US Federal Sentencing Guidelines (proposed 2004 amendments)

The Federal Sentencing Guidelines for Organizations contain seven elements of an “effective compliance program,” consisting of:

1. Established policies, procedures and standards
2. Leadership knowledge; executive level personnel responsible for compliance program
3. Not include persons with bad history
4. Communication of policies and procedures to high level persons, employees and other agents
5. Monitoring and auditing systems; periodic evaluation; and guidance/reporting system
6. Incentives to perform/discipline
7. Response to offenses and prevention of similar offenses

# Compliance Risk Assessment

- Risk assessments identify compliance exposures, and are the basis for making improvements
  - Adequate policies, training, communications, and other systems to address risks?
  - Identify gaps – needs for improvement
  - Implement auditing and monitoring functions, periodic reporting, self-evaluations, and continuous improvement
- Risk Assessments Specifically Required by 2004 Sentencing Guidelines Amendments
  - Actions must be prioritized
  - Relevant to the business
  - On-going risk assessments

# Likely Priority Compliance Risks

- Research
  - Fraud in Clinical Trials
  - Animal Research
  - Patient Privacy Requirements
  - Institutional Review Board Requirements (Subject Protection)
- Manufacturing
  - Good Manufacturing Practices/Quality
  - Environmental
  - Worker Safety/Health
- Sales & Marketing
  - Physician/Customer Promotion and Programs
  - Samples
  - Grants and Continuing Medical Education

# Measuring Ethics & Compliance Program Effectiveness

Presented by: L. Stephan Vincze, J.D., LL.M.  
Vice President, Ethics & Compliance Officer / Privacy  
Officer  
TAP Pharmaceutical Products Inc.

# Food For Thought

***“Wisdom comes only through suffering.”***

Aeschylus, Agamemnon, 458 B.C.

# Overview

- I. The Multiple Dimensions of Effectiveness
- II. HCCA Resource Document
- III. Sample Metrics
- IV. Q&A

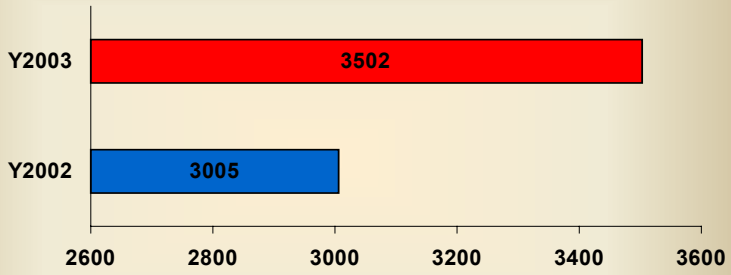
# Multiple Dimensions of Effectiveness

- Macro – Organizational Impact
  - Legal
  - Operational
- Micro – Programmatic Impact
  - Structural
  - Substantive
  - Effort/Input
  - Outcomes/Results

# HCCA Resource Document

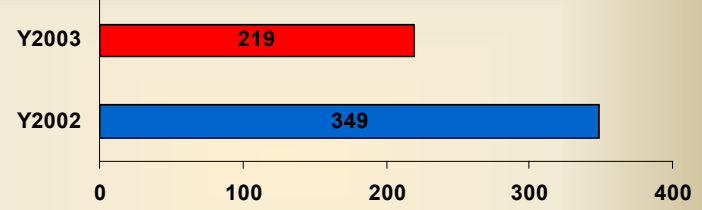
- *“Evaluating and Improving a Compliance Program: A Resource For Health Care Board Members, Health Care Executives and Compliance Officers”*
- Available on home page of HCCA website, [www.hcca-info.org](http://www.hcca-info.org)

Covered Persons



	Y2002	Y2003
Covered Persons	3005	3502

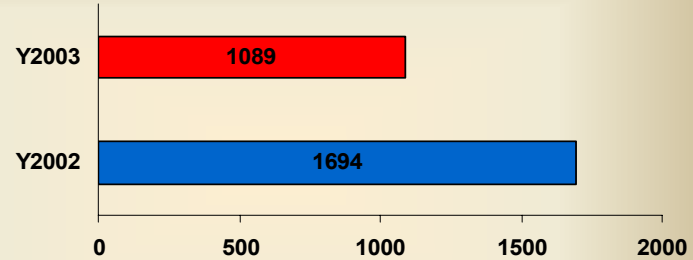
AOV Costs (\$000's)



	Y2002	Y2003
AOV Costs (\$000's)	349	219

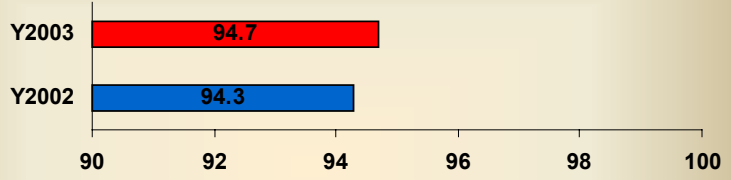
\*Vendor development and MIS support costs

MIS Training Support Calls



	Y2002	Y2003
MIS Training Support Calls	1694	1089

Employee Survey Results\*



	Y2002	Y2003
Employee Survey Results*	94.3	94.7

<u>Area</u>	<u>Y2002</u>	<u>Y2003</u>	<u>% Change</u>
1. Covered Persons	3005	3502	17%
2. AOV Costs	349	219	-37%
3. MIS Training Support Calls	1694	1089	-36%
4. Employee Survey Results	94.3	94.7	0.4%

Conclusions:  
 Data points demonstrate increased efficiency of E&C Training in terms of both financial impact and employee positive survey results regarding training/materials and understanding/awareness. Specifically, overall cost and number of support calls were reduced by 37% and 36% respectively, while the number of employees trained increased by 17%. Employee survey results increased by 0.4%.

# Acting on Our Values

## 2003 Survey Results Summary

### Percent Positive Responses

#### Surveyed Area

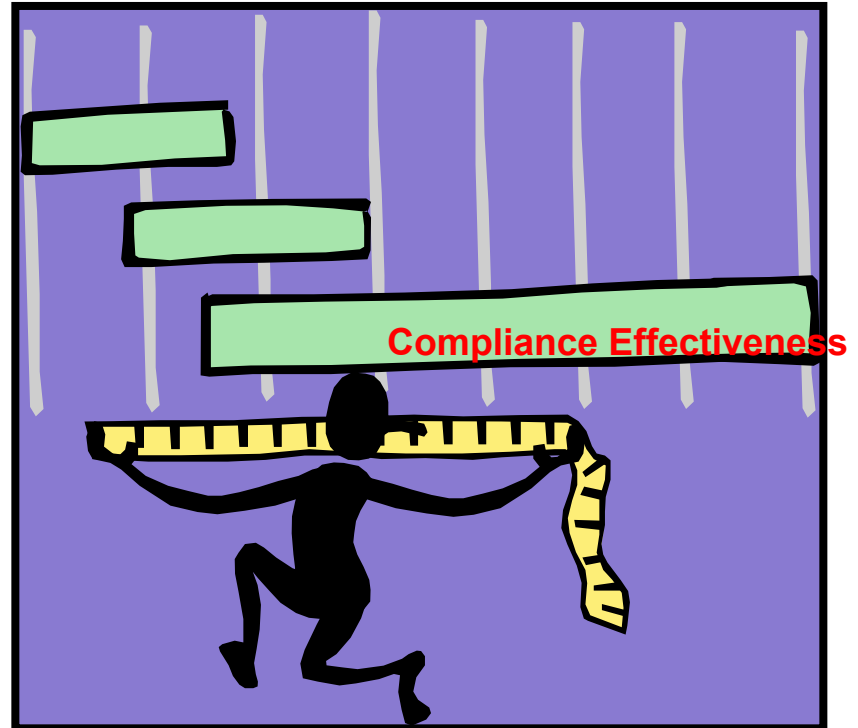
Year	Materials & Training	Understanding & Awareness	Hotline / Helpline	Support & Usage	Overall
2001	84.2%	81.4%	66.3%	86.3%	80.7%
2002	93.7%	95.5%	86.8%	93.0%	92.4%
2003	93.9%	96.3%	87.7%	93.7%	93.0%

## Acting on Our Values 2003 Survey Results Summary

	<u>1**</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>
<b>Strongly Agree/Agree 2001</b>	91.1	93.8	92.7	87.6	86.3	90.0	79.0	60.1	94.1	75.6	61.7	61.5
<b>Neutral 2001</b>	5.7	3.2	5.8	6.9	9.1	4.7	15.1	20.3	4.7	19.5	34.3	26.8
<b>Disagree/Strongly Disagree 2001</b>	3.3	2.9	1.5	5.5	4.6	5.3	5.9	19.7	1.3	4.9	4.0	11.6
<b>Strongly Agree/Agree 2002</b>	97.8	95.9	98.3	95.2	97.2	98.2	92.9	74.6	98.4	89.8	83.8	80.2
<b>Neutral 2002</b>	1.8	2.8	1.3	3.7	2.3	0.9	5.8	18.6	1.4	7.8	13.7	13.7
<b>Disagree/Strongly Disagree 2002</b>	0.5	1.3	0.4	1.1	0.5	0.9	1.4	6.9	0.3	2.4	2.5	6.1
<b>Strongly Agree/Agree 2003</b>	98.2	96.1	98.5	95.5	97.4	97.3	92.2	76.4	98.6	89.8	84.1	81.8
<b>Neutral 2003</b>	1.4	2.4	1.2	3.4	2.1	1.3	6.1	17.1	1.1	8.0	13.6	13.3
<b>Disagree/Strongly Disagree 2003</b>	0.3	1.4	0.3	1.1	0.5	1.4	1.6	6.5	0.3	2.2	2.3	4.9
<b>2003 vs. 2002 SA/A</b>	0.4	0.2	0.2	0.3	0.2	-0.9	-0.7	1.8	0.2	0.0	0.3	1.6
<b>2003 vs. 2002 Neutral</b>	-0.4	-0.4	-0.1	-0.3	-0.2	0.4	0.3	-1.5	-0.3	0.2	-0.1	-0.4
<b>2003 vs. 2002 SD/D</b>	-0.2	0.1	-0.1	0.0	0.0	0.5	0.2	-0.4	0.0	-0.2	-0.2	-1.2
	<u>14</u>	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>	<u>20</u>	<u>21</u>	<u>22</u>	<u>23</u>	<u>24*</u>	<u>25</u>
<b>Strongly Agree/Agree 2001</b>	67.9	52.2	89.9	88.3	89.2	70.6	92.2	96.5	88.2	91.9	22.2	71.8
<b>Neutral 2001</b>	20.2	20.5	5.6	7.7	7.1	18.5	6.2	3.4	10.5	7.5	23.2	18.3
<b>Disagree/Strongly Disagree 2001</b>	12.0	27.3	4.6	4.0	3.8	11.0	1.6	0.1	1.4	0.6	54.7	9.9
<b>Strongly Agree/Agree 2002</b>	95.1	88.5	93	97.2	93.2	83.7	97.5	98	95.6	97.3	42.7	85.7
<b>Neutral 2002</b>	4.1	8.2	4.9	2.3	4.5	12.1	2.2	1.7	3.9	2.4	23.2	10.6
<b>Disagree/Strongly Disagree 2002</b>	0.8	3.3	2.2	0.6	2.3	4.3	0.4	0.3	0.6	0.3	34.1	3.8
<b>Strongly Agree/Agree 2003</b>	95.7	91.1	94.0	97.2	93.5	85.2	97.6	98.1	96.2	97.6	44.3	87.1
<b>Neutral 2003</b>	3.6	6.9	4.2	2.3	4.5	11.0	2.0	1.6	3.4	2.2	22.1	10.1
<b>Disagree/Strongly Disagree 2003</b>	0.7	2.0	1.8	0.5	2.0	3.9	0.4	0.3	0.4	0.2	33.7	2.9
<b>2003 vs. 2002 SA/A</b>	0.6	2.6	1.0	0.0	0.3	1.5	0.1	0.1	0.6	0.3	1.6	1.4
<b>2003 vs. 2002 Neutral</b>	-0.5	-1.3	-0.7	0.0	0.0	-1.1	-0.2	-0.1	-0.5	-0.2	-1.1	-0.5
<b>2003 vs. 2002 SD/D</b>	-0.1	-1.3	-0.4	-0.1	-0.3	-0.4	0.0	0.0	-0.2	-0.1	-0.4	-0.9
	<u>Overall</u>	<u>Materials &amp; Training</u>			<u>Understanding &amp; Awareness</u>			<u>Hotline/Helpline</u>		<u>Support &amp; Usage</u>		
<b>2001 Average Positive Response</b>	80.7	84.2			81.4			66.3		86.3		
<b>2002 Average Positive Response</b>	92.4	93.7			95.5			86.8		93.0		
<b>2003 Average Positive Response</b>	93.0	93.9			96.3			87.7		93.7		
* Omitted from Overall and Support & Usage Averages												
**Numbering follows the 2001 and 2002 Presentations - NOT either the schema in the database or order asked in AOV												

# Next Steps/What's Ahead?

- Empirical Measurement Using Technology
- Accountability
- More, more, more....



# Next Steps/What's Ahead?

- **A Theme of Partnership and Common Purpose Between Public & Private Sectors**



# More Food For Thought

***“With regard to excellence, it is not enough to know, but we must try to have and use it.”***

Aristotle, *Nichomachean Ethics*, circa 340 B.C.

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# “The Special Compliance Challenges of Biopharmaceutical Enterprises”

**Liz Lewis,  
Associate General Counsel, Commercial  
Millennium Pharmaceuticals, Inc.**

# Challenge 1: Focus on Innovation

- Do the impossible/change the world
- Reward “out of the box” thinking/acting
- Disdain of rigidity and inflexibility
- Resistance to process and formality

# Challenge 2: “Rip Van Winkle Syndrome”

- Pre-marketed products “bubble”
- Getting new challenges
- Making a difference

# Challenge 3: Resources

- Funding
  - External pressures
  - Internal pressures
  - Trade-offs (pipeline, personnel)
- Personnel
  - Head count limitations
  - Flexible & fluid job descriptions; Everyone is a “Jack of all trades”

# Meeting the Challenges

- Capitalize on culture of making the world a better place
- Recognize and address resistance to process
  - Flexibility
  - Matrix approach
- Become a strategic partner: know your employees and your products

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# “The Special Compliance Challenges of the Device Industry”

Link Bonforte

Vice President, Government Affairs, Policy and Compliance

ConvaTec, a Bristol-Myers Squibb Company

# Objectives

- Highlight key differences between the device and pharmaceutical industries
- Explain the special challenges facing the device industry

## **DRUGS**

- Typically large
- Relatively few
- Many with long history
- “Grand Slam” Block Busters
- Discovered

## **DEVICES**

- Typically smaller
- Relatively many
- Many new, family owned
- Singles / Doubles
- Developed

# HCP Involvement in Development

- HCPs often generate ideas for new products
  - Natural relationships- collaboration
  - Proper consulting arrangements
- Research, participation on advisory boards and presentation at firm-sponsored training can be appropriate and done ethically

# Product Training

- Device firms train HCPs on the safe and effective use of their products
  - Some FDA clearances require training
  - Good business practice
    - Customer service
    - Avoid misuse, injury and related litigation
- Some training appropriate to conduct at firm's location or commercial facilities
  - Large equipment, etc.

# Special Challenges

- Maintain ethical and lawful relationships with HCPs during legitimate interactions
- Promote safe and effective use of devices without unlawful inducement to sell, lease or recommend

# Special Challenges

- Provide information and training to your sales & marketing personnel
- Make aware of fraud and abuse laws
  - Federal anti-kickback statute
  - False Claims Act
- Nothing of value should be offered as an inducement or reward
- OIG Compliance is the goal  
AdvaMed Code of Ethics is the vehicle

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**“The Ethics and Compliance Program  
of the Future”**

Charles Brock

Vice President and Chief Ethics and Compliance Officer

Abbott Laboratories

# Key Drivers of the Current and Future Program

- A. Internal alignment and integration of the program
  - Alignment with the operating structure of the company’s evolving businesses
  - Integration with other key company initiatives
  - Process integration: risk assessment, process efficiency and the cost of compliance
- B. External drivers
  - Evolving regulatory frameworks
  - Amended concept (proposed) of the elements of program effectiveness (U.S. Sentencing Commission)
- C. Strategic value of the program: “Effectiveness”

# Structural Alignment with Abbott's Evolving Businesses

- Abbott Laboratories' central purpose – to develop breakthrough health care products that advance patient care for diseases with the greatest unmet medical need
- Principal businesses – pharmaceuticals and medical products
- See <http://abbott.com/> for additional information

# Structural Alignment

## Pharmaceutical Products Group

- Abbott's Pharmaceutical Products Group (“PPG”) –  
Globalization Model
  - Global pharmaceutical research and development
  - Global strategic planning and business development
  - Global pharmaceutical manufacturing and operations
  - Global pharmaceutical regulatory affairs
- PPG strategy
  - “...a single global team, focused on using innovation to create breakthrough pharmaceutical products that address large unmet medical needs.”

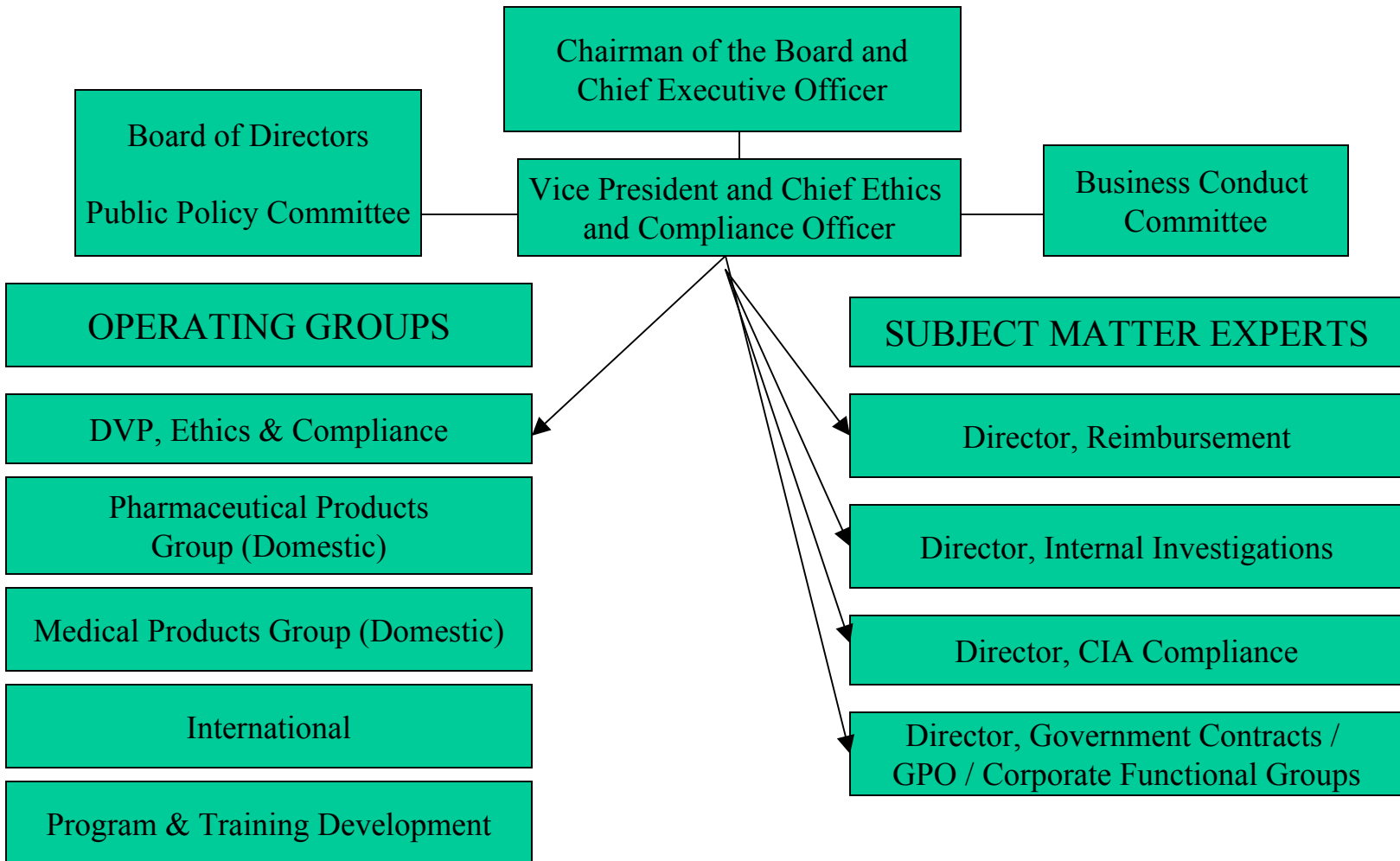
# Structural Alignment

## Medical Products Group

- Abbott's Medical Products Group ("MPG") – Decentralized entrepreneurial model – 8 business units
  - Diagnostics
  - Molecular Diagnostics
  - Diabetes Care
  - Point-of-Care
  - Vascular Devices
  - Nutritionals
  - Spinal Concepts
  - Animal Health
- Spin-off of global core hospital products business into stand-alone public company (Hospira, Inc.) (April 30, 2004)
- MPG strategy
  - “...distinct markets characterized by rapid technological advancements that require agile responses to evolving market conditions....an operating model where each business operates independently with full responsibility for performance and growth.”

# Structural Alignment

## Abbott's Office of Ethics and Compliance



# Integration of Ethics and Compliance; Integration of Program with Other Key Company Functions/Initiatives

- Integration of ethics and compliance
  - Sarbanes-Oxley Act, Section 406 (“code of ethics”)
  - New York Stock Exchange, Corporate Governance Rules (“code of business conduct and ethics”)
  - Amended concept (proposed) of the elements of effectiveness (U.S. Sentencing Commission) (“effective compliance and ethics program”)
  - Abbott Code of Business Conduct:  
<http://abbott.com/investor/CodeBusinessConduct/INDEX.html>
- Integration of ethics and compliance program with other key functions/initiatives
  - Internal Audit (compliance risk auditing)
  - Human Resources (performance excellence; diversity and inclusion; employee background checking)
  - Global Citizenship ([http://abbott.com/citizenship/gcr\\_2003/index.htm](http://abbott.com/citizenship/gcr_2003/index.htm))
  - Corporate Governance ([http://abbott.com/investor/gov\\_guidelines2.html](http://abbott.com/investor/gov_guidelines2.html))

# Process Integration:

## Risk Assessment, Process Efficiency, and the Cost of Compliance

- Risk assessment – ethics and compliance
  - Part of the company’s total operational risk assessment process
  - Incorporated into Abbott Office of Ethics and Compliance  
three-year long-range planning process
- Process efficiency
- Cost of compliance

# **Evolving Regulatory Frameworks – United States (Examples)**

- **OIG Voluntary Compliance Guidances**
- **Corporate Integrity Agreements**
- **Potential impact of amended concept (proposed) of the elements of effectiveness (U.S. Sentencing Commission)**
  - **On OIG Compliance Guidances**
  - **On future Corporate Integrity Agreements**

# Amended Concept (Proposed) of the Elements of Effectiveness

## 1991 Organizational Sentencing Guidelines

- Leadership (Compliance Officer)
- Standards
- Training
- Communications
- Assessment
- Accountability
- Remediation

## April 30, 2004 proposed amendments by USSC (partial list)

- Promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law
- Management involvement
- Board involvement
- Periodic evaluation of the effectiveness of the program
- Adequate resources
- Appropriate incentives to perform in accordance with the program
- Periodic assessments of the risk of criminal conduct

([http://www.usc.gov/FEDREG/05\\_04\\_notice.pdf](http://www.usc.gov/FEDREG/05_04_notice.pdf))

# Strategic Value of the Program: “Effectiveness”

- Is the ethics and compliance program well designed?
- Does the program work?