

# AdvaMed Code of Ethics on Interactions with Health Care Professionals in China

**Stephanie Chew**

Head, Ethics and Compliance

Medtronic Greater China



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**AdvaMed**

Advanced Medical Technology Association

# About the Speaker

## Stephanie Chew

Head of Ethics and Compliance, Greater China  
Medtronic

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The Speaker recommends you seek independent professional advice prior to making any decision involving matters outlined in this presentation or meeting.

# Agenda

- Who is AdvaMed?
- China Device Industry Environment
- AdvaMed China Code
- Direct Sponsorships



# Agenda



**Who is AdvaMed?**

**China Device Industry Environment**

**AdvaMed China Code**

**Direct Sponsorships**

# Who is AdvaMed?



## Advanced Medical Technology Association (AdvaMed)

- World's largest medical technology association
- Nearly 300 members with a global presence in countries including China, Europe, India, Brazil and Japan
- Advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products and economic policies that reward value recreation
- Act as the common voice for companies producing medical devices, diagnostic products and health information systems



**AdvaMed**

Advanced Medical Technology Association



# AdvaMed Member Companies in China





# Agenda



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AdvaMed China Code

Direct Sponsorships

# Corruption and Bribery: Headline News

## THE ECONOMIC TIMES

Siemens, Philips, GE medical devices units face bribery probe in China

## COMPLIANCE WEEK

THE LEADING INFORMATION SERVICE ON CORPORATE GOVERNANCE, RISK, AND COMPLIANCE

China Targets Medical Device Companies in Bribery Probe

## THE WALL STREET JOURNAL

Medical Device Company Settles Foreign Bribery Charges



近四百名医生倒在医疗反腐风暴中 医用耗材成腐败新高



U.S. SECURITIES AND EXCHANGE COMMISSION

SEC Charges Medical Device Company Biomet with Foreign Bribery



REUTERS

AstraZeneca to pay \$5.52 million to resolve SEC foreign bribery case

中国医疗器械

medchina

涉嫌行贿，美敦力代理经销商、医械公司老总等被抓！（还有大量医院科室主任落马）



医械行业反腐重锤，纪委介入采购全过程！

2017-04-27 09:07

新华网 新闻

央视曝光医生回扣占药价三四成 卫计委连夜回应





# China Enforcement Overview

- Enforcement hot spot for U.S. authorities
- Recent settlements show need for adequate internal controls and timely disclosure of misconduct
- China's domestic anti-corruption campaign continues, including scrutiny of health care industry
  - Major healthcare cases may be jointly handled by several ministries/agencies
  - Local Administration of Industry and Commerce (AIC) continue to target commercial bribery in health care sector
  - Local AIC have broadened scope of misconduct considered commercial bribery
  - New draft amendments to the Anti-Unfair Competition Law (“AUCL”) could reshape the commercial bribery scheme, including more precisely defining commercial bribery, expanding the scope of liability, and heftier fines



# Corruption Criminal Investigations

## 2016 Corruption Criminal Investigations in Device Industry

- People's Procuratorate publicized at least 32 criminal bribery actions against medical device companies
  - Companies *and* individuals were penalized
  - Largest number of implicated institutions were in Jiangsu and Henan provinces
  - Orthopedics departments and clinical laboratories were most often implicated
- Over 386 HCPs, including well-known director-chiefs of hospitals or hospital departments, were brought down in criminal corruption investigations



# Looking Ahead .....

- National Health and Family Planning Commission (NHFPC) announced inspections of 85 third-grade class-A hospitals for potential corruption and compliance problems in 2017
- Trends indicate bribery crackdown in health care sector (including the device industry) will continue, especially with respect to the purchase of consumables



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# AdvaMed China Code



- AdvaMed Code of Ethics on Interactions with Health Care Professionals in China (AdvaMed China Code)
- Adopted March 2015; Effective 1 January 2016)
- Jointly signed by China Association for Medical Devices Industry (CAMDI) in October 2016
- Goals & Background:
  - Industry **self-regulatory approach** designed to proactively **address potential anti-bribery/anti-corruption concerns** in the Chinese marketplace
  - Derived from **best practices** and global compliance **trends**
  - Establishes **baseline compliance guidelines** for companies to incorporate into their policies on customer and HCP interactions
  - Serves as a **foundational document** for medical device industry in China
    - Helps ensure collaborative, necessary relationships between device companies and HCPs meet **high ethical standards**
    - Conducted with **transparency** and in **compliance** with laws



# AdvaMed China Code (cont'd)



- Addresses critical topics:

- Company-Conducted Product Training and Education
- Supporting Third-Party Educational Conferences
- Sales, Promotional, and Other Business Meetings
- Consulting Arrangements with HCPs
- Prohibition on Entertainment & Recreation
- Modest Meals & Travel Associated with HCP Business Interactions
- Educational & Branded Promotional Items
- Research, Academic and Public Education Grants; Charitable Donations
- Evaluation and Demonstration Products
- Third Party Sales and Marketing Intermediary (“SMI”) Relationships



CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS IN CHINA  
ADOPTED BY THE CHINA BOARD OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION  
Revised Effective January 1, 2017

I. Preamble: Goal and Scope of AdvaMed China Code

1. 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.

2. The AdvaMed China Board is a China-based governance group of AdvaMed that consists of AdvaMed member companies’ most senior company executives in China.

3. The China Board recognizes the obligation to facilitate ethical interactions between Companies and institutions 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 People’s Republic of China (“Institutional Health Care Professionals”) as well as the individuals employed by these institutions (and who are not full-time employees of a Company) who are also involved in the provision of health care services and/or items to patients and who also purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies (“Individual Health Care Professionals”). Unless otherwise specified, the term “Health Care Professionals” refers to individuals and institutions.

4. 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

<sup>1</sup> Medical Technologies (also referred to as Medical Devices and/or In Vitro Diagnostics) are further defined in the Global Harmonization Task Force (GHTF) document Definition of the Terms “Medical Device” and “In Vitro Diagnostic (IVD) Medical Device” [http://www.medical-exp.com/gtf/Global\\_Technical\\_Docs/gtf\\_12013\\_2013\\_Definition\\_of\\_Terms\\_120114.docx](http://www.medical-exp.com/gtf/Global_Technical_Docs/gtf_12013_2013_Definition_of_Terms_120114.docx)

<sup>2</sup> Bringing innovation to patient care worldwide



与中国医疗卫生专业人士互动交流的道德规范  
美国先进医疗技术协会中国理事会议  
2016年1月1日生效

I. 前言: AdvaMed 中国规范的总目标和范围

1. 美国先进医疗技术协会 (“协会”) 代表了从事研发、生产、制造和销售医疗产品、技术和相关设备与治疗方法 (“医疗技术”) 等设备的公司, 所开展的设备用于诊断、治疗、预防、管理、和缓解健康条件与病症, 以提高患者寿命并改善患者的健康, 协会致力于促进医学发展, 改善患者健康, 特别通过提高高质量、创新医疗技术来达成这些目标。

2. 协会中国理事会议协会在中国设立的理事机构, 由协会会员公司在中国的最高级别的管理人员组成。

3. 中国理事会议以促进成员公司与为患者提供医疗保健服务和消费品材料以及这些机构所雇佣的个人(包括成员公司的非全职员工)合理的互动交流合作为使命。这些机构为中华人民共和国、香港、澳门、台湾、安提瓜和巴布达、波多黎各和美国公司的医疗技术, 称为 “医疗技术”, 包括药物和生物制品、医疗器械和植入物、设备与患者数据应用和集成系统, 以及手术、检查、筛查、使用、安排和实施, 或者为提供方公司的医疗技术, 称为 “医疗技术”, 包括药物和生物制品、医疗器械和植入物、设备与患者数据应用和集成系统, 以及手术、检查、筛查、使用、安排和实施, 或者为提供方公司的医疗技术, 称为 “医疗技术专业人士”, 除非特别说明, 后者 “医疗技术专业人士” 包括了上述个人和机构。

4. 医疗技术

医疗技术通常高度依赖于医疗卫生专业人士从研发到应用, 不稳定的生物制品制造过程, 药物、器械或基因治疗等方式用于人体。例如, 可植入性医疗技术通常用于替换或加强人体特定组织, 并和医疗技术通常用于诊断和治疗的设备。在其他时候, 医疗技术为手术、介入式治疗、诊断和成像、患者和临床医疗卫生专业人士沟通、监测和集成系统, 一些医疗技术可以和其它技术协同使用, 或者与其它产品配合, 通过医生和有效的方式操作这些设备, 许多医疗技术也操作和软件也都需要技术支持。<sup>1</sup>

5. 与医疗卫生专业人士的互动交流

医疗卫生专业人士与公司的有效互动交流是国际最佳实践, 主要出于如下目的:  
A. 加强医疗技术使用的安全性和有效性, 为了安全、有效地使用医疗技术, 提供培训, 教育和示范医疗技术, 需要家公司为医疗卫生专业人士提供适当的指导, 教育和支持, 这包括向患者提供信息以及作为产品的组成部分。

<sup>1</sup> 医疗技术 (包括药物和生物制品) 和医疗器械 (包括 IVD) 的定义在 GHTF 文件 “医疗设备和医疗器械 (IVD) 医疗设备的定义” 中提供 [http://www.medical-exp.com/gtf/Global\\_Technical\\_Docs/gtf\\_12013\\_2013\\_Definition\\_of\\_Terms\\_120114.docx](http://www.medical-exp.com/gtf/Global_Technical_Docs/gtf_12013_2013_Definition_of_Terms_120114.docx)

- Includes FAQs that provide additional details to assist companies in implementation and decision-making





# AdvaMed China Code (cont'd)



Companies may make **training and education** on products and medical technologies available to HCPs

• Including:

- Hands-on training sessions
- Cadaver workshops
- Lectures and presentations



• Principles for conducting training and education programs:

- Conducted in settings that are conducive to the effective transmission of information
- Held in appropriate facilities
- May provide HCPs with modest meals/refreshments
- May pay for reasonable travel and modest lodging of the attending HCP



# AdvaMed China Code (cont'd)



Companies may conduct sales, promotional and other business meetings with HCPs:

•Purpose:

- To discuss medical technology features, sales terms, or contracts

•Location:

- Most commonly occur close to the HCP's place of business
- Can occur in other cities within China or overseas

•Expenses:

- May pay for reasonable travel costs of attendees
- May not pay any expenses of guests of HCPs
- May not pay any expenses of any other person who does not have a *bona fide* professional interest in the information at the meeting



# AdvaMed China Code (cont'd)



## Companies may pay HCP consultants for *bona fide* consulting services

- Examples: contracts for research; product development; development and/or transfer of intellectual property; participation on advisory boards; conducting technical training on products
- Must pay fair market value
- Must fulfill a legitimate business need
- Must not constitute an unlawful inducement



### Must:

- Be in writing, and describe all services to be provided
- Be entered into only where a legitimate need for the services is identified in advance and documented
- Be based on the consultant's qualifications and expertise to meet the desired need
- Include compensation consistent with the fair market value in an arm's length transaction
- Include a written research protocol where necessary



### Must NOT:

- Involve HCPs selected, controlled, or influenced by sales personnel
- Be based on the consultant's value or business volume
- Be paid in cash



# AdvaMed China Code (cont'd)

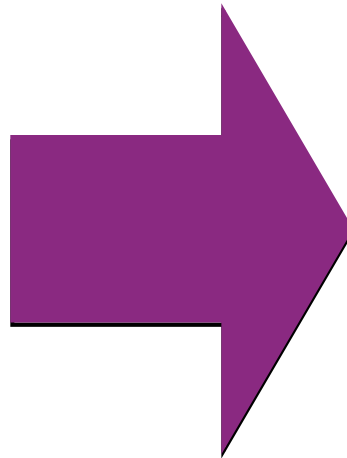


Companies may not provide or pay for any **entertainment or recreational event** or activity for any HCP

○All company interactions with HCPs should facilitate the exchange of medical or scientific information that will benefit patient care

Examples of prohibited activities:

- Theater
- Sporting events
- Lavish meals
- Leisure or vacation trips



Such events and activities should not be provided regardless of:

- Value
- Whether HCP is engaged as a speaker or consultant
- Whether the entertainment or recreation value is secondary to an educational purpose



# AdvaMed China Code (cont'd)



## Companies may provide **modest meals** as an occasional business courtesy

### •Purpose:

- Incidental and conducive to a *bona fide* presentation of scientific, educational or business information
- Not part of an entertainment or recreational event

### •Setting & Location:

- At HCP's place of business, unless impractical or inappropriate:
  - Where medical technology cannot easily be transported to HCP's location
  - When it is necessary to discuss confidential product development or improvement information
  - Where a private space cannot be obtained on-site

### •Guidelines for appropriate participants at meals:

- Only those HCPs who actually attend the associated meeting
- Only when a Company representative is present
- Not provided to an entire office staff (where everyone does not attend meeting)
- Not provided to guests of HCPs
- Not provided to any person who does not have a *bona fide* professional interest in the information shared at the meeting



# AdvaMed China Code (Cont'd)



Companies may provide **reasonable travel expenses** for individual HCPs

## ○ Purpose:

- *Bona fide* scientific, educational, or business purpose for HCP travel
- Length of trip commensurate with purpose
- No recreational activities, side trips, city tours, or other activities that do not support *bona fide* professional purpose



## ○ Location:

- Adopt objective criteria to select locations and venues
- Consider local alternatives before sponsoring travel for HCPs
- Consider China-based alternatives before sponsoring international travel for HCPs

### Reasonable Expenses:

- Flights
- Hotels
- Meals
- Incidentals

### Reimbursement:

- Pay airlines and hotels directly if possible / practical
- No cash reimbursement for expenses > RMB 500

### Participants:

- No reimbursement to guests of HCPs
- Reimbursement only to persons with a *bona fide* professional interest in the activity requiring travel



# AdvaMed China Code (cont'd)



Companies may occasionally provide HCPs with items that benefit patients or serve a **genuine educational function**

- Should be of modest, fair-market value, with two exceptions:
  - Medical textbooks
  - Anatomical models used for educational purposes
- Branded Promotional Items
  - Should be of minimal value,  $\leq$  RMB 200
  - Ex: stationery items; USB drives; mouse pads; other items bearing the company's logo
- Prohibited items:
  - Any items banned by local law
  - Items capable of use for non-educational or non-patient-related purposes, such as smartphones, tablet computers, laptops
  - Alcohol
  - Tobacco
  - Cash, gift cards, or other cash equivalents



# AdvaMed China Code (cont'd)



## Companies may provide **research & educational grants and charitable donations** to HCPs

- Grants/donations may not be provided as an unlawful inducement:
  - Adopt objective criteria, and implement procedures to ensure compliance
    - Criteria should not include sales considerations (e.g., volume of business from the recipient)
  - Fully document all grants and donations
  - Companies should not control or unduly influence who receives grants/donations, or the amount awarded
- Impose requirements on the grant or donation:
  - Must be accepted by the legal institutional entity
    - Not internal departments
    - Not individual HCPs
  - Should be handled by the institution's financial department
  - Used for *bona fide* non-profit activities
  - Not conditioned on buying products/services, or other factors affecting fair competition



# AdvaMed China Code (cont'd)



## Companies may provide reasonable quantities of no-charge products to institutions for **evaluation and demonstration purposes**

- Allows HCPs to assess appropriate use and functionality of product, to determine future need
- Must not be conditioned on buying products or services, or otherwise affect fair competition

### Single Use / Consumables / Disposables:

- Provide no greater amount than necessary for product evaluation
- Terms of no-charge status and evaluation to be disclosed in writing to the HCP
- Make any additional disclosures required by local

law/regulation

### Multiple Use / Capital Equipment:

- May be provided for a reasonable period of time to allow evaluation
- Terms of evaluation to be disclosed in writing to the institution (not internal departments; not individual HCPs)
- Company retains title to product during eval period
- Promptly remove product at end of eval period, unless institution purchases or leases

### Demonstration Product:

- Unsterilized single-use products, or mockups
- Used for patient awareness, education, and training
- Must not be used in patient care
- Labeled as “Sample,” “Not for Human Use,” or other suitable designation (on product, packaging, and accompanying documentation)



# Agenda



Who is AdvaMed?

China Device Industry Environment

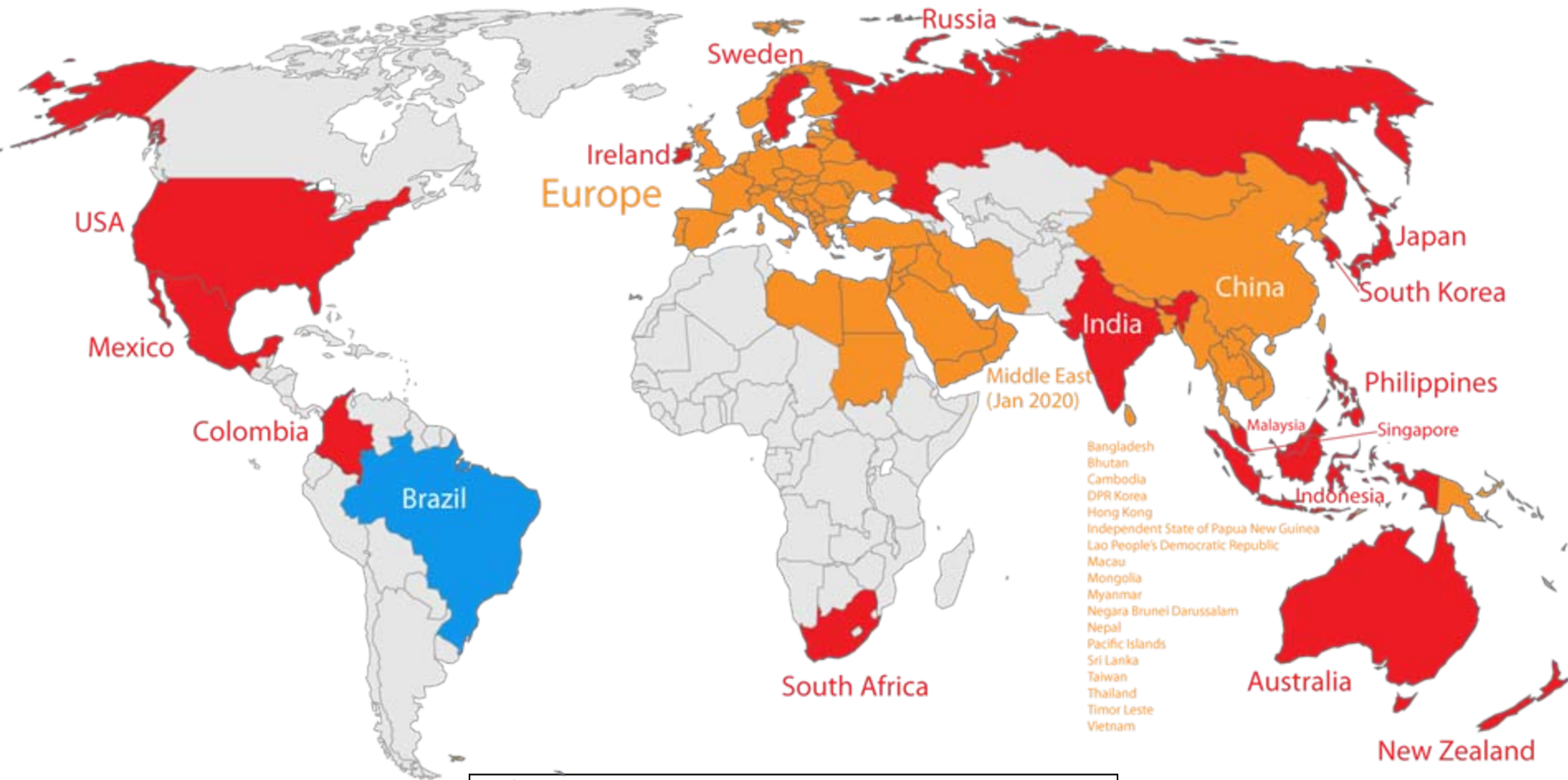
AdvaMed China Code

Direct Sponsorships

# Addressing Direct Sponsorships in China

- Status of **sponsorships under Chinese law is unclear**
  - Various anti-bribery & competition laws
  - Prohibitions on what health care organizations and professionals can accept
  - Recently issued rules on donations call sponsorships into question
- Recent **enforcement** highlights sponsorships allegedly used as bribes or expenses falsely recorded as “sponsorship fees” to disguise bribes
- Some biotech companies have **voluntarily phased out** direct sponsorships
- **Global Trend** – direct sponsorship not permitted in the U.S. and being phased out by MedTech Europe and APACMed (both effective 1 Jan. 2018); other geographies do not permit direct sponsorship

# Phasing Out Direct Sponsorships





# Addressing Direct Sponsorships in China – Phase Out

Accordingly, **AdvaMed member companies** plan to phase out direct sponsorship of HCPs to attend third-party educational events, **effective 1 Jan. 2018**

- **No direct travel, lodging, meals, or registration fees for individual HCPs to attend third-party educational conferences**
- Rather, companies can **provide educational grants/donations** to conference organizers (or other legitimate grant/donation recipients) to support third-party educational conferences
- Educational grant/donation recipient and/or conference organizer can use grant funds to defray or underwrite HCP costs

Companies can also provide:

- Company-conducted product training and educational meetings;
- Company-conducted satellite symposia in connection with third-party educational conferences; and
- Direct support for HCPs' attendance at technical procedure training courses

These changes are intended to help avoid even the appearance of impropriety and ensure transparency of relationships between companies and HCPs in China

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**THANK YOU!!**