Business Ethics for APEC SMEs:

Promoting SME Innovation and Access to Global Markets through Training in Business Practices in the Medical Device Sector

Gifu, Japan

September 27, 2010

The "Business Ethics for APEC SMEs" Initiative and APEC Commitments to Fight Corruption

Lynn Costa
Senior Trade Development Advisor
US Department of Commerce
USA

Welcome:
APEC Host Economy Japan

Takashi Omote
Director, International Affairs Office, SME Agency
Ministry of Economy, Trade and Industry
Japan

The Business Case for Ethical Practices

Philip M. Nichols
The Wharton School
University of Pennsylvania
USA

ethical practices

- small and medium sized enterprises
- dynamic and innovative industries
- what do we know about ethical practices and in particular about corruption?

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what are ethical practices?

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what are ethical practices?

- act accountably
- act responsibly
- act in good faith


Course helps woman move her business to a higher level

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what is corruption?

- abuse or misuse of an office, trust or responsibility for personal gain

  or

- legally defined acts

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corruption and business

- “speed money” hypothesis or the “that is the way it has always been done argument

versus

- dynamic analysis

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corruption hurts business

- micro business case

- macro business case

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micro business case

- bottom line
- office environment
- future costs and lost opportunities

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micro business case

- bottom line
  - cost of maintaining secrecy
  - uncertainty/unenforceability
  - echo effect (reputation)
  - “ratcheting”

(Kaufman & Wei, 2000)

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micro business case

- bottom line
  - lower sales growth, more bureaucratic interference (Latin Am.) (Gavivia, 2002)
  - 10% lower productivity (Tanzania) (Lambsdorff, 2004)
  - slower market entry (entrepreneurs) (Choi & Thum, 2003)

micro business case

- office environment
  - enterprises that cheat give permission to their own employees to cheat
  - higher levels of self-serving opportunistic behaviour
  - more office theft (US$50 billion annually)

micro business case

- future costs and lost opportunities
  - criminal liability
  - constricted access to capital
  - constricted access to transnational relationships

particularly for SMEs

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macro business case

- generalized trust
- misallocation of resources

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macro business case

- generalized trust
  - buying a Snickers bar

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macro business case

- generalized trust
  - offload transaction costs
  - decrease enforcement costs
  - increase range of potential relationships
  - platform for innovation

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macro business case

- generalized trust

there is a strong positive relationship between generalized trust and economic performance

(Putnam 1993; Whitely 1997; Knack and Keefer 1997; La Porta et al. 1997; van der Heijden and Lensberg 2003)

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macro business case

- generalized trust

World Value Survey: ***most people can be trusted***

Scandinavia	**65%**
Asian tigers	**50%**
Western Europe	**45%**
former Soviet	**25%**
Latin America	**15%**
Africa	**<10%**
Brasil	**4%**

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macro business case

- misallocation of resources

market: price and quality

rational producer → goods and services

corrupt: quality of bribe

rational producer → high quality bribe

macro business case

- misallocation of resources

  - one percent increase in level of corruption decreases GDP by ¾% (Pak, 2001)
  - misallocation of public resources undermines productivity of private capital (Chakraborty & Dabla Norris, 2009)

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macro business case

- misallocation of resources
  - depreciation of national currency (Bahami & Nasir, 2002)
  - inflation (Al-Marhubi, 2000)
  - distortion greater than equal amount of taxation (Vinod, 1999; Wei, 2000)

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macro business case

- misallocation of resources
  - decreased viability of health system (Lewis, 2006)
  - increased child mortality, lower birthweight, less schooling (Gupta, Davoodi & Tiongson, 2000)
  - environmental degradation (Pellegrini & Gerlach, 2006)

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macro business case

- your market speaks
  - bond spread: 1 = 1/5 (Ciocchini, Durbin & Ng, 2003)
  - lower capital market value (Lee & Ng, 2002)
  - decreased foreign investment (Wei, 1997)

macro business case

- degradation of business environment
- contraction of economy/hollow growth
  contraction of customer base
- smaller range of potential relationships

macro business case

- assurance problem
  - everyone is better off if no one cheats
  - if someone else cheats and you do not you will die
  - if you cheat you will be poor but alive
  - you cannot monitor the behavior of others

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should you cheat?

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ethics is good business

- micro

  sme solution: strategy, company code, relationships

- macro

  sme solution: coordination, industry code

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ethics is good business

among other things, ethics is good business

thank you

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Unique Ethical Issues in Medical Device Innovation

Christopher L. White, Esq.
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Unique Ethical Issues in Medical Device Innovation

Christopher L. White, Esq.
Executive Vice President, General Counsel, and Secretary

Advanced Medical Technology Association (AdvaMed)

September 27, 2010
Gifu, Japan

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Who is AdvaMed?

- **World's largest medical technology association**
- **1,600+ member companies and subsidiaries**
- **Member device and diagnostics manufactures produce 90% of sales in U.S. market, 50% of sales in global market**
- **70%+ of member companies have less than $30 million in annual revenue; large SME Membership**
- **65 staff with global expertise, bi-partisan backgrounds**

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Agenda

AdvaMed
Advanced Medical Technology Association

Agenda

1. **What are Medical Devices?**
2. **The Device Industry Difference**
3. **Unique Ethical Issues in the Medical Device Industry**
4. **A Self Regulatory Approach to Ethical Arrangements**

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What are Medical Devices?

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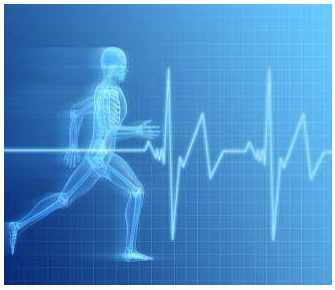
Advanced Medical Technology Association



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What are Medical Devices?

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Advanced Medical Technology Association

Unique Characteristics of Medical Devices and Diagnostics

- Vast majority of companies are smaller – often the incubators for most cutting – edge innovations
- 18 month average life-cycle of Medical Devices
- Replace or augment a bodily function; typically local effects
- Incremental improvements made over time
- Diverse family of products. Any single generation may be distributed to small or niche patient populations
- Technical and technique specific training required for safe and effective use

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The Device Industry Difference

AdvaMed
Advanced Medical Technology Association

Close and ongoing collaboration between health care professionals and medical technology companies is necessary for patient safety and medical innovation

- Medical technologies require hands-on training and practice to assure safe and effective use and retraining as medical technologies undergo repeated changes (short life cycle)

- Physicians bring practical field and other experience vital to continued development and improvement of medical technology

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The Device Industry Difference

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Advanced Medical Technology Association

Company-Clinician Collaboration Essential to Safe & Effective Patient Care

"The early development stage of a new device typically exhibits huge variations in operator techniques and skills. Clinicians are indispensable in refining and standardizing techniques, which can lead to significant improvements in outcomes, as reductions in driveline infections with left ventricular assist devices illustrate. This standardization is reinforced by industrial modifications that render devices more teachable, learnable, usable, and perhaps less expensive."

— Annetine Gelijns, PhD
Professor of Health Policy, Columbia University
JAMA;287:72-77

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The Device Industry Difference

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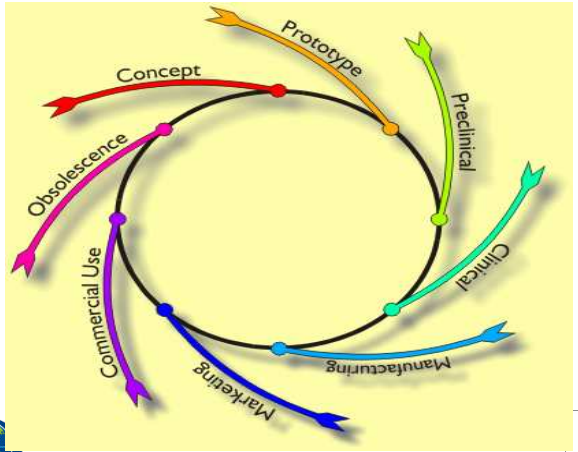
Device Product Life Cycle



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Unique Ethical Issues in the Medical Industry

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Advanced Medical Technology Association

Clinicians and Industry are Intimately United in Procedure Based Medicine

Clinicians' Involvement in the Device Life Cycle

Concept / Prototype
- As inventors and co-inventors

Preclinical
- Assisting in development of trial protocol (e.g., recommend appropriate endpoints and ensuring study robustness)

Clinical
- Conducting trials – participation may be essential to ensure patient safety

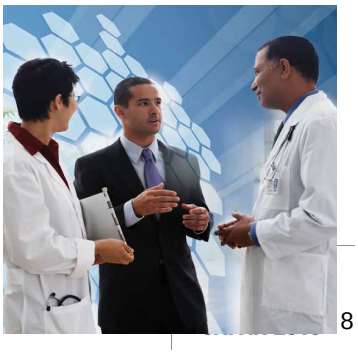
Commercial use
- Conducting and receiving technique-specific device training

Commercial use / Obsolescence
- Providing ongoing recommendations in iterative device development process and adverse event reporting

Device-specific training promotes safe and effective use of devices

- FDA often mandates training as a condition of clearance/approval; Clinicians well-suited to train other clinicians using diverse training models

Clinical Roles
- Patient Care
- Product/Service Selection
- Research
- Management



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Unique Ethical Issues in the Medical Device Industry

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Patient safety requires:

- Device-specific training
- Collaborative consulting (Product Development and other Consulting)
- Equipment Loaners; Demonstration Products (Samples)
- Hospital access; technical support

Other Interactions:
- Charitable donations
- Educational programs & events

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A Self Regulatory Approach to Ethical Interactions

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INDUSTRY WIDE BENEFITS OF AN ETHICAL APPROACH

- Ethical Business Arrangements Ensure Product Selection is based on the Best Interest of Patients
- Enhance Public Confidence in Health Care Delivery
- Predictable, Transparent, and Level Business Environment Fosters Innovation, Industry Growth and Small Company Access
- Enhanced Development of New Technology through Predictable and Ethical Collaborations
- Ethical Companies can Attract and Refrain Educated and Qualified Workers
- Investors Increasingly Expect Compliance Programs and Adherence to Ethical Codes

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A Self Regulatory Approach to Ethical Interactions

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Advanced Medical Technology Association

Challenges to Self Regulatory Approach to Business Ethics

- Device Development and Collaborations are Global
- Rapid Global Dispersion of Breakthrough Medical Technologies
- But…fragmented patchwork of Ethical Codes (Where They Exist) Causes Uncertainty and Unpredictability

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Advanced Medical Technology Association

Thank You!

Christopher White, Exec. Vice Pres., General Counsel and Secretary
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Business Ethics Requirements:

What Companies Should Know and Enforcement Trends in the Medical Technology Sector

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Business Ethics Requirements: CHINA

Mr. Li Yang
Deputy Director General
Department of Corruption Prevention
Ministry of Supervision
China

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I. The Enforcement Trend in China

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- 1. Medical Device Sector in China

Sound & Orderly Development

v. s.

Some Unethical Behaviors

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- 2. China's Efforts in Developing Business Ethics in the Medical Device Sector.

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- (1) Actively Building a Credit System
  ---specific institutions
  ---implementation of projects
  ---a blacklist of business bribery

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- (2) Rigorously Combating Business Bribery
  ---self-examination of enterprises
  ---investigation of illegal cases
  ---a long-term mechanism to prevent business bribery

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- (3) Largely Strengthening Inspection
  on Violation of
  Business Ethics
  ---multi-departmental actions

II. What Foreign Medical Device Enterprises Need to Know When Operating in China?

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- 1. China Welcomes Foreign Investment

---an open, fair and transparent environment

---treat domestic and foreign enterprises equally

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- 2. The Requirements for Foreign Enterprises

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- (1) Enhance Self-awareness of Business Ethics
  ---integrate business ethics into the concepts, strategies and cultures of enterprises
  ---establish relevant management systems

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- (2) Abide by Laws and Regulations of China
  ---a must for enterprises to operate in any country or region
  ---a number of laws related to business ethics in China

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- (3) Regulate Manufacturing and Operating Processes
  ---ensure quality and safety of all the processes
  ---safety of product circulation
  ---reasonable pricing
  ---marketing regulation

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- (4) Take Social Responsibility
  ---promote medical care
  ---environmental protection
  ---public welfare undertakings

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China is Willing to Work Together with All the Friends!

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Thank You!

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Business Ethics Requirements: UK Bribery Act 2010

Geraint Owen
Head of International Regulatory & Corporate Crime
Crowell & Moring
UK

UK Bribery Act 2010

- When will it come into force?
- What are the main/new offences?
- Jurisdiction
  - Will it apply in the Asia Pacific region?
- Comparison with US laws (FCPA)?

UK Bribery Act 2010

- April 2011
- Government will issue its “adequate procedures” guidance to companies early in 2011.

UK Bribery Act 2010

- Four main offences:
  - **Bribing another** (s.1),
  - **Being bribed** (s.2),
  - **Bribing a foreign public official (“FPO”)** (s.6),
    - “*intention to influence*”
  - **Corporate offence: failing to prevent bribery** (s.7).
    - “...a relevant commercial organisation will be guilty of an offence if a person associated with the company bribes another, intending ...to obtain or retain business...”

UK Bribery Act 2010

- Jurisdiction:
  - **s.1, 2 or 6**
    - Offence in the UK?
    - If outside the UK – a "*close connection*" to the UK is required.
    - The following are all said to have a "close connection" to the UK:

(a) a British Citizen,
(b) a British overseas territories citizen,
(c) a British National (overseas),
(d) a British Overseas citizen,
(e) a person who under the British Nationality Act 1981 was a British subject,
(f) an individual ordinarily resident in the UK,
(g) a body incorporated under the law of any part of the UK
(h) a Scottish partnership

UK Bribery Act 2010

- Jurisdiction:
  - **s.7**
    - No "*close connection*" requirement – but there does need to be proximity to the UK. Where a company is not registered in the UK, the UK authorities will only have jurisdiction where the company conducts <u>all or part of its business in the UK</u>.
    - This means that a company registered in Japan could be held liable under section 7, where it had some or all of its operations in the UK, and where an associate of the company pays a bribe in another jurisdiction (e.g. France).
    - Strict liability <u>unless</u> you can show adequate procedures were in place.

UK Bribery Act 2010

- Bribery Act 2010 v FCPA
  - Private/public sector
  - Strict liability offence (unique to UK law)
  - No corrupt intent required for s.6 or s.7 offences
  - No exception for facilitation payments
  - No exception for promotional/hospitality expenditure
  - No civil penalties under UK Bribery Act
  - Criminal penalties:
    - US – individuals – up to 5 years and/or $250,000 fine
    - US – company – up to $2,000,000 per violation
    - UK – individual – up to 10 years and/or unlimited fine
    - UK – company – unlimited fine

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Business Ethics Requirements: USA

Kathleen Hamann
Anti-Corruption Policy Counsel
Fraud Section
US Department of Justice
USA

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Business Ethics Requirements: General observations and common themes

Katherine Wang
Sidley Austin LLP – Beijing office
China

Agenda

- Key regulations
- Scope of application
- Requirements
- Penalties
- Defenses

Key Regulations

- **PRC**
  - Criminal Law
  - Anti-Unfair Competition Law
- **UK**
  - Bribery Act (to be implemented from April 2011)
- **US**
  - Foreign Corrupt Practices Act (FCPA)

Scope of Application

- **PRC**
  - Limited territorial application
    - Offense of bribery committed in China (excluding Hong Kong, Macau and Taiwan)
- **UK**
  - Extensive territorial application
    - Offense of bribery committed in the UK, and abroad by a person having a close connection with the UK
    - Could be unrelated to UK operations
- **US**
  - Extensive territorial application
    - Offense of bribery committed in the US and abroad
    - US connection required

Requirements

- **PRC**
  - Both offeror and recipient of bribes liable
  - Recipient of bribes: any organization or individual; not limited to “state functionaries”
  - Intent:
    - to seek improper benefits or to unduly influence a person or an entity to sell or purchase products/services
  - No minimum value to establish violation (except for criminal liabilities associated with receiving bribes by non-state functionaries or offering bribes)

Requirements

- **UK**
  - Both offeror and recipient of bribes liable
  - Recipient of bribes: any organization or individual (including foreign government official)
  - Corporate Offence: failure of a commercial organization to prevent bribery by a person associated with it
    - Only available defense: adequate procedures
    - Non-UK commercial organizations carrying on business in UK also covered
  - Promise alone sufficient to establish violation
  - Intent:
    - to induce improper conduct
    - strict liability applicable to corporate offense
  - No *de minimis* exception

Requirements

- **US**
  - Only offeror of bribes liable
  - Recipient of bribes: an individual
  - Promise alone sufficient to establish violation
  - Intent:
    - a corruptive intent
    - companies liable for third party actions only if they take actions in furtherance of the corrupt payments
    - Corruptive intent of quid pro quo generally assumed
  - No *de minimis* exception

Penalties

- **PRC**
  - Administrative
    - Fines (RMB 10k to 200k, around US $1,500 to 30,000)
    - Disgorgement of illegal gains
    - 2-year block from tender bidding
  - Civil
    - Damages to 3rd parties
  - Criminal
    - Fines, confiscation of illegal gains, criminal detention, imprisonment and death

Penalties

- **UK**
  - Criminal
    - For corporate offence:
      - Unlimited fines
    - For other offences:
      - Unlimited fines for companies
      - Imprisonment (for up to 10 years) and unlimited fines for individuals

Penalties

- **US**
  - Civil (anti-bribery provision)
    - Fines up to US$ 10,000
    - Disgorgement of illegal profits
  - Criminal (anti-bribery provision)
    - Corporations: A fine up to US$ 2 million
    - Individuals: A fine up to US$ 250K and imprisonment for up to 5 years

Defenses

- **PRC**
  - Not clear in precedents
- **UK**
  - Adequate procedures in place for corporate offence
  - Written laws of the country of the foreign official
  - Reasonable and bona fine expense not explicitly provided
  - Facilitation payments not explicitly provided
- **US**
  - Written laws of the country of the foreign official
  - Reasonable and bona fide expenses allowed
  - Facilitation payments allowed

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Panel Discussion: Role of Industry Codes of Ethics

Moderated by Katherine Wang
Sidley Austin LLP – Beijing office
China

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Faye Sumner
CEO
Medical Technology Association of New Zealand

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MTAA / MTANZ Code of Practice

- Australia & New Zealand industry associations harmonised Code
- First edition adopted in 2005 – now Ver. 6
- Continued alignment with AdvaMed Code
- Compliance is mandatory for members and advisory for non-members
- Code of Practice Committee
- Code of Practice Monitoring Committee

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Monitoring and Enforcement

- Code provides for a monitoring function with production of material evidencing:
  - Education & training of healthcare professionals (HCP)
  - Sponsorship arrangements of third party conferences
  - Research grants
  - Competitions for healthcare professionals (HCP)
- Code complaints process:
  - Requires company to company interface
  - Followed by independent complaints hearing with penalties

Australia's Reform Objectives

- Government:
  - Supports industry self-regulation
  - Seeks strengthening of codes to ensure consistent adherence to high level principles
- High level principles to address:
  - Common core standards
  - Principles of conduct
  - Governance arrangements (reporting, compliance, education)

New Zealand's Emerging Medical Technology Sector

- 60 x Device manufacturers
- USD 400 million exports
- 80% exports to US / Europe
- Growing Asian market

Compliance as a Competitive Advantage

- Foundation to build & maintain trust
- Protect the ability of companies to collaborate with HCP on go-forward basis
- Regulators & enforcement agencies will expect compliant systems
- Bring transparency to business practices and enable ethical sales & marketing operations.
- Role of preferred manufacturers for HCP collaboration

Thank You

- Medical Technology Association of Australia
  www.mtaa.org.au
- Medical Technology Association of New Zealand
  www.mtanz.org.nz

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Masaaki Naito
Nihon Kohden
Chairperson, International Policy Committee of the Japan Federation of Medical Devices Associations

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Business Ethics of Japan's Medical Device Industry

promoted by 2 organizations

1. JFMDA

   Japan Federation of Medical Devices Associations

2. JFTC

   Japan Fair Trade Council of Medical Devices Industry

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Introduction of JFMDA

- 20 industrial association members
  - JIRA, JEITA, JAMDI, JMED, JAHID, HAPI, JMOIA, JDTA, JAIMA, JCLA, IPT, JOIA, JHHCA, JHIMA, T-MIA, JHIDA, JHPIA, JIOLA, JASS, JCI
  - **4900 companies**
  - **30,000 items of medical devices**

JFMDA Goal

Communicate the consensus of the medical device industry to society and provide guidance for association members should take.

Basic mission

We contribute to health care progress and growth of medical device industry through business activity

Main business activities

Various committees provide information and work with Conpetent Authorities and other administrative bodies and international bodies

- Business Ethics Committee

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JFTC of Medical Devices Industry

- Establish standard business practices and fair/ free competition in the medical devices trade
- Promote" The Fair Competition code" which is based on "Act against Unjustifiable premiums and Misleading Representations" law

→http://www.jftc-mdi.jp/

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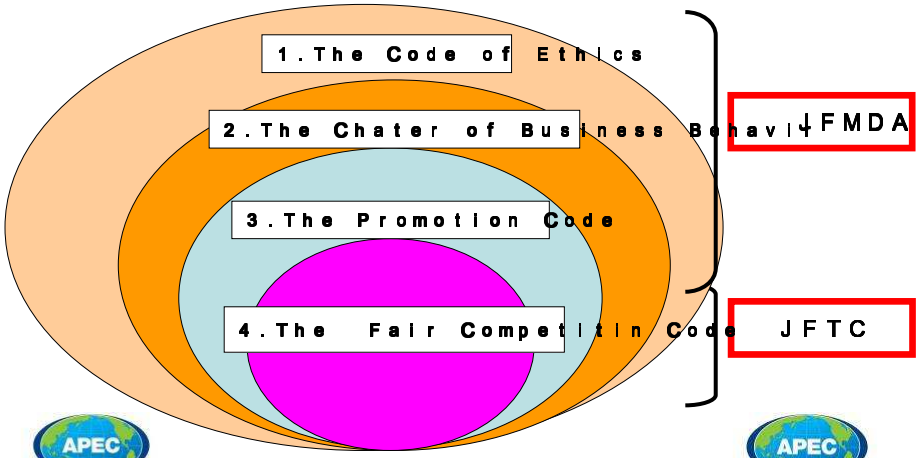
For establishment fair trade and standard business practice

Ethics code is composed of 4 rules



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Background of ethics code

1991 ~ 2 **Scandals in medical devices industry**

Bribery and corruption in National Universities hospital

JFMDA

1993 **The Code of Ethics**

1997 **The Promotion code**

2005 **The Charter of Business Behavior**

JFTC

1998 **Establish JFTC**

1999 **The Fair Competition Code**

- limitation of premiums

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Position of these rules

1. JFMDA's 3 rules

   -Recommendation for medical devices industry

   -should comply with appropriate law and regulations

   -should take more ethical/ social responsibility

2. JFCT's rule

   -Voluntary rule for medical devices industry

   -based on the Act, involves penalty

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4 rules of ethics code

1. The Code of Ethics

   Do the right thing in society with the high sense of ethics

2. The Charter of Business Behavior

   The corporate activity standard and top management's obligation

3. The Promotion Code

   The written guideline which the whole industry should follow

4. The Fair Competition Code

   shall not offer excessive premiums as a means of getting business

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The Code of Ethics

Basic idea

・ The social responsibility of JFMDA

・ The business activity that originates in high ethics

・ contribute to medical improvement and earn social trust.

Provisions

1. The validity of the product and securement of safety
   It's also considered in an environmental issue.

2. Obeying of regulations and high ethical awareness "Corporate activity charter" is added this revision.

3. Fair and free competition, in domestic and abroad
   Earn the trust of society through the public medical insurance system

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The Charter of Business Behavior

The behavior standard

- Compliance
- Social responsibility of an enterprise
- Development of the business activity for sustainability

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The Charter of Business Behavior

- **Behavior principle**

7 principles

1. The validity, sacrament of safety and stable supply
   The importance of post marketing surveillance
2. Fair and free competition and improvement of lawful spirit
3. Environmental issue
4. Protection of personal information
5. Top management
   Sufficiently inform employees about this charter
6. Top management
   Whistle-blowing and protection of Whistle-blowing
7. Top management
   Clarification of information disclosure and responsibility and strict handling

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Contents of the promotion code

1. Obligations and Practices of Members
2. Obligations of Top Management
3. Product Development
4. Manufacturing and Marketing
5. Market Research
6. Advertising /Promotion (Representations of Printed Materials and Advertisements for Promotion)
7. Surveillance after Manufacturing and Marketing (Post-Marketing Surveillance)
8. Marketing Activities
9. Holding Seminars
10. Scientific Display of Unapproved Medical Devices
11. Promotion in Foreign Countries (Provision of Information on Medical Devices in Foreign Countries)
12. Relationship between this "Code" and the "Fair Competition Code"

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The promotion code for advertisement

(1) Ensuring fair competition and fair trade

(2) Prohibiting slanderous or defamatory acts

(3) Prohibiting the preparation of unfair comparison tables

(4) Offering service

(5) Offering goods

(6) Offering money or the like

(7) Offering sample medical devices

(8) Offering medical devices on loan

(9) Confidentiality of information on customers and like persons

(10) Concluding agreements in writing

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The Fair Competition Code JFTC

- **Purpose**

  The Fair Competition Code(FCC) aims to prevent unfair inducement of customers through restrictions on unjustifiable premium offers in the medical devices manufacturing and distributing industry, and to ensure fair competition and order within the industry.

  FCC is a rule for medical devices industry to restrict the offering of free gifts when dealing medical devices.

  -more detail rule：Donation / Rent / Session etc

“Premiums"

The term "premiums" as used in the FCC shall mean any articles, money, or other kinds of economic benefits which business entities (medical devices manufacturers and distributors and those engaged in related activities) may offer, irrespective of methods employed, to the other parties in connection with transactions of their medical devices as a means of inducing customers, (with the exception of premiums that do not include any economic benefits such as discounts or after- sales services in light of normal business practices, nor any economic benefits which are found as belonging to the medical devices in light of normal business practices) as listed below;

(1)Goods, land, buildings and other structures
(2)Money, money certificates, bank deposit certificates, lottery certificates, bond or share certificates, shopping certificates, and other securities
(3)Entertainment (including invitation free of charge or with favorable fees to movies, shows, sports, travel, and other amusements)
(4)Conveniences, labors, and other services

Christopher L. White, Esq.
Executive Vice President, General Counsel, and Secretary
Advanced Medical Technology Association (AdvaMed)
USA

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AdvaMed
Advanced Medical Technology Association

Role of Industry Codes of Ethics

Christopher L. White, Esq.
Executive Vice President, General Counsel, and Secretary
Advanced Medical Technology Association (AdvaMed)

September 27, 2010
Gifu, Japan

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AdvaMed's Longstanding Commitment to Ethical Business and Compliance Leadership

AdvaMed
Advanced Medical Technology Association

- 1991 – First AdvaMed Code of Ethics
- 2003 – Board adopts revised Code
- 2005 – Supplementary FAQs
- 2006 – Code Logo program
- 2008 – Endorsement of Physician Payment Sunshine Legislation
- 2008 – (New) Revised Code of Ethics
- 2009 – Code Certification by Early Adopters
- 2010 – Health Reform Statute incorporates Physician Payment Sunshine Legislation
- 2010 – Transatlantic Statement on Ethical Interactions

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The AdvaMed Code as a Tool to Promote Ethical Business Relationships

AdvaMed
Advanced Medical Technology Association

- Encourages voluntary, ethical interactions between Medical Device Manufacturers and health care professionals.
- Distinguishes between interactions that:
  - Advance Medical Technology
  - Have Potential to Influence Medical Decision-Making Inappropriately

Code Addresses:

- Arrangements with Consultants; Royalties
- Member-Sponsored Product Training & Education
- Supporting Third Party Educational Conferences
- Sales & Promotional Meetings
- Demonstration Units; Evaluation Products
- Provision of Reimbursement and Other Economic Information
- No Entertainment; Recreation, Gifts
- Grants and Charitable Donations

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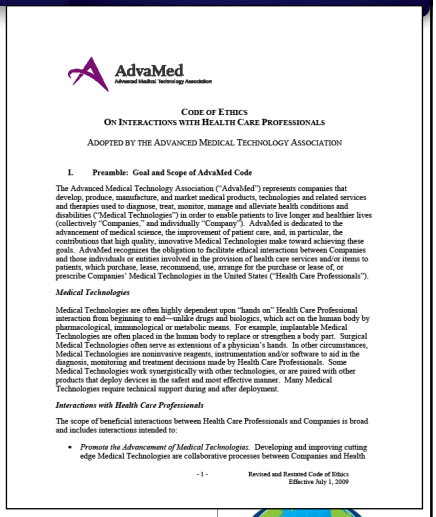
Revised and Restated Code of Ethics

AdvaMed
Advanced Medical Technology Association

New Code: Effective July 1, 2009

- Expanded scope
- Greater clarity throughout
- New "Code Compliance" section



AdvaMed
Advanced Medical Technology Association

CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association ("AdvaMed") represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities ("Medical Technologies") in order to enable patients to live longer and healthier lives (collectively "Companies," and individually "Company"). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies' Medical Technologies in the United States ("Health Care Professionals").

Medical Technologies

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician's hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

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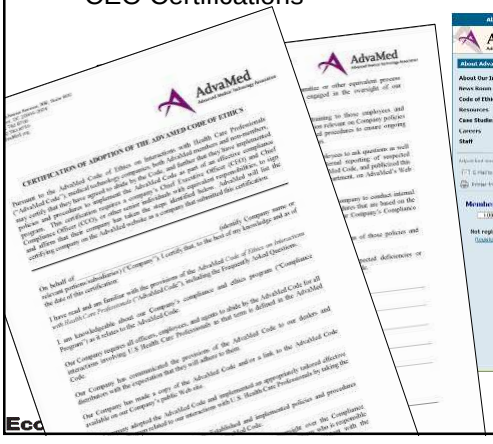
Code of Ethics Certification

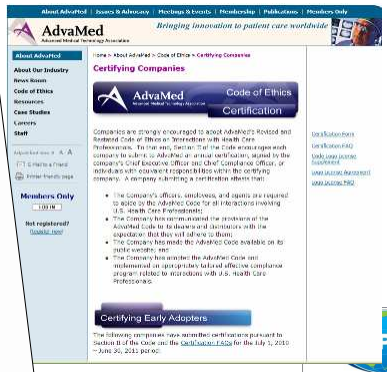
AdvaMed
Advanced Medical Technology Association

"Code Compliance"

- Designed to encourage company adherence
- CEO Certifications
- Certifications were published on AdvaMed's website on January 1, 2010
- *Currently 108 companies certified*!



CERTIFICATION OF ADOPTION OF THE ADVAMED CODE OF ETHICS



Certifying Companies

Code of Ethics Certification

Certifying Early Adopters

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Code of Ethics Certification

AdvaMed
Advanced Medical Technology Association

Company Certifications as of Sept. 15, 2010

Code of Ethics Certification

AdvaMed
Advanced Medical Technology Association

Company Certifications as of Sept. 15, 2010 (Cont.)

Code of Ethics Certification

AdvaMed
Advanced Medical Technology Association

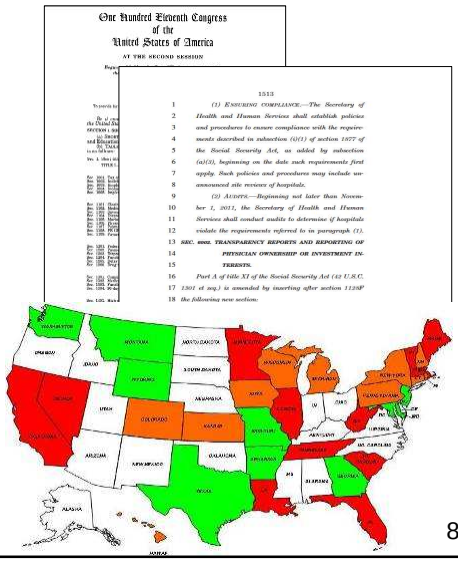
Company Certifications as of Sept. 15, 2010 (Cont.)

MEDERI THERAPEUTICS INC
NUTEK ORTHOPAEDICS
Application of New Technologies in Orthopaedic Surgery
smith&nephew Orthopaedics
TYRX
Trans1
Medtronic
ORTHOFIX
smith&nephew Endoscopy
MEDRAD
Ortho Clinical Diagnostics
a Johnson & Johnson company
SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY
VERIDEX LLC
a Johnson & Johnson company
MENTOR
MAKE LIFE MORE beautiful
spinal restoration
VQ OrthoCare
VisionQuest Industries, Inc.
Phadia
STEREOTAXIS
MedRep
PHOTOTHERA
stryker
VISTAKON
Johnson & Johnson Vision Care, Inc.
MICELL TECHNOLOGIES
Teleflex MEDICAL
WelchAllyn
RecoverCare
Equipment. Solutions. Results!
STERIS
MICROVENTION TERUMO
TERUMO
Terumo Cardiovascular Systems
micrus endovascular
Roche
Semprus BIOSCIENCES
TERUMO
Terumo Heart, Inc.
WRIGHT
MÖLNLYCKE HEALTH CARE
smith&nephew Advanced Wound Management
TERUMO
Terumo Medical Corporation
XDx EXPRESSION DIAGNOSTICS
Novasys Medical
smith&nephew Biologics & Spine
Therakos PHOTOPHERESIS
zimmer

Code Context in the US

AdvaMed
Advanced Medical Technology Association

- Scrutiny of Industry Relationships
- Physician Payment Sunshine included in Health Care Reform Statute
- Increasing State Activities; Incorporation of AdvaMed's Code in State Law


One Hundred Eleventh Congress
of the
United States of America
AT THE SECOND SESSION

1513

(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act, as added by subsection (a)(3), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

(2) AUDITS.—Beginning not later than November 1, 2011, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1).

SEC. 6002. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

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Looking Ahead:
Ethical Business is a Global Commitment (and Challenge)

AdvaMed
Advanced Medical Technology Association

Joint Transatlantic Statement on Ethical Interactions

Core Principles:

- Appropriateness
- Transparency
- Legitimacy
- Independence

AdvaMed

JOINT TRANS-ATLANTIC ST
MEDICAL TECHNOLOGY C

Medical technology industry Code
Eucomed Codes, support and
diagnostics companies ("Companie
ongoing development of advance
effective use of medical technologie

Healthcare and medical technol
cultural boundaries, and there is
Companies' interactions with HCP

Even though different in their wor
goals and spirit. They promote the

- Legitimacy;
- Transparency;
- Independence, and
- Appropriateness of rela

These ethical standards are illus
arrangements, such as:

- Research and Develop
improve existing produ
for patients. Through
in, for example, product
- Education of HCPs,
programs and educatio
- Training HCPs on dev
effective use of medical

AdvaMed

Eucomed

- Providing donations for charitable or other philanthropic purposes to support bona fide charitable organizations and missions

Ethical behaviour is a prerequisite for continued professional collaborations necessary to the ongoing advancement of medical technology and to the appropriate use of medical technologies in healthcare systems in the best interest of the patient. It is critical that these medically beneficial and collaborative interactions among Companies and HCPs preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.

The undersigned medical technology associations will further their longstanding work to promote ethical collaborations among Companies and HCPs globally, and together commit to:

- Promote ethical interactions among Companies and HCPs by encouraging Companies to adopt compliance programs and policies consistent with the AdvaMed and/or Eucomed Codes;
- Provide guidance to the medical technology industry at large on ethical business conduct relating to Companies' interactions with HCPs;
- Support education and compliance of Companies with all applicable laws, regulations or professional codes (including national association codes) that may impose more stringent requirements, relating to Companies' interactions with HCPs; and
- Work together to advance ethical collaborations consistent with the AdvaMed and Eucomed Codes globally, through regular communication, joint policies (where appropriate), joint activities, and other appropriate collaborations.

Advanced Medical Technology Association
Stephen J. Ubl
President and CEO

Eucomed
John Wilkinson
Chief Executive

European Diagnostic Manufacturers Association
Christine Farnan
Director General

2

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AdvaMed
Advanced Medical Technology Association

Thank You!

Christopher White, Exec. Vice Pres., General Counsel and Secretary
cwhite@advamed.org

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Sujata Dayal
Biomet and Eucomed (European medical technology industry association)

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1. Eucomed compliance vision

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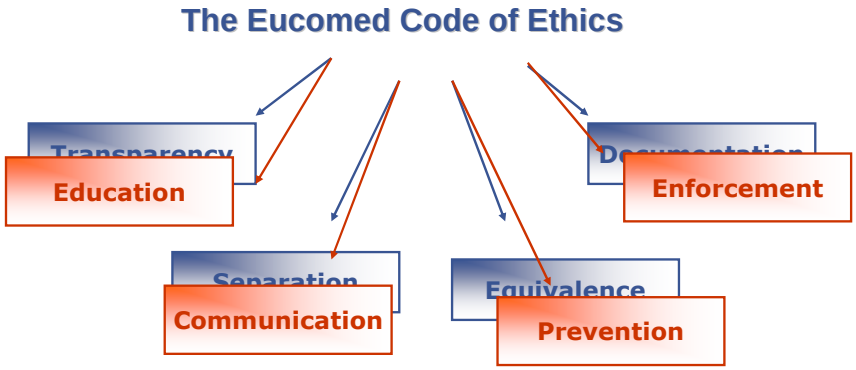
2. The underlying principles



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3. Content of the guidelines

1. Who is covered by those rules?
2. Core principles
3. Events & Educational support
4. Financial arrangements – exchange of monetary value against bona fide services
5. Donations (to institutions only)
6. Gifts
7. Meals

PS: the Eucomed Code is composed of the following parts:

- The Guidelines on the Interaction with HCPs (and the Guidance Document, i.e. the Q&A)
- The Guidelines on Competition Law
- The Procedural Framework

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Harmonisation & consistency

1. Compliance Network
2. Communication
3. Training
4. Congresses

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1. Eucomed Compliance Network

Charter Component	Description
Mission	Take a leadership role in promoting a culture of integrity and ethical business practices across the medical technology industry, drive development and improve implementation of the code.
Sub-groups/actvities	► Training TF ► Communication TF ► Congress TF ► Logo TF ► Code Committee ►Common AdvaMed/Eucomed "survey" sub-group
Audience	NAs, Companies (i.e. legal, compliance), Board, AdvaMed, EDMA

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2. Internal & external communication

- **Internal objectives**
  - Raise awareness and level of understanding
    - E.g. Compliance Network, conferences & events
  - Drive implementation and alignment within the industry (i.e. NAs & corporate members)
  - Eucomed Code and principles as a baseline across Europe
- **External objectives**
  - Establish common level of understanding and awareness
    - Scientific societies/Congress organisers: Sectoral approach
    - Sister organisations (e.g. AdvaMed, EDMA, EFPIA)
    - Others (e.g. TI, OECD)
  - Facilitate alliance building
    - E.g. Common declarations
  - Drive alignment with key stakeholders and policy makers

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3. Live and online trainings

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4. Congress related activities

- Direct communication to European and international scientific societies
  - Orthopaedics
  - Cardiology
  - Neurology
  - Other?

► Development of an tool for the use by companies to assess the appropriateness of congresses according to the Eucomed Code

- EU 1/3 party organisation giving recommendations?

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"Procedural framework": a dispute handling process

- Objective:
  - Provide an effective and efficient complaint handling that enjoys confidence of involved stakeholders at European level
    - Each National Association member of Eucomed to include provisions of resolution of complaints under national codes of conduct
- Underlying principles:
  - Proportionality
  - Speed
  - Due process
  - Fairness
  - Transparency
  - National settlment of national disputes

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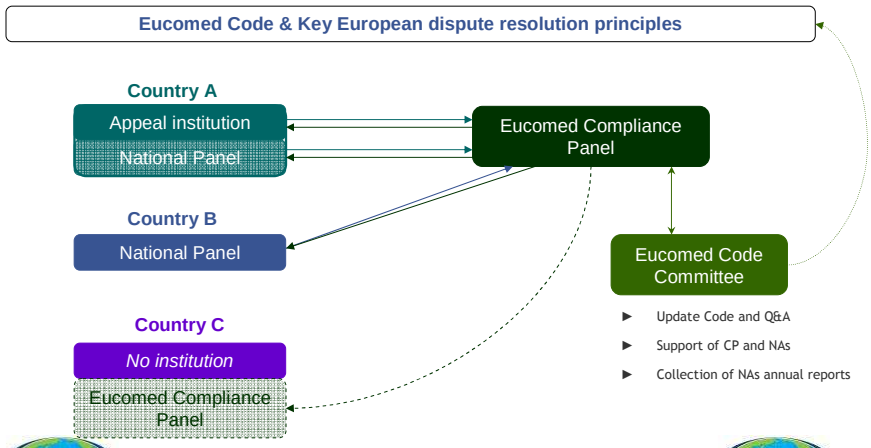
Underlying philosophy



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Thank you very much.

Questions? Comments?

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Panel Discussion:
Ethical Challenges in Practice

How do Medical Device Companies Operationalize Legal, Ethical and Code Standards?

Moderated by Ron Oleynik
Holland & Knight
Beijing & Washington DC

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Jessie Yap
General Counsel, Asia Pacific

COVIDIEN

Asia-Pacific Economic Cooperation

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COVIDIEN

- Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies.
- With 2009 revenue of $10.3 billion, Covidien has 42,000 employees worldwide in more than 60 countries, and its products are sold in over 140 countries.

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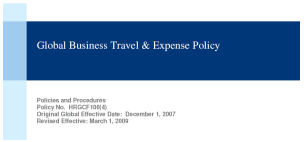
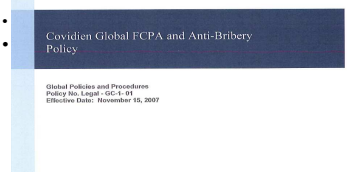
Key Company Policies

Global Business Travel & Expense Policy

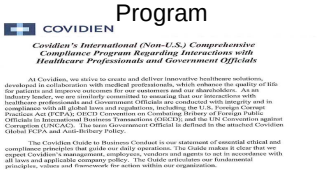


Global FCPA and Anti-Bribery Policy



Guide to Business Conduct

Comprehensive Compliance Program



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What is bribery?

This doctor is looking to buy a car for himself. Can he accept any of these offers?

Doctor, buy the car from me and you can have cash back of USD2,000!

Doctor, buy the car from me and I will give you free petrol for 6 months!

Doctor, buy the car from me and I will give you an all expenses paid holiday to Las Vegas!

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Healthcare Industry

Government
Registers medical products which are safe for use on patients

Hospital/ Healthcare professional
Buys medical products to treat patients

Register Company A's products and we will give you $$

Buy Company B's products and we will send you to that Congress in Europe

Covidien offers world-class medical products and we are committed to the highest degree of ethical conduct

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Key Compliance Programs

- Ethics Circle - regular mandatory meetings with quizzes, role plays, real life scenarios, etc., co-led by Integrity Champions and Covidien's senior management
- Grants and Compliance Committee - made up of Heads of Medical Affairs, Legal and Finance to review sponsorship, grant, training, consultancy, donation and gift applications
- Distributor Compliance Program – includes compliance managers who conduct compliance due diligence and on-site assessment on distributors
- Compliance Toolkit – Take-along material on company policies for sales and marketing employees when interacting with healthcare professionals (includes summary with "dos" and "don'ts")
- A Trusted Partnership (Integrity Helpline/Ombudsman)

Masaaki Naito
Nihon Kohden
Chairperson, International Policy Committee of the Japan Federation of Medical Devices Associations

Japan Business Ethics System with Nihon Kohden Example

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Nihon Kohden Corporation

Incorporation : August 7, 1951
Paid-in Capital : ¥7,544 million
Activities : Manufacturer and distributor
Employees : 3,588 (group total, March 2010)
Stock : Tokyo Stock Exchange, Section A

Head office (Shinjuku)

International Operations (Nakano)

■ **Since its founding, Nihon Kohden has continued 59 years to introduce innovative products and grow into one of the world's leading medical equipment companies.**

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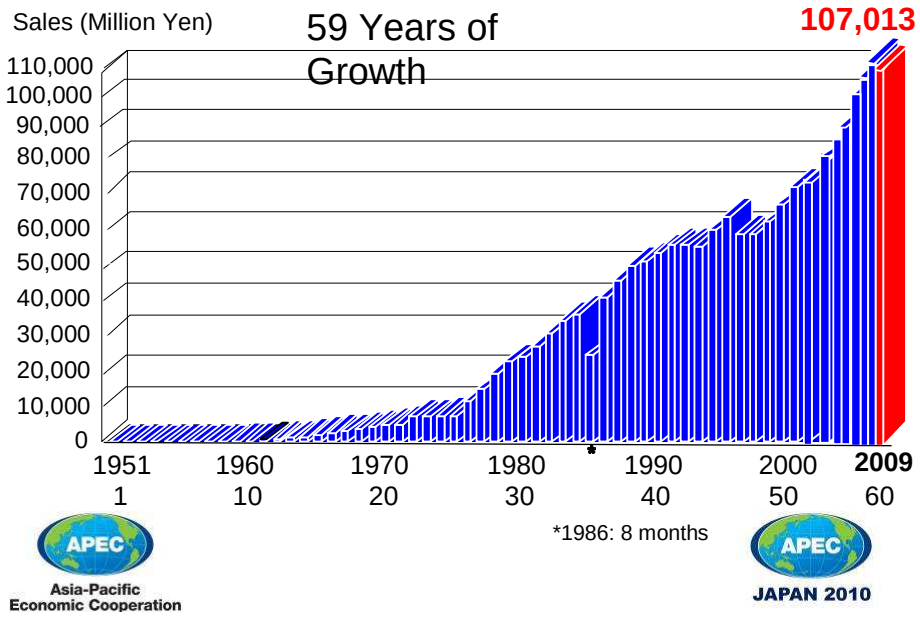
Nihon Kohden Net Sales



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Nihon Kohden Group Subsidiaries

Japan

3,242 employees as of June 30, 2010

【Sales】
NK Hokkaido Corp.
NK Tohoku Corp.
NK Higashi Kanto Corp.
NK Kita Kanto Corp.
NK Tokyo Corp.
NK Minami Kanto Corp.
NK Chubu Corp.
NK Kansai Corp.
NK Chushikoku Corp.
NK Kyushu Corp.
Sales Offices: 120
Service Offices: 74

【Service】
NK Service Corp.

【Production】
NK Tomioka Corp

【R&D】
Beneficks Corp.
Nippon Biotest Laboratories Inc.

International

497 employees as of June 30, 2010

【Europe】
Nihon Kohden Europe GmbH
Nihon Kohden France Sarl
Nihon Kohden Iberica S.L.
Nihon Kohden Italia S.r.l.
Nihon Kohden Firenze, S.r.l

【Americas】
Nihon Kohden America, Inc.
NK US Lab
Neurotronics Inc.

●R&D
■Production
●Sales

【Asia】
Nihon Kohden Trading (Shanghai) Co., Ltd.
Shanghai Kohden Medical Electronic Instrument Corp.
Medinet Kohden Shanghai Corporation
Nihon Kohden Singapore Pte Ltd.
Nihon Kohden Korea, Inc.
Span Nihon Kohden Diagnostics Private Ltd.

Nihon Kohden Products

Major product lines

- Patient monitors, defibrillators, ECG, EEG, EP/EMG, hematology analyzers

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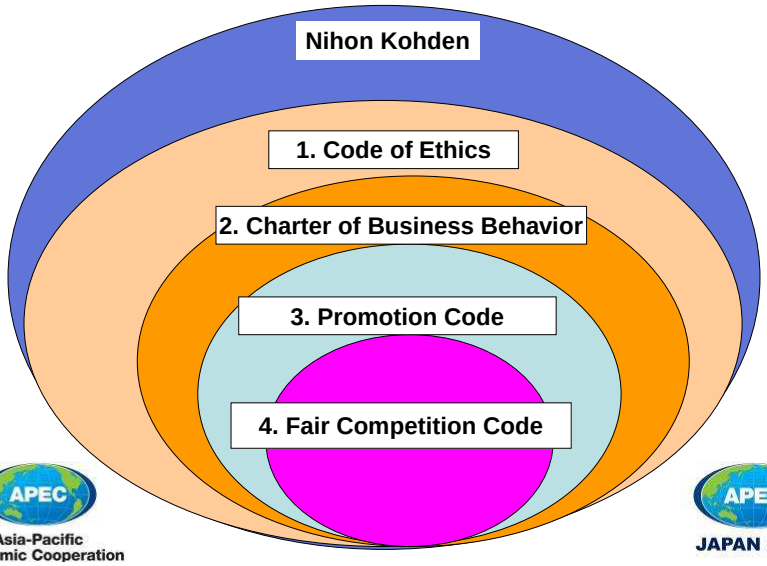
Nihon Kohden's Business Ethics



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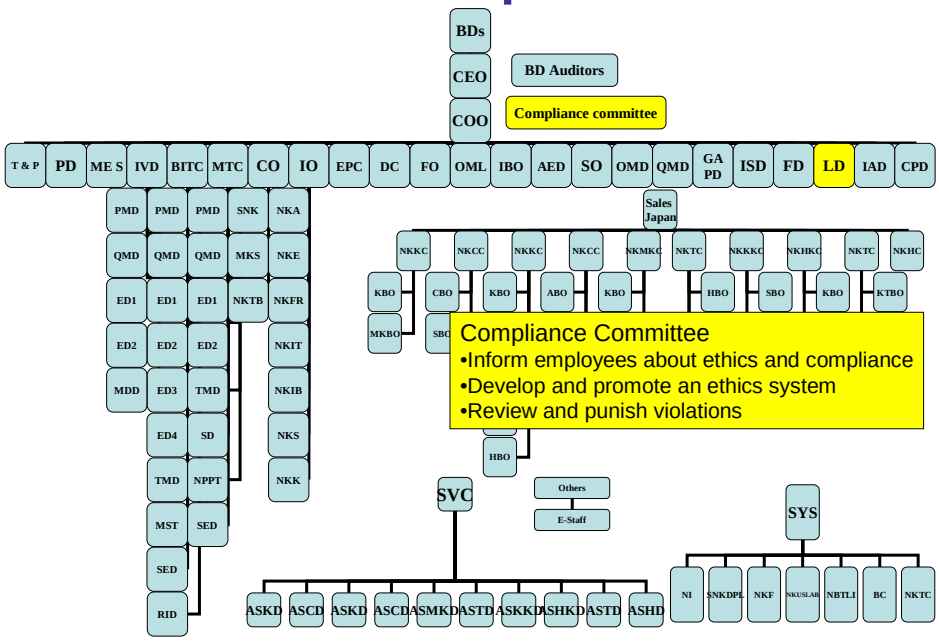
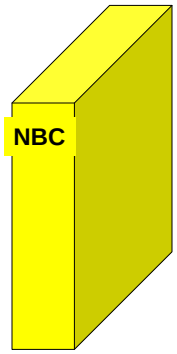
Nihon Kohden Corporate Structure



Nihon Kohden Business Rules



NBC-A-006 NK's Charter of Business Behavior

NBC-A-006-1 Promotion Code Promote Rules

NBC-A-006-2 Ethics Behavior Rules

NBC-C-112 Insider Trading Prevention Measures

Guidelines for Medical Treatment Assistance

Guidelines for Device Lending

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NK Compliance Pocket Book

- Summarizes key points

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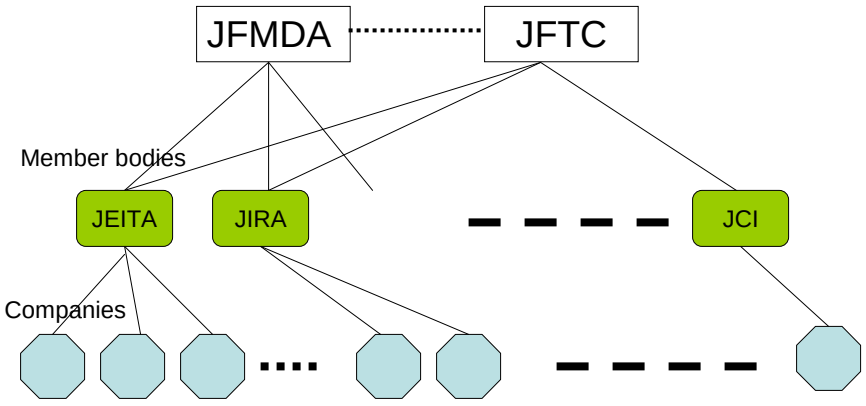
Communication and Cooperation



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Education and Training

- JFMDA
  - Business Ethics Seminar
    350-500 participants every year
  - Education for member bodies
- JFTC
  - Instructor Certificate
  - Education for members
  - Teaches the Fair Competition Code at various medical congresses

How to Handle Excessive Premiums

- Free device rental
  →JFTC Guidance No. 307(2004)
- Direct assistance in medical treatment
  →JFTC Guidance No. 1045(2007)
- Excess inappropriate donation
  →Acceptance criteria

Issues in the Fair Competition Code

4 step punishment

1. Caution
2. Warning
3. Major Warning
4. Penalty, expulsion

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Summary

- Difficult to know the right thing to do
  - The answer is more thinking is needed
- It is difficult but we should try to harmonize business ethics in the APEC region

Thank you

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Lori Reber
Vice President
Office of Ethics & Compliance
International & Emerging Markets
Smith & Nephew

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smith&nephew

About us

- 9,500 employees around the globe
- $3,772 million global sales
- 1,000+ products that help people regain their lives
- Sales in 90 countries
- Offices in 32 countries

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Global market position

- No. 1 in arthroscopy, endoscopy
- No. 2 in wound care
- No. 3 in trauma, clinical therapies; orthopaedics
- No. 4 in reconstruction, orthopaedics

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Commitment from the Top

Acting with integrity is more than just compliance with the law.

Those who deal with us should also expect that we will meet accepted ethical standards.

Nothing - not making the numbers, competitiveness or direct orders from a superior - will ever compromise our commitment to integrity.

- David Illingworth, Chief Executive Officer

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Global Compliance Program

Smith & Nephew has committed to a World-Class compliance program that provides high level of assurance on compliance to the Board and senior management and embeds compliance in the business with a culture of integrity.

We achieve this vision by having:

1. Tone at the top
2. Clear standards, effective training, and communication
3. Risk based focus and measurement of program effectiveness

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Compliance Organizational Design

Dedicated Global Business Unit (GBU) Compliance Groups

- Dedicated GBU CO and support groups to assist GBU Presidents with their accountability for compliance and to assist with GBU specific compliance processes

Cross-GBU Shared Services for best practices, efficiency and flexibility

- **International / Emerging Markets**: supporting Global Markets on a cross GBU basis with Regional Compliance Officers, supported by Local Compliance Liaisons
- Third Party Sellers: supporting markets with distributor screening, contracting, training, monitoring
- Operations: supporting quarterly monitoring of key controls, data analysis and trending, project management and CIA management
- Training & Education: shared resource for design, development, technology solutions, web sites

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Looking Ahead: Next Steps to Strengthening Ethical Standards in the Asia-Pacific Medical Technology Industry

Carolyn Brugera
Vice President & General Counsel
Micrus Endovascular Corporation

Looking Ahead: Next Steps to Strengthening Ethical Standards in the Asia-Pacific Medical Technology Industry

Carolyn M. Bruguera
Vice President & General Counsel
Micrus Endovascular Corporation

September 27, 2010
Gifu, Japan

What Have We Learned?

- Overwhelming evidence supports the business rationale for ethical business practices.
- Industries have sector-specific needs.
  - *In the medical device industry, innovation depends on ethical interactions between companies and healthcare providers*
- Self-regulation and industry codes of conduct help companies address ethical challenges and reduce legal risk as they enter new markets
- However, companies face challenges as they try to comply with diverse, and sometimes confusing, business rules.
  - *These challenges are particularly acute for SMEs*

Challenges for SMEs

Complying with standards that very from country to country

Competing with large corporations with vast resources and depth of experience

Risk and uncertainties create barriers to entry

– may lose out on lucrative markets

– may decide smaller markets not worth pursuing

Example

Micrus Endovascular Corporation

San Jose, California

A medium-sized enterprise developing and manufacturing devices for minimally-invasive prevention and treatment of stroke

History of Micrus Endovascular

1996: founded to develop physician-invented technology

2004: disclosed improper consulting payments to physicians

- payments totalled $105,000 and were paid to physicians in France, Germany, Spain and Turkey

2005: Entered Deferred Prosecution Agreement with US Department of Justice

- IPO delayed by one year during investigation and negotiation of DPA
- Paid $450,000 to DOJ in settlement
- Agreed to corporate monitor for 3 years
- Millions of dollars in fees for monitor, attorneys, auditors

History of Micrus Endovascular (continued)

2008: Deferred Prosecution Agreement ends

Eucomed Adopts Amended Code of Ethics

2009: Micrus Reports First Profitable Quarter

2010: Micrus Reports First Profitable Year

Micrus begins sales of its products in several Asian countries and obtains regulatory approval to commence sales in China

Micrus Endovascular Corporation

Challenge: operate within constraints of DPA and applicable law while growing the company globally, cutting costs, and succeeding in a highly competitive market

Advamed-Eucomed Joint Statement

- May 4, 2010, statement addresses interactions between industry and healthcare professionals
- Highlights 4 common principles
  - Legitimacy;
  - Transparency;
  - Independence; and
  - Appropriateness of relationships between Companies and HCPs.

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Benefits of a Harmonized Approach

Uniform standards for interactions between medical device industry and health care providers can *facilitate beneficial interactions* while reducing *harmful or anticompetitive interactions*.

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Benefits of Harmonized Approach

Facilitate

- ***Innovation***
- ***Development, Clinical Trials***
- ***Product Education***
- ***Training***

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Benefits of Harmonized Approach

Reduce

- ***Corrupt or anticompetitive interactions***
- ***Legal risk***
- ***Public mistrust***
- ***Barriers to entry***

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Applying Basic Principles to Industry-HCP Interactions

These ethical standards may be embodied in practical guidance on appropriate conduct of interactions, for example:

- consultancy agreements between healthcare providers and institutions and industry to conduct R&D
- scientific education of healthcare professionals
- training of healthcare professionals in the the safe and effective use of medical technologies
- donations for charitable or other philanthropic purposes.

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The Case for a Medical Device Industry Code of Conduct

- A streamlined, consistent, harmonized approach to business ethics codes in the medical device sector is necessary.
- Such an approach would make it cheaper, easier, and faster for resource-constrained SMEs to understand and comply with business ethics rules and help SMEs do business in a sustainable manner.

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The Case for a Medical Device Industry Code of Conduct

Streamlined codes of conduct in high-priority sectors, such as the medical device sector, will help APEC economies foster industry-academic collaboration and R&D, attract and support innovative SMEs, create highly-skilled knowledge-based jobs, and enhance access to new, innovative life-saving medical technologies.

What Can APEC Do?

APEC can develop an “APEC Code of Conduct Principles for the Medical Device Sector.”

Such an effort should build on the 2007 APEC Code of Conduct for Business, customizing it as appropriate for the unique needs of the medical device sector, and reference best practices, learnings, and commonalities found in voluntary industry codes of conduct in APEC member economies (e.g., Australia, Canada, Hong Kong, Japan, Korea, Singapore, Thailand, and the United States).

Thank you!