







# Lessons Learned in Medical Device Sector Voluntary Code Implementation & SME Challenges

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#### Overview and Vision



## Top Lessons Learned in Voluntary Code Drafting, Development & Implementation

- Integrate Ethics into the Association Mission
- An Effective Code is a Longstanding Commitment
- Address Top Industry-Specific Risk Areas & Focus on Industry Credibility
- Broad Industry Engagement: Include Every Sector
- Executive Level Commitment
- Tools & Training for Companies & Stakeholders
   Embrace transparency!

#### Overview and Vision



#### Who is AdvaMed?

#### **Vision**

AdvaMed will be the leader in advancing medical technology to achieve healthier lives and healthier economies around the world.

#### **Mission**

AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.



## AdvaMed's Commitment to Ethical Business Practices



- 1991: First AdvaMed Code of Ethics
- 2003: Board adopts revised Code
- 2005: Supplemental FAQs
- 2006: Code Logo program
- 2008: Endorsement of Physician Payment Sunshine Legislation
- 2008: Revised Code of Ethics
- 2009: Code Certification by Early Adopters
- 2010: Health Reform Statute incorporates Sunshine Legislation: Transparency
- 2010: Transatlantic Statement on Ethical Interactions
- 2011: Best Practices Tools & Resources
- 2011: Joint Distributor Guidance
  - 2012: Off Label Guidance

## The AdvaMed Code as a Tool to AdvaMed Promote Ethical Business Practices Advanced Medical Technology Association

- Encourages voluntary, ethical interactions between Medical Device Manufacturers & Health Care Professionals
- Distinguishes between interactions that:
  - Advance Medical Technology
  - Have the Potential to Influence Medical Decision-Making Inappropriately

#### **Code Addresses:**

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



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 midridually "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 in the ake 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 Commonies' Medical Technologies in the United States ("Health Care Professionals").

#### Medical Technologie

Medical Technologies are often highly dependent upon "hands on" Health Care Professional interaction from beginning to end—unlike drugs and biologies, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies one 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 work synergistically with other products that deploy devices in the safest and most effective manner. Many Medical Technologies work synergistically 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
  - Revised and Restated Code of Ethics Effective July 1, 2009



### Code of Ethics Certification



701 Pennsylvania Avenue, NW, Suite 800 Washington, DC 20004-2654 Tel: 202788 8700

Fax: 202 783 8750



#### CERTIFICATION OF ADOPTION OF THE ADVAMED CODE OF ETHICS

Pursuant to the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"), medical technology companies, both AdvaMed members and non-members, may certify that they have agreed to abide by the Code, and further that they have implemented policies and procedures to implement the AdvaMed Code as part of an effective compliance program. This certification requires a company's Chief Executive Officer (CEO) and Chief Compliance Officer (CCO), or other senior individuals with equivalent responsibilities, to sign and affirm that their company has taken the steps identified below. AdvaMed will list the certifying company on the AdvaMed website as a company that submitted this certification.

(identify Company name or relevant portions/subsidiaries) ("Company"), I certify that, to the best of my knowledge and as of the date of this certification:

I have read and am familiar with the provisions of the AdvaMed Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"), including the Frequently Asked Questions.

I am knowledgeable about our Company's compliance and ethics program ("Compliance Program") as it relates to the AdvaMed Code.

Our Company requires all officers, employees, and agents to abide by the AdvaMed Code for all interactions involving U.S Health Care Professionals as that term is defined in the AdvaMed

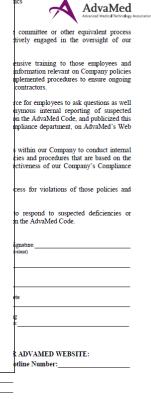
Our Company has communicated the provisions of the AdvaMed Code to our dealers and distributors with the expectation that they will adhere to them

Our Company has made a copy of the AdvaMed Code and/or a link to the AdvaMed Code available on our Company's public Web site.

Our Company adopted the AdvaMed Code and implemented an appropriately tailored effective compliance program related to our interactions with U.S. Health Care Professionals by taking the

- 1. Written Policies and Procedures: Established and implemented policies and procedures consistent with the provisions of the AdvaMed Code.
- 2. Compliance Officer/Committee: Established effective oversight over the Compliance Program, including: (a) identifying a senior manager in our Company who is responsible for compliance with our Company's policies and procedures consistent with the

Bringing innovation to patient care worldwide



#### "Code Compliance"

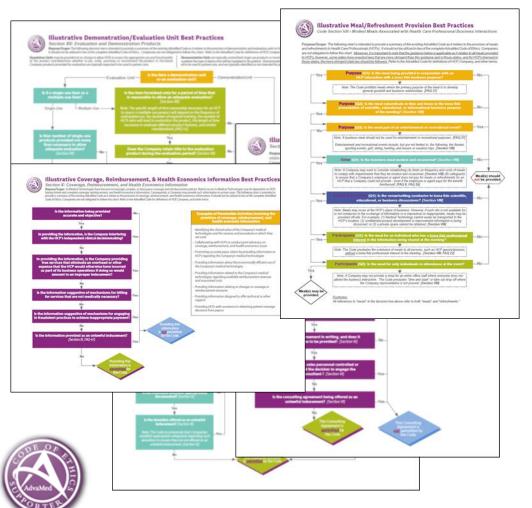
- Designed to encourage company adherence
- **CEO Certifications**
- Certifications published online beginning in 2010
- Currently 133 companies certified!



### Best Practices Guidance to Facilitate Implementation



#### **Best Practices Guidance**



#### **Current Library:**

- Charitable Donations
- Demo/Eval Units
- Fellowships
- HCP Travel
- Plant Tours
- 3D Party Conferences
- Consulting Arrangements
- Educational Items
- Grand Rounds
- Modest Meals
- Reimbursement Information

#### **Next Working Group Topics:**

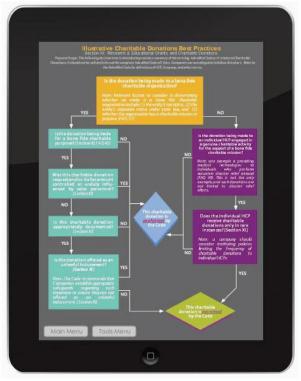
- Royalty Arrangements
- Research Grants

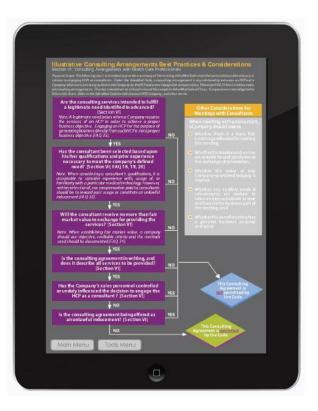
## Best Practices Guidance to Facilitate Implementation



#### **AdvaMed Code Best Practices Smartphone App**









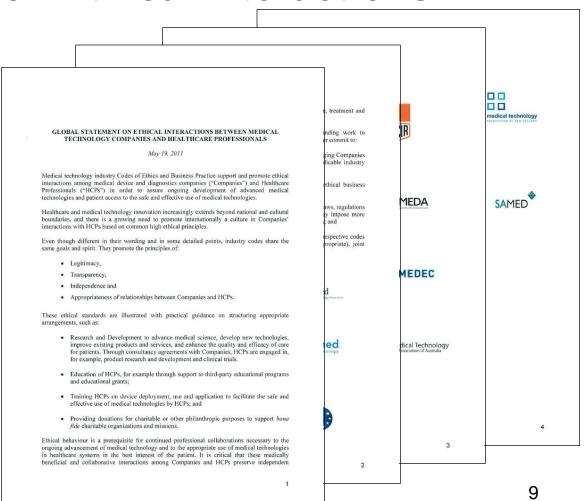
## Ethical Business is a Global Commitment



#### **Global Statement on Ethical Interactions:**

#### **Core Principles:**

- Appropriateness
- Transparency
- Legitimacy
- Independence





### Overview of Sunshine Law



#### Patient Protection and Affordable Care Act (PPACA)

- Signed into law March 23, 2010
- P.L. 111-148
- Section 6002: Transparency Reports and Reporting of Physician Ownership of Investment Interest
- First report due March 31, 2013
- Information submitted will be available to the public on-line
- Effective January 1, 2012, the federal law will preempt state laws that require disclosure of the same type of information, but not state laws that require information outside the scope of PPACA

#### Proposed Rule: "Transparency Reports and Reporting of Physician Ownership of Investment Interests"

- Published on December 19, 2011
- Comments to the Proposed Rule filed on February 17, 2012
- Now awaiting Final Regulations

### Overview of Sunshine Law



#### **Main Elements of Sunshine Law**

- Section 6002 requires medical device manufacturers to report "payment or other transfers of value" to "covered recipients"
  - "Payment or other transfers of value" means a transfer of anything of value. Certain payments and transfers are excluded, including, e.g., transfers of value less than \$10/\$100 annual aggregate, certain educational materials, in-kind items for charity care.
  - Covered Recipients limited to physicians and teaching hospitals
  - Reportable information includes name/address of covered recipient, amount/date of payment, form of payment (e.g., cash, stock), nature of payment (e.g., consulting fees, gift, entertainment)
- Section 6002 also requires "any applicable manufacturer or applicable group purchasing organization" to report information regarding any physician ownership or investment interests