

**NATIONAL MEDICAL DEVICE
AUDIOCONFERENCE: Lessons
Learned About Anti-Bribery Foreign
Corrupt Practices from Recent Cases**

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Audioconference Agenda

- The Ramifications of the Current Enforcement Environment
- How Companies Get in Trouble and Lessons Learned
- Key Compliance Issues
- Effective Compliance Implementation Strategies
- Questions/Discussion

The Ramifications of the Current Enforcement Environment

- The FCPA
- OECD Convention on Combating Bribery
- National Legislation from Other Countries
- Other Multilateral Initiatives
- Specific Country Laws/Guidelines
 - EU Directive 2001/83/EC
- Industry Codes
 - The WHO Criteria
 - The EucoMed Code

The U.S. Government's View of the Importance of the FCPA

At the outset, let me address the most basic questions some of you might have about the government's attitude toward FCPA enforcement. Do we care about the FCPA? Is the FCPA relevant in today's global business climate? Is enforcing the FCPA a high priority?

The answer to all of those questions is yes. Prosecuting corruption of all kinds is a high priority for the Justice Department and for me as head of the Criminal Division. That includes public corruption, corruption in the procurement process, and the Foreign Corrupt Practices Act.

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FCPA Details: How Are the FCPA Bribery Provisions Violated?

- An offer, payment or gift of any money or thing of value is made
- To any foreign official or other person while knowing that some or all of the payment will be passed on to a foreign official
- For the purpose of obtaining or retaining business or obtaining any improper advantage

FCPA Details: How Are the FCPA Accounting Provisions Violated?

- ◆ A company and its subsidiaries must maintain accurate books and records that reflect transactions in reasonable detail
- ◆ A company and its subsidiaries must maintain appropriate controls
 - Showing a bribe on the books as a payment for a consulting arrangement is a violation
 - Supporting payment of bribe with an invoice for a consulting arrangement is maintaining a false record

OECD Convention

- Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (adopted 1997, entered into force 1999)
- 37 countries are parties to the Convention
- Monitoring Phase I: Implementation
 - Evaluates adequacy of a country's legislation to implement the Convention
- Monitoring Phase II: Enforcement
 - Assesses whether a country is applying its legislation effectively
- OECD has launched an inquiry into why the U.K.'s Serious Fraud Office dropped its investigation into BAE Systems' alleged corrupt dealings with Saudi Arabian contracts (a possible violation of the OECD Convention)

How Companies Get in Trouble and Lessons Learned

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #1

- A U.S. medical device manufacturer operated in China through a distributor
- Between 1997 and 2005, the company agreed to make corrupt payments, through a Chinese distributor to government-employed Chinese doctors in exchange for their purchase of company products
- In December 1997 a company official signed and executed a distributorship agreement with a Chinese distributor for medical products for government-owned Chinese hospitals. The Chinese distributor said that hospitals wanted a 10% discount, and that physicians in the hospitals wanted a 10% commission, on all the products sold.
- In a separate incident in May 2001, the Chinese distributor told AGA about a meeting with an official in China's Patent Protection Bureau, and the distributor agreed he could hasten the review of the application if AGA would submit payments to "sponsor" the patent official for speeding up the patent approvals

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #1

Consequences:

- Anti-bribery/Anti-corruption VIOLATION: anti-bribery provision
- DEFERRED PROSECUTION AGREEMENT
- CRIMINAL PENALTY: \$2,000,000
- MONITORING: External compliance monitor imposed on company for three years

(AGA Medical, 2008)

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #1

Lesson: Companies must have standard due diligence procedures and controls for selecting, retaining and overseeing distributors, consultants, and other key third parties

Discussion: Strategies, approaches and implementation challenges

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #2

- Senior non-U.S. government regulator sought a charitable contribution from a U.S. company's European subsidiary
 - The charity – the regulator's favourite – is legitimate
 - The regulator has a lot of influence over the subsidiary's business
 - He makes clear that it would be in the subsidiary's interest if the contribution is made
- Total contribution exceeds the manager's authorization
 - So the contribution was made in several smaller payments
 - Not described properly in the accounting records

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #2

Consequences:

- Anti-bribery/Anti-corruption VIOLATION: inaccurate accounting records
- Anti-bribery/Anti-corruption VIOLATION: inadequate internal controls
- FINE: \$500,000

(Schering-Plough, 2004)

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #2

Lesson: Companies must have standard due diligence procedures and controls governing charitable contributions

Discussion: Policies, Training and Implementation

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #3

- Several subsidiaries of a U.S. healthcare company gave commissions and “gifts” to non-U.S. doctors
 - Cash, computers, digital cameras, wine, wristwatches
 - Leisure travel and sponsoring lavish social events
- Officers of the U.S. parent company knew about the gifts
- The gifts were not properly recorded
 - Recorded as capital or business expenses
 - On the books of a foreign subsidiary (enforcement was less strict)

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #3

Consequences:

- Anti-bribery/Anti-corruption VIOLATION: anti-bribery provisions
- Anti-bribery/Anti-corruption VIOLATION: accounting and internal controls provisions
- FINES & PENALTIES: \$2.5 million
- EXTERNAL Anti-bribery/Anti-corruption MONITOR

(Syncor, 2002)

How Companies Get in Anti-bribery/Anti-corruption Trouble: Real World Lesson #3

Lesson: Companies must have clear policies and procedures governing gifts and entertainment provided to non-U.S. healthcare providers and other government officials

Discussion: HCP relationships, “meeting the competition,” Cross-function activities and Valuation Issues

Key Compliance Issues and Responses

Key Compliance Issues

- Dealing with Typical FCPA Internal Control Issues:
 - Unauthorized payments/off-books accounts
 - Payments contrary to company policies
 - Payments without prior due diligence
 - Payments just under authority limits
 - Payments without adequate documentation
- Dealing with facilitating (“grease”) payments
 - Induce a non-U.S. official to expedite routine ministerial government action (e.g., document processing, phone service, mail collection)
- “Hospitality.” Payments that are “reasonable and bona fide expenditures, such as travel and lodging expenses ... directly related to:
 - a) The promotion, demonstration, or explanation of products or services; or
 - b) The execution or performance of a contract with a non-U.S. government or agency thereof.

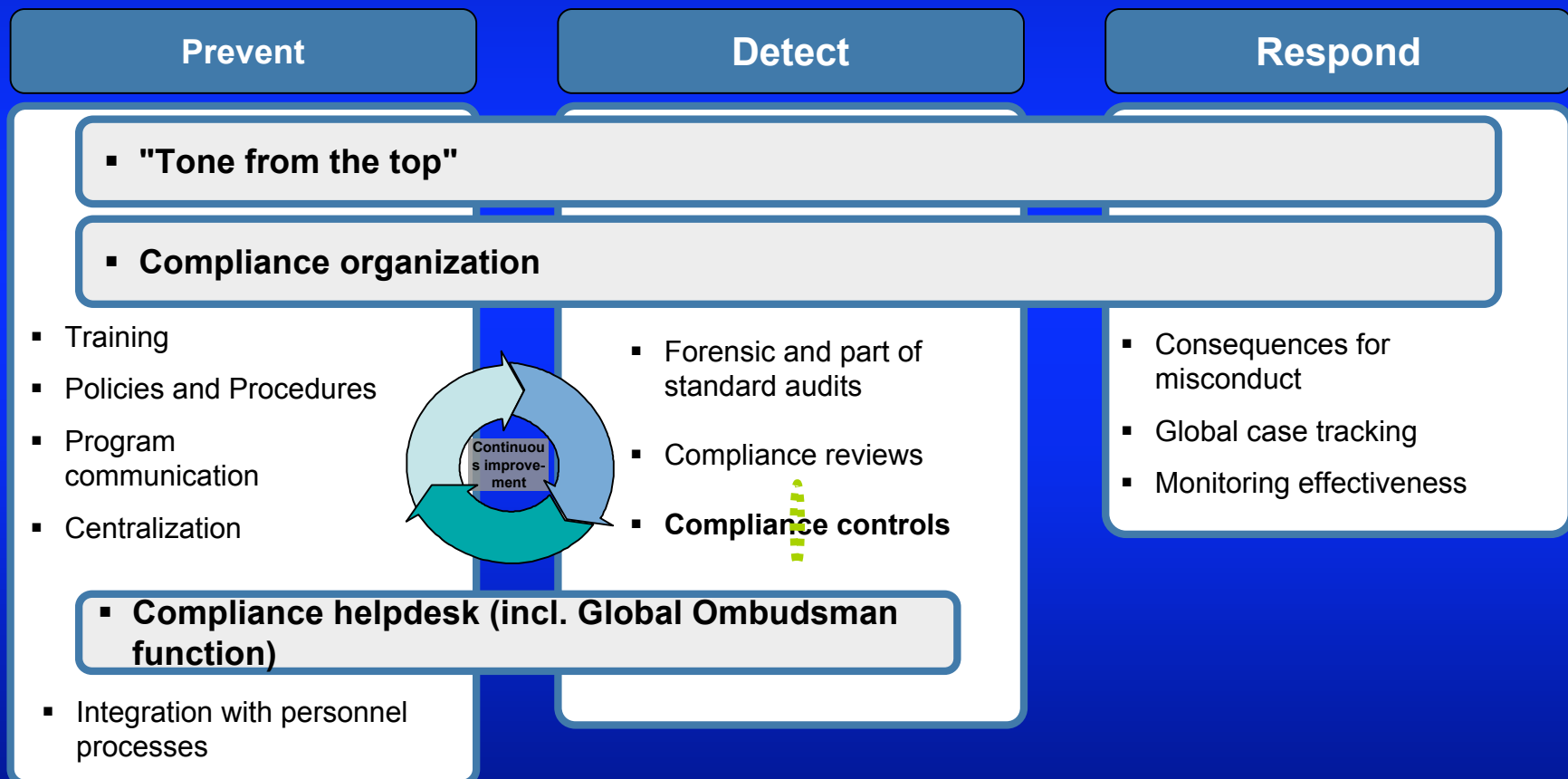
Key Compliance Issues

- Establishing Financial Control Priorities:
 - Government Dealings
 - Regulatory approval, coverage and reimbursement decisions, procurement and tender, pharmacists and clinicians, hospital personnel
 - Vendor approval, maintenance, and payment
 - Agents and Consultants
 - Cash
 - Petty Cash
 - Customs
 - Gifts
 - Executive T&E
 - Training of Financial Personnel

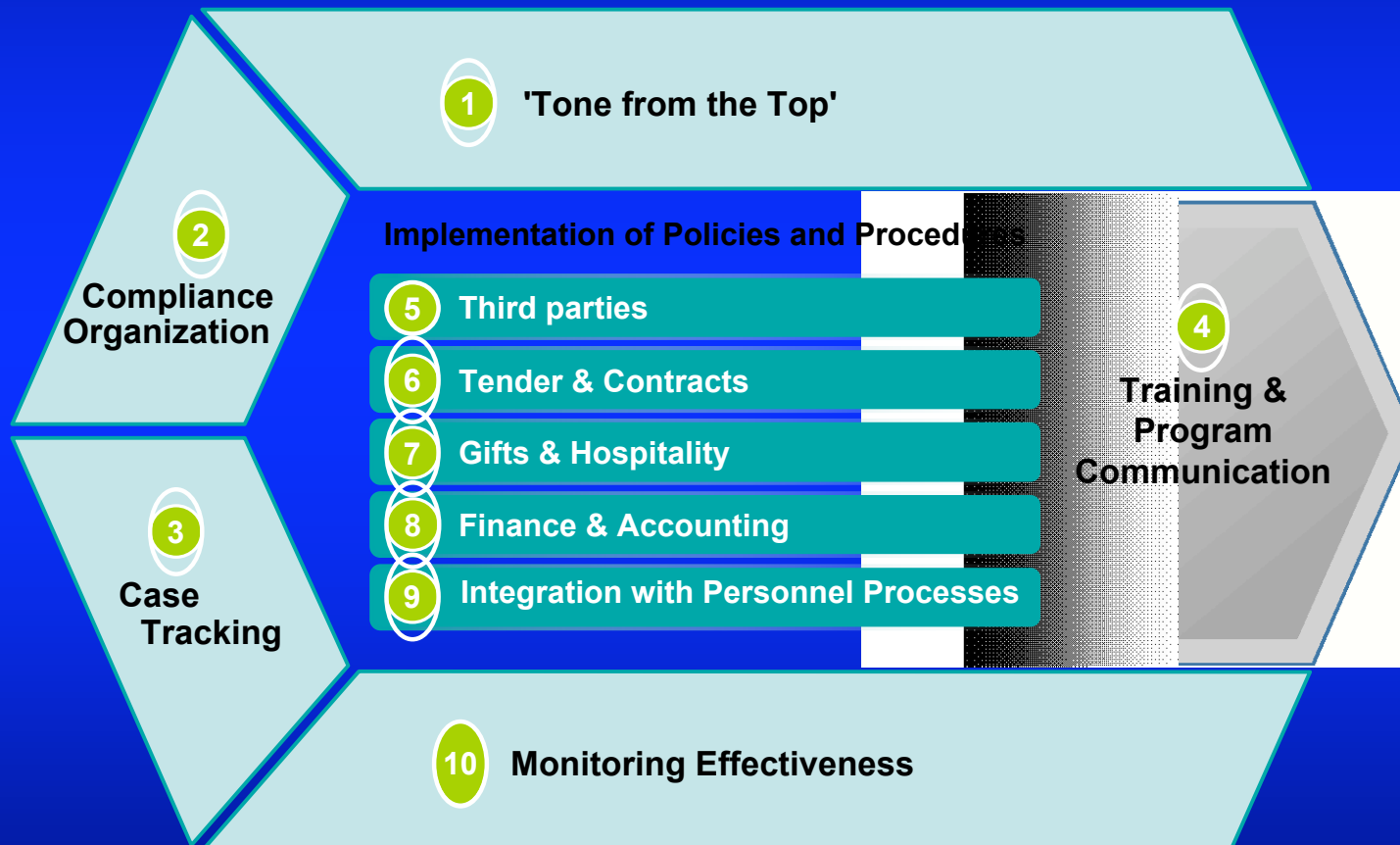
Effective Compliance Implementation Strategies

Implementation Strategies: What is the Siemens Anti-Corruption Implementation Toolkit Rollout about?

A comprehensive Compliance Program has been defined with a focus on Prevent – Detect - Respond



Implementation Strategies: Siemens Implementation Toolkit - Overview of 10 Focus Areas



Continuous Control Monitoring - Potential Indicators

TYPES	TRANSACTIONAL	BEHAVIORAL	BUSINESS MODEL/ ENVIRONMENT/ PERFORMANCE
WHERE THEY MAY BE FOUND	<ul style="list-style-type: none"> ▪ Disbursements ▪ Contracting ▪ Sales and receivables ▪ Segregation of duties ▪ Approvals and authorizations 	<ul style="list-style-type: none"> ▪ Sales call notes ▪ Time and expenses reports ▪ Performance evaluations ▪ Emails ▪ Management communications ▪ System access 	<ul style="list-style-type: none"> ▪ Foreign government official identification ▪ Regulatory requirements ▪ Historical performance ▪ Legislative/enforcement climate ▪ Product portfolio/market share/pipeline ▪ Forecast, budgeting, planning ▪ Market profile and business history ▪ Product regulatory and reimbursement profile and lifecycle ▪ Customs and import activities ▪ Local business model
SAMPLE MONITORING TASKS	<ul style="list-style-type: none"> ▪ Track completion of training modules/lessons and comprehension scores ▪ Track number of contracts with HCPs per hospital of affiliation and by type and compensation ▪ Track totality of payments (honoraria, gifts, meals) to HCPs ▪ Track totality of disbursements to hospitals and foundations 		
SAMPLE AUDITING TASKS	<ul style="list-style-type: none"> ▪ Test comprehension of policies and procedures ▪ Test contracts on government status, written document; timeline of key events; proof of service; approvals ▪ Test donations on government status, timeline of key events, originator/requestor, approval ▪ Test disbursements: nature, supporting documentation, approvals 		

Implementation Strategies: Defining CEO and CFO Responsibilities

	YES	NO
Section 1 of the anti-corruption control set "Tone from the Top" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 2 of the anti-corruption control set "Compliance Organisation" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 3 of the anti-corruption control set "Case Tracking" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 4 of the anti-corruption control set "Training & Communication" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 5 of the anti-corruption control set "3rd Parties" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 6 of the anti-corruption control set "Tender & Contracts" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 7 of the anti-corruption control set "Gifts & Hospitality" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 8 of the anti-corruption control set "Accounting & Finance" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Section 9 of the anti-corruption control set "Integration with Personal Processes" is assessed effective in design and operation?	<input type="checkbox"/>	<input type="checkbox"/>
Considering all elements of the anti-corruption standards - do you assess them as adequate and effective <u>with regard to design and operation</u> ?	<input type="checkbox"/>	<input type="checkbox"/>

- Appointment of an Implementation Manager by the CEO and CFO
- Weekly CEO and CFO briefings throughout the length of the implementation
- Endorsement of the controls as effective and adequate by CEO and CFO

Pfizer Proactive Compliance Review Approach

- **Risk Assessment / Market Selection**
 - Markets targeted for review are selected based on historical audit findings, Corruption Index scores and other relevant factors
- **Document Review**
 - Corporate Compliance and outside counsel review documents, including financial information, SOPs, copies of contracts with vendors, etc.
- **Internal Audit Review**
 - Forensic transaction auditing (e.g., improper payment reviews, etc.) conducted by Internal Audit colleagues, or outside providers
- **In-Market Interviews**
 - Conduct interviews with market leadership and other organizational levels to develop perspectives on risk areas and possible violations
- **Educational Component**
- **Development of Findings**



Voluntary Disclosure In The FCPA Context

- Department of Justice (Holder, Thompson and McNulty Memos)
 - In determining whether to charge, prosecutors should consider the corporation's timely and voluntary disclosure of wrongdoing
- When should the disclosure be made?
 - Want to understand the situation (to demonstrate credibility from the outset, need to make an accurate and complete disclosure)
 - But still want to get credit for timeliness
- Is disclosure mandatory?
 - Public company + material issue = mandatory disclosure
 - The bribe itself may be immaterial (ex. \$1k U.S.), but you also need to examine the business potentially obtained (ex. \$10M U.S.)
 - Industry specific mandatory disclosure – if you have a US government contract you may have a disclosure requirement
 - Auditors – if they find a material weakness in internal controls, they might not certify your financials and then disclosure is mandatory

Making The U.S. DOJ And SEC Disclosure

- Retain competent and appropriate counsel
 - Experienced conducting internal and FCPA investigations
- DOJ and SEC (if public company) – generally make the disclosure simultaneously to both agencies
- Some questions that DOJ/SEC (and counsel) will ask:
 - How was conduct discovered? (relevant to internal controls)
 - How long have you known? (relevant to timing of disclosure)
 - What was the bribe paid or commercial benefit obtained? (relevant to potential penalty)
 - How were the payments recorded?
 - What was the company's response? (relevant to company's credibility and government's willingness to stand down)
 - What was the corrective action taken and the plan forward?
 - Are local prosecutors involved?
 - And how do you know you don't have problems elsewhere?

What About Voluntary Disclosure Locally?

- Should the company ever make a local disclosure?
 - Circumstance driven; must analyze local market conditions
 - Ex. China – death penalty for some corruption offenses
 - Ex. Italy – Law 231 – disclosure by the company may be part of demonstrating that its compliance procedures work
 - Ex. Russia – how do you navigate complex domestic politics?
 - In some cases, however, DOJ/SEC may require disclosure
- How would you make a voluntary disclosure locally?
 - Go straight to their Ministry of Health or notify the country's Ambassador to the United States in Washington?
 - Notify the Commercial Attache in the market's US embassy
 - Any other agencies identified during the process?
 - Who makes that disclosure?
 - Would it even be recognized?

Questions/Discussion