

Ethics & Compliance

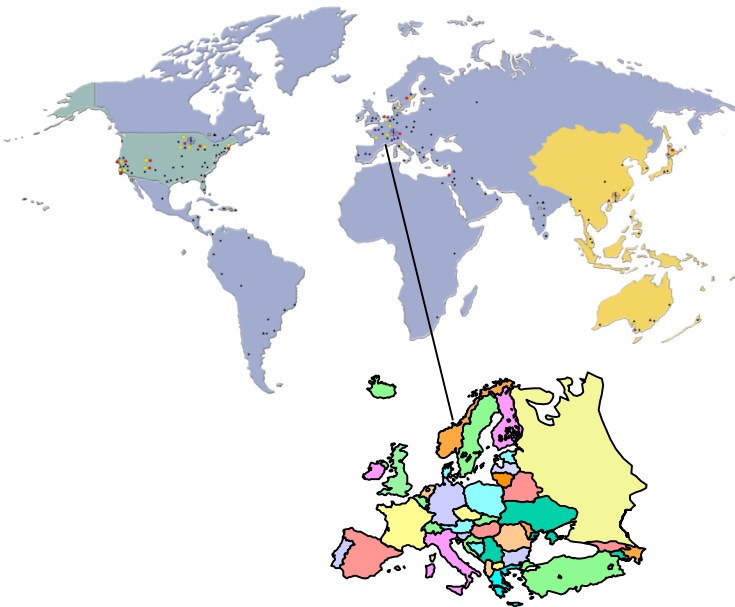
EVERY DAY EVERY WAY EVERY ONE



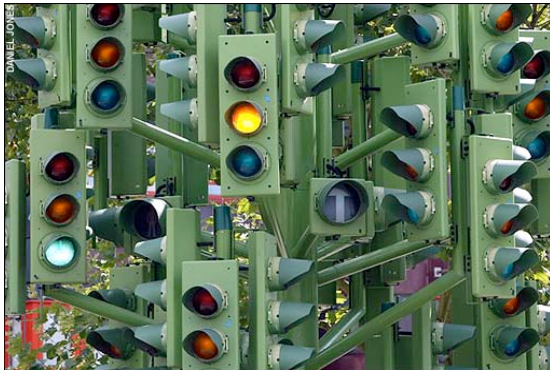
Today's Discussion

- **International Health Care Systems**
- **Medtronic's Approach to Compliance**
- **BCS Compliance Mechanisms**
- **BCS Compliance Training**
- **Distributor/Agent Compliance**
- **Lessons Learned**

Each Country (Region) Has Own HC System



No “United States of Europe”



- Multiple decision makers in multiple locations applying multiple criteria for multiple budgets
- Each country (region) makes own funding, reimbursement and physician compensation decisions
- Each country (region) has own rules for regulation of HC professionals
- Clinical and economic data are essential (scientifically valid studies)
- Centralized procurement and pricing mechanisms play widely varying roles; declining ‘purchasing power’ of physicians
- Private sector HC financing and HC delivery play widely varying roles

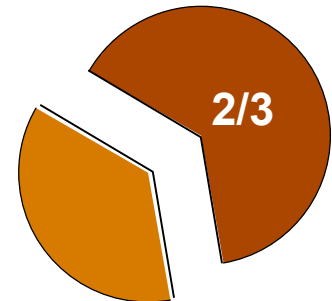
Aggressive Enforcement Environment

- **US-based, publicly traded companies are subject to certain US laws everywhere they do business**
- **Avalanche of criminal/civil enforcement actions involving the health care industry; now medical devices are in the spotlight**
- **Why? Rising HC costs, budgetary pressures, loss of corporate credibility, profit margins**
- **FCPA 30th anniversary: increasing enforcement actions (5x over 2001), larger fines and now prosecutions of company executives**
- **Increasing anti-corruption actions in Europe (Siemens, BAE, Alstom)**

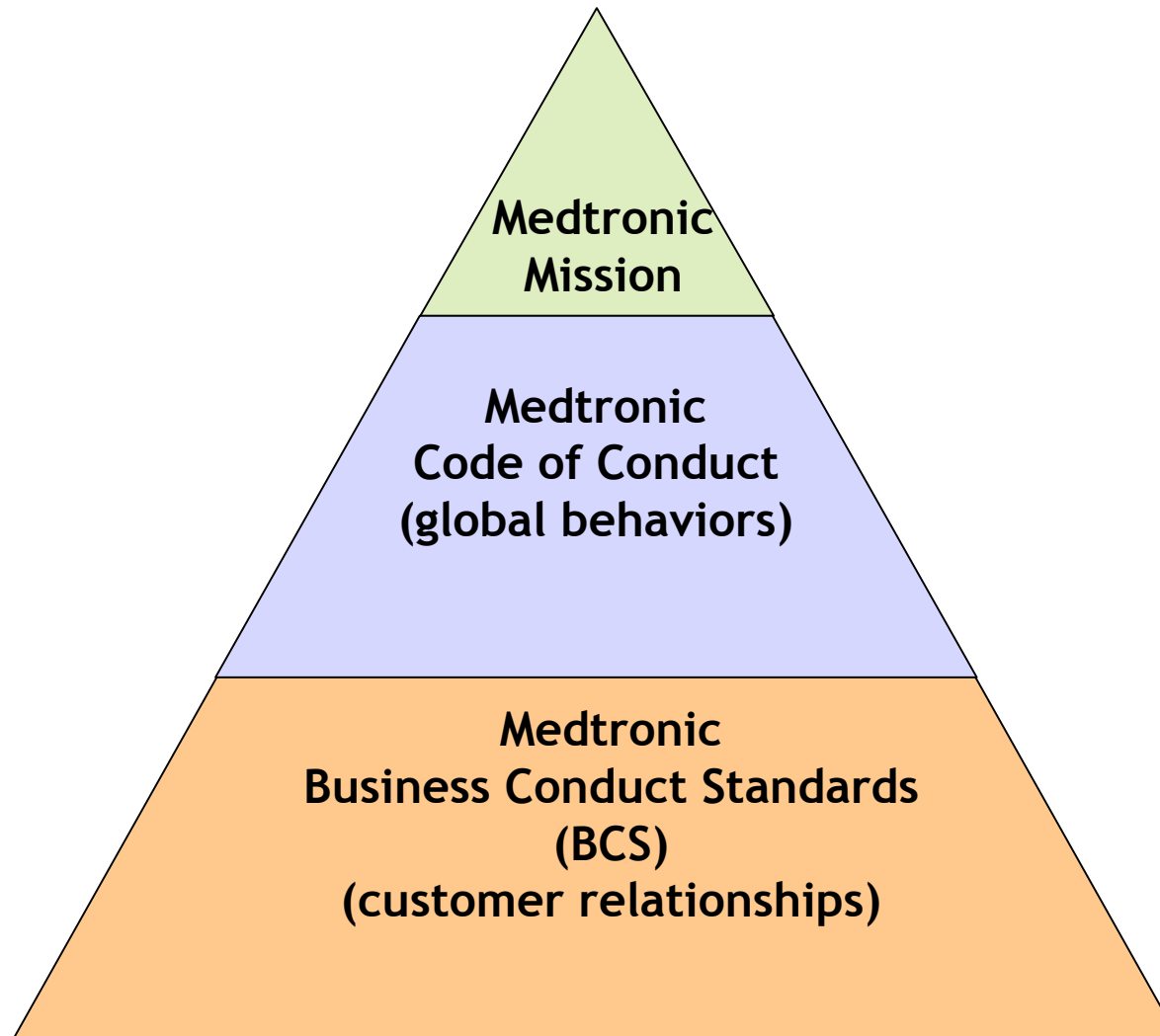
Key Features of Medical Technology Industry

- Dominated by SME's
- Continuous innovation and iterative improvements – new science, technology and available materials
- Most R&D, testing done in clinical setting via close collaboration with physicians
- Short product lifecycle ~18-24 months
- New products add functions (e.g., transmit data) & clinical value (ease of use, duration, etc.)
- High distribution & service/support costs
- Training & education essential for safe & effective use
- Often has higher up-front cost than pharmaceutical treatment but delivers therapy over extended period

% of MDT revenues
from products
introduced in the
last 2 years



Medtronic's Approach to Compliance



Responsibilities of Medtronic Employees

- **Know and understand applicable laws**
- **Comply with the Code and the Business Conduct Standards («BCS») (customer relationships)**
- **Provide annual Code certifications**
- **Report violations of the Code or BCS to their Manager or Legal Department**
- **Adhere to laws, regulations, the Code and the BCS -- as an integral part of employment**

Focus: Customer Relationships (BCS)

- **No «benefit» may be provided to a Customer with a linkage to the Customer using or buying MDT products**
 - Donations, gifts, business courtesies (meals, entertainment), training & education, conferences
- **A «Customer» is a doctor, a medical institution, or any other person or entity in a position to buy, prescribe, recommend, use or lease Medtronic products**
- **Globally compliant, but tailored to local law & reg's**
- **Collaborative agreements (consulting, research, training, etc.) with physicians must involve real services, fair compensation, proper written agreement**

BCS Compliance Operating Mechanisms

Legal Compliance Paralegal in charge of country/region, BCS Country Coordinators, Lawyers, Business and Finance Dept collaborate to ensure compliance by:

- **Matching payments vs. executed contracts**
- **Review/audits of local processes and procedures**
- **Random checks of expense reports**
- **Distributor/agent selection & mngt. procedures**
- **Developing country-based BCS Coordinators**
- **Leadership role in national medical device assoc's to implement business practice codes**

BCS Compliance @ Industry Level

Since 2000 Medtronic has proactively worked to support industry initiatives to codify legal and ethical business practices by & among suppliers, 3rd parties acting on their behalf and HC pro's



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") is dedicated to the advancement of medical science, the improvement of patient care, and in particular to the contribution that high quality, cost-effective health care technology can make toward achieving those goals. In pursuing this mission, AdvaMed members ("Members") recognize that adherence to ethical standards and compliance with applicable laws are critical to the medical device industry's ability to continue its collaboration with health care professionals. Members encourage ethical business practices and socially responsible industry conduct related to their interactions with health care professionals. Members also respect the obligation of health care professionals to make independent decisions regarding Member products. Consequently, AdvaMed adopts this voluntary Code of Ethics, effective January 1, 2004, to facilitate Members' ethical interactions with those individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Members' medical technology products in the United States ("Health Care Professionals").



BCS Compliance Operating Mechanisms

- **BCS approval and contract management infrastructure set up to process standard requests**
- **Pan-regional tools and resources are necessary to drive efficiencies**
- **Efficiencies of process are tested because:**
 - **complex, varied environment**
 - **majority “non-standard” agreements**
 - **multiple communication channels**
 - **multiple language issues**

BCS Compliance Resources

- **Team of Paralegals, BCS Coordinators, Lawyers and assistants covering 100+ countries where we do business**
- **BCS and associated BCS procedures**
- **Intranet sites: Legal Compliance Dept., Core Coordinators Network; Distributor Relations**
- **Contract Templates and Guidelines**
- **Checklists and Guidance Documents related to compliance and general legal matters**
- **BCS Core Coordinators Network**

BCS Compliance Objectives (2008)

- **Strengthen alignment between lawyers and compliance paralegals, and bolster compliance resources**
- **Clarify roles and responsibilities for addressing legal/compliance issues**
- **Focus experience and talent to drive critical employee training, BCS compliance group capacity building and technology projects**
- **Drive initiatives to streamline processes and increase speed of service delivery using technology**
- **Foster paralegal development via exposure to different types of legal work**

Legal Compliance Training



WEB-BASED TRAINING (OUTSIDE VENDOR)	Rollout/Frequency/Deadline
<ul style="list-style-type: none"> ➤ Foreign Corrupt Practices Act ➤ EU Competition Law ➤ Export Controls ➤ Insider Trading ➤ EU Data Protection ➤ Intellectual Property ➤ EU Data Protection ➤ Code of Conduct: ✓ Rollout of local language version as refresher to all registered users ✓ Systematic rollout to all new hires 	<p>Registered users: intervals of 6 weeks to users who have not already taken the programs</p> <p>New hires: will be started on this curriculum upon beginning of their employment with Medtronic</p> <p>2008</p> <p>Monthly</p>

IN-CLASS TRAINING	at Europe HQ	in the Field
<ul style="list-style-type: none"> ➤ Code of Conduct ➤ BCS ➤ BCS Workshops ➤ Do it Right-Write it Right ➤ FCPA ➤ EU Competition Law ➤ EU Data Privacy ➤ Pricing & Discounting Guidelines ➤ Sales Reps in the OR 	<ul style="list-style-type: none"> quarterly quarterly when necessary quarterly quarterly quarterly quarterly quarterly 	<ul style="list-style-type: none"> by the Country Coordinators <i>or</i> at request by HQ Legal/Compliance <i>or</i> during visits

People Acting on Behalf of Medtronic

- **Independent Distributors and Agents are expected to comply with the Code**
- **All Distributor and Agent relationships must be based on approved written contract with compliance T's&C's**
- **Distributor/Agent management program includes**
 - **Due diligence**
 - **Standard contracting terms/procedures**
 - **Close tracking of finances and business**
 - **Distributor training**
 - **Distributor relations intranet site**

Distributor/Agent Compliance

➤ **Due Diligence Procedure**

- Database and intranet searches; 3rd party checks as necessary
- Updated Medtronic Distributor Profile submitted by business to legal and finance for due diligence approval (including Code of Conduct compliance statement)

➤ **Distribution Agreements include**

- Relevant compliance provisions, including Code of Conduct/FCPA
- Right to verify/inspect

➤ **Distributor Code of Conduct Training**

- Annual compliance communications to distributors
- F2F training for distributors; training program

➤ **Distributor Relations Intranet Site**

- Info sharing: guidelines; due diligence; terminations; templates
- List of distributor agreements and scanned copies of agreements

Legal Compliance – Lessons Learned (1)

Essential to have:

- **Management commitment to compliance and employee buy-in**
- **Policies, guidelines and tools (user friendly)**
- **Partnership with Finance and business managers**
- **Training and communication**
- **Internal controls and compliance reviews/audits**
- **Monitoring and reporting**
- **Compliance network**
- **Continuous improvements in program**

Legal Compliance – Lessons Learned (2)

Communicate messages – aligned with leadership:

- **Be sensitive to current environment: violations of public trust not tolerated**
- **Exercise good judgment and leadership (role model)**
- **Discuss tough issues in advance and raise concerns any time (no retaliation)**
- **DO NOT turn ‘blind eye’ to high risk behavior – be prepared to walk away from suspicious sales**
- **Make sure employees, customers and 3rd parties understand our compliance program and consequences of behaviors**

Legal Compliance – Lessons Learned (3)

Legal Compliance organization and ways of working:

- **Need to have the right people (trained), in the right places (HQ+country), doing the right things (well)**
- **Be clear on who/what/where: clear roles and responsibilities of Legal and Compliance, HQ and country, operating in a network**
- **Think globally and act locally – globally aligned but tailored to local laws and regulations; communicate!**
- **Be efficient – risk-based processes; develop tools and streamline where appropriate, without sacrificing quality**

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