PAROS Industry Liaison

Updates

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Snr Vice President

Singapore Clinical Research Institute

3rd PAROS Meeting, 9 Oct 2010, Tokyo

OUTLINE

1. Role of PAROS Industry Liaison
2. FCPA/HCC Environment Today
3. Best Practices
   - Some General Do's & Don'ts

Definition of Roles

FINAL

Definition of Role:
PAROS Clinical Research Network – Industry Liaison Person

- The Industry Liaison Person (ILP) for PAROS Clinical Research Network:
- is appointed by the Chair of the PAROS Clinical Research Network;
- serves as the principal adviser to the PAROS Clinical Research Network, representing industry viewpoints as a function of past expertise/experience
- may provide strategic advice and technical inputs where applicable;
- In circumstances where the ILP is not available for meetings/activities, a proxy – agreeable to the Chair may be designated to represent the ILP's function.

- The primary role of the ILP is to facilitate potential scientific collaborative and research opportunities with industry (proactively or via referrals) on behalf of the Network
  - He may, through the Singapore Clinical Research Institute (SCRI), facilitate grant application(s) for research projects, where appropriate.
  - He may, with coordination work done by the Network Secretariat, oversee such efforts.
  - He may, at the discretion of the Chair of PAROS Clinical Research Network, attend specific meetings with potential industry partners.
- The Industry Liaison Person, as a representative of SCRI, shall not solicit, receive or administer external funds on behalf of the Network.

- **SCRI shall not solicit, receive or administer external funds on behalf of the Network, except as it relates to clinical research and scientific collaboration projects only.**

Role of PAROS Industry Liaison*

- Appointed by Chair of PAROS
- Primary Role: Facilitate potential scientific collaborative & research opportunities with industry proactively, or via referrals
  - through Singapore Clinical Research Institute (SCRI) Network Secretariat, facilitate grant application(s) for research projects, where appropriate
  - may attend specific meetings with potential industry partners
- Serves as principal adviser to PAROS
  - Representing industry viewpoints as function of past expertise/experience
- Provide strategic advice and technical inputs, where applicable
- **Shall not solicit, receive or administer external funds on behalf of Network**

* Dr Sam Lim appointed at June 2010 PAROS meeting as Industry Liaison

SCRI Support

- Industry Liaison
- PAROS Network Secretariat
- Network logistics, administration & Communications
- Clinical trials & Project planning, coordination & execution
- Research Informatics, biostatistics support

Foreign Corrupt Practices Act & Healthcare Compliance Environment

In the News…

TAIPEI (November 2004):

NTUH Doctors Given a Free Trip by GlaxoSmithKline

***GlaxoSmithKline** faces a series of lawsuits*

The Wall Street Journal (August 15, 2005):

*Some doctors helping evaluate the effectiveness of an increasingly popular device for clearing clogged arteries own **stock and options** in the company that makes it, regulatory filings show*

FDANews (December 2005):

*Your Next **Off-Label Promotion**: Know the Rules (or Risk Paying the Price)*

The New York Times (January 2006):

*Drug Makers Scrutinized Over Grants…. an article in The New York Times detailed how **Johnson & Johnson** gave grants to doctors, medical societies and patient advocacy groups that promoted Propulsid's use in children*

British Medical Journal (August 2006):

***Roche** defends buying lavish meals for doctors at Sydney's restaurants*

In The News… FCPA in action

J&J Reports Improper Payments
Drug Firm Tells Regulators Of Expenditures Overseas; A Senior Executive Resigns
By AVERY JOHNSON, KARA SCANNELL and JON KAMP
February 13, 2007; Page A20

Johnson & Johnson said it alerted federal officials to improper overseas payments and that one of its senior executives is resigning over the probe.

The New Brunswick, N.J., health -care conglomerate voluntarily told the Department of Justice and the Securities and Exchange Commission that it believes its subsidiaries made improper payments in two countries regarding the sale of medical devices. (See J&J statement.) Michael J. Dormer, world -wide chairman for Medical Devices & Diagnostics, stepped down as a result of the revelations. Mr. Dormer had been in charge of several medical -device divisions, including Ethicon, Ethicon Endo -Surgery and DePuy.

The company didn't name the countries involved. A J&J spokesman declined to comment beyond the press release, which said that Mr. Dormer told the company in a letter that he has "ultimate responsibility by virtue of my position" for the subsidiaries involved in the disclosure. The J&J spokesman said Mr. Dormer was not available. An SEC spokesman declined to commen t.

The disclosures are a bitter pill for a company that prides itself on its clean corporate image . It was not immediately clear whether the probe extended beyond the countries, which J&J described as "small" markets, or what specific allegations or subsid iaries it involves. But J&J said that the payments in question may fall within the jurisdiction of the federal Foreign Corrupt Practices Act, which prohibit improper payments to foreign officials in order to win or keep business.
The Justice Department and SEC have stepped up their pursuit

FCPA in Brief

- **Overview:**
  - The **Foreign Corrupt Practices Act** of 1977, ("FCPA"), was enacted for the purpose of making it **unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business.**
  - Specifically, the anti-bribery provisions of the FCPA prohibit the willful use of the mails or any means of instrumentality of interstate commerce corruptly in furtherance of **any offer, payment, promise to pay, or authorization of the payment of money or anything of value** to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to **influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business to, any person.**

US Dept of Justice: http://www.justice.gov/criminal/fraud/fcpa/

Regulatory & Investigational Agencies Involved: who are the players

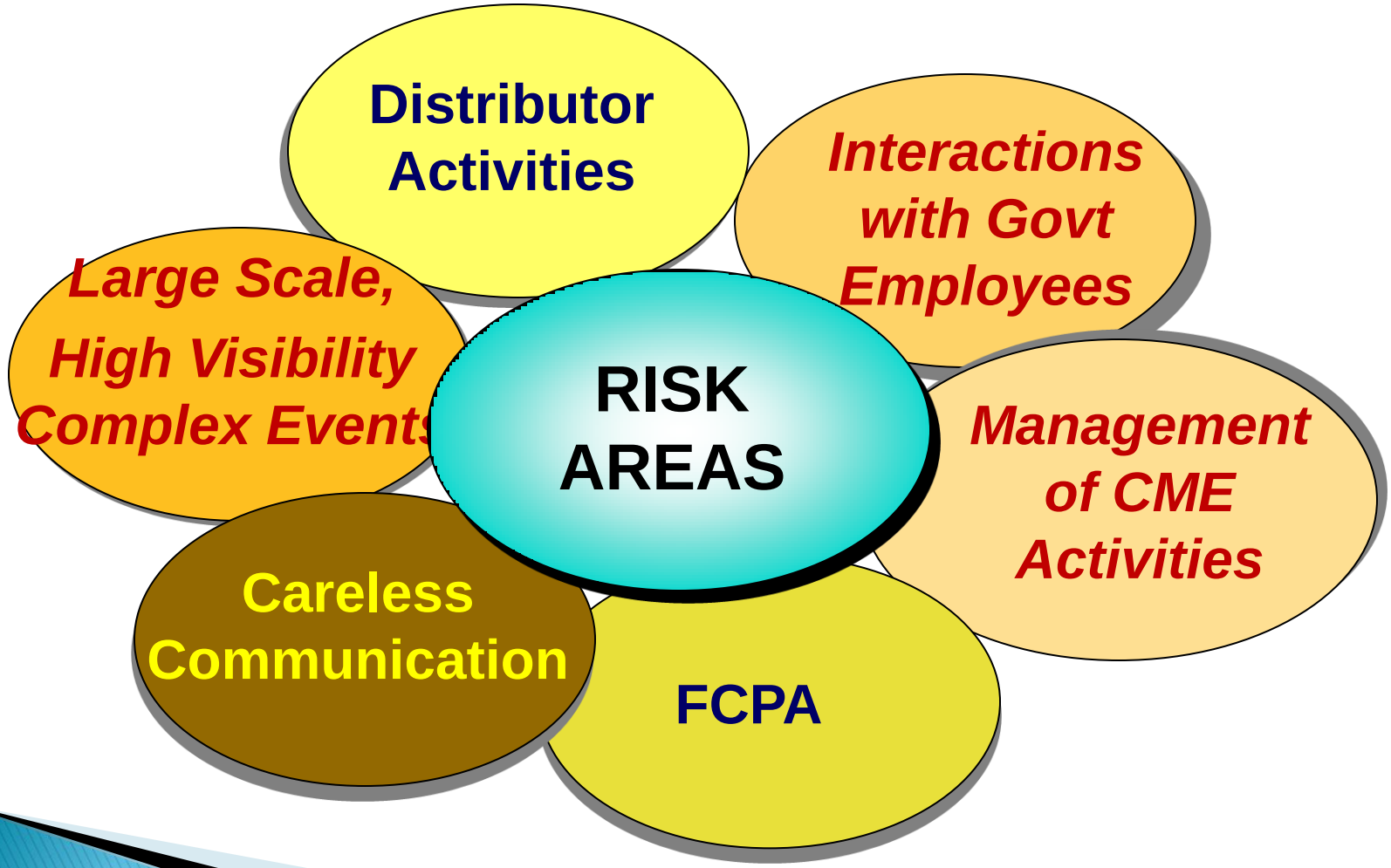
US

- Dept of Justice
- Securities Exchange Commission
- In collaboration with local anti-corruption agencies
  - Where US law does not apply, local laws will apply

Who are Affected:

- Essentially any company based/headquartered, or have a presence on US soil
- Activities in any foreign country that involves govt officials, public sector, govt-funded institutions & HCP

Vulnerabilities & Risk Areas



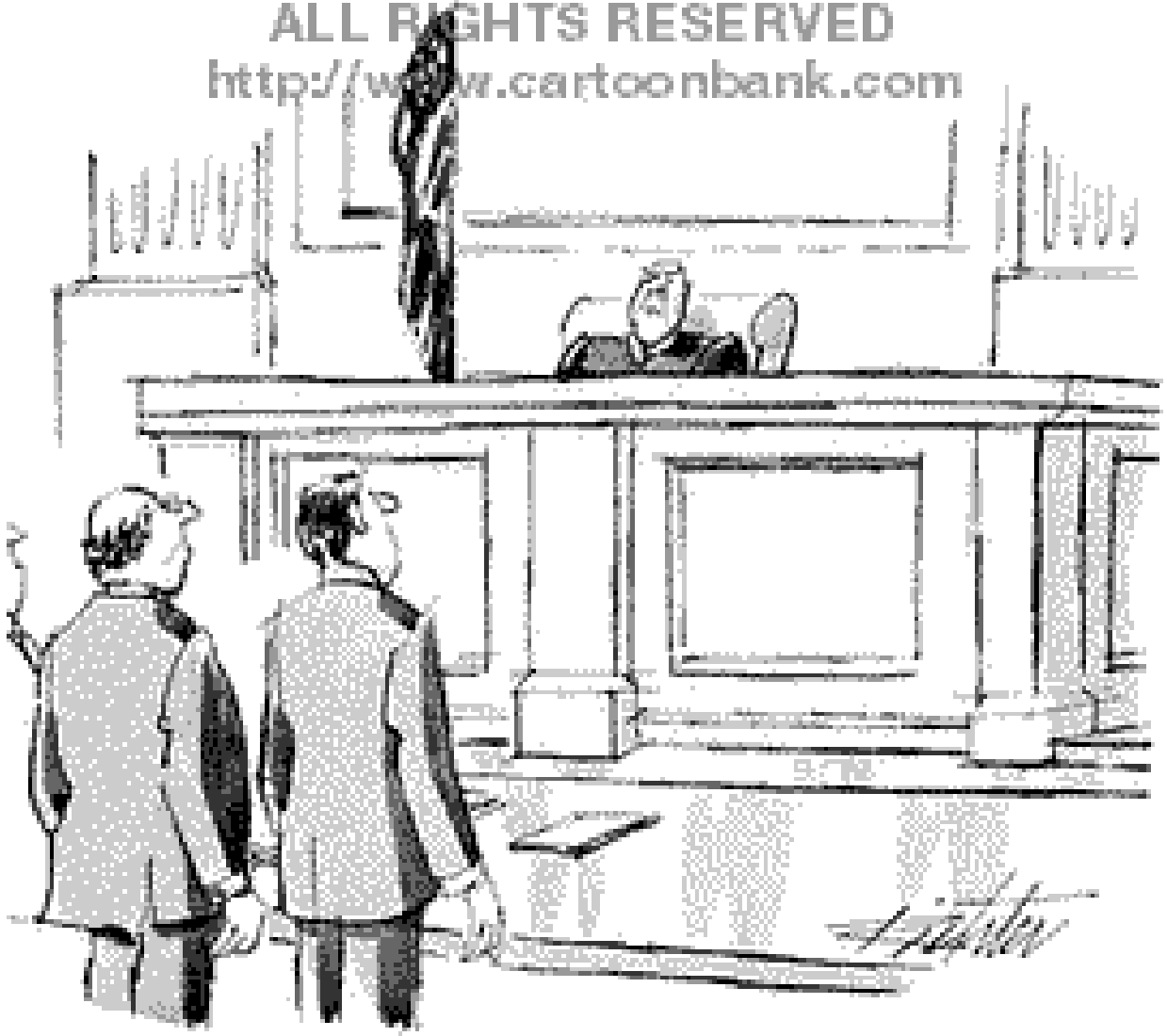
Focus Targets

- Events, meetings, travel, entertainment
  - essentially anything of value exchanged, or discussed with intent/perception to influence
- Direct or indirect links to commercial benefit or inappropriate influence
- Intent vs perception

Penalties

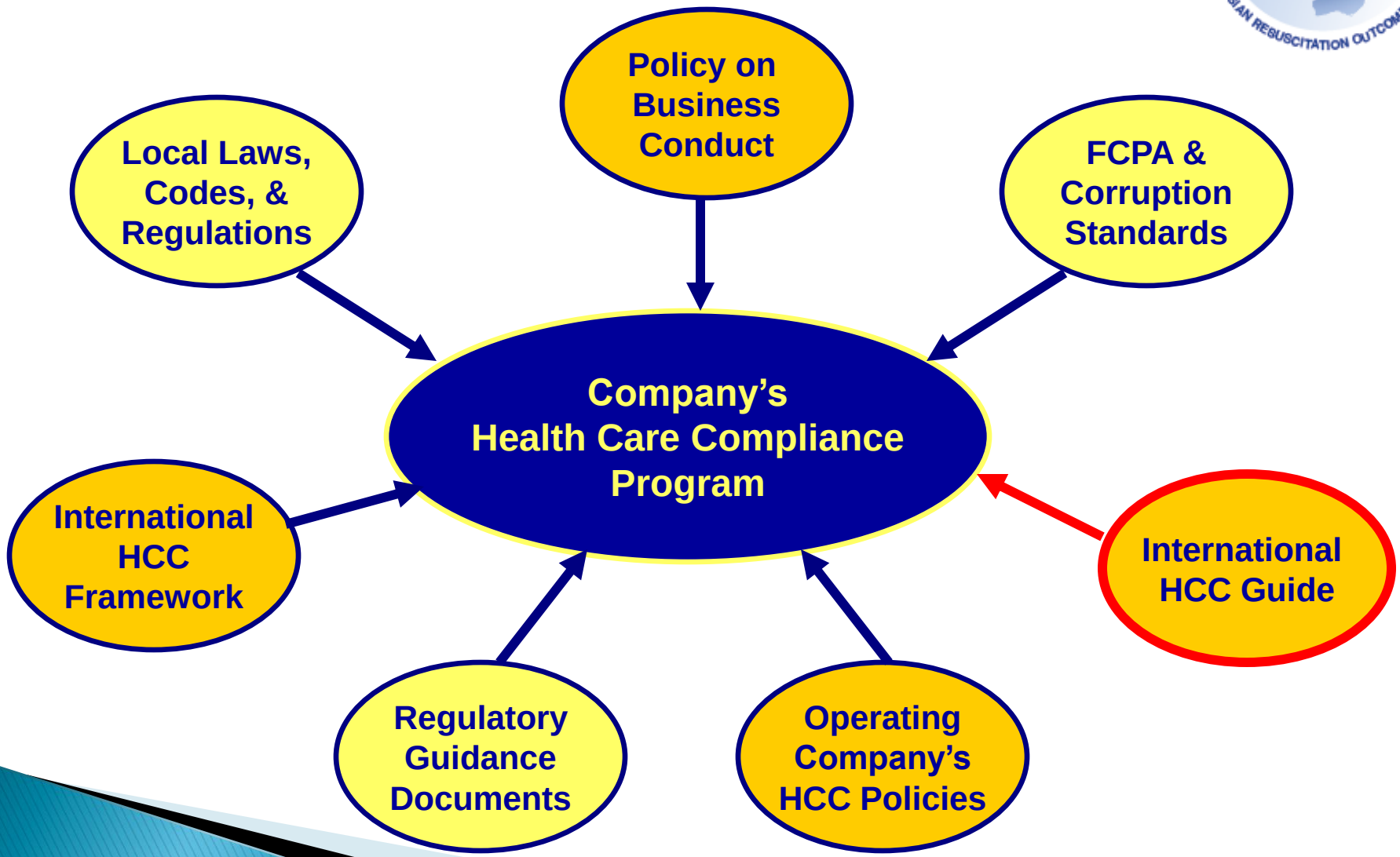
- May impact **companies** as well as **individuals** involved
  - Heavy multi-million dollar fines
  - Exclusion from US govt contracts
  - Criminal indictments and jail time for executives
  - SEC sanctions

- Local investigations & prosecutions may further apply based on local law



"Since you have already been convicted by the media, I imagine we can wrap this up pretty quickly."

Governance Standards



Some General Do's & Don'ts

- Check compliance & know your the local laws
- Maintain high ethical professional standards
- Avoid high-profile activities/events/venues which may give rise to wrong perceptions
- Be wary of investigative media
- Be fully transparent in planning activities & more importantly have full detailed accounting of funding & expenditure
- Soliciting funds should preferably be on a scientific, or specific clinical study project basis only & have no ties/offers of commercial benefits
- ***ALWAYS Avoid Unrestricted Grants*** **& poorly documented funding practices**

Some General Do's & Don'ts

PAROS Meeting/events

- Consider host country funding meeting from local organisations
  - delegates responsible for travel/accommodation
- Approaching trade associations may be preferred over individual companies
  - advantage of "anonymised" funding – reduced actual, or perceived influence
  - Cross-border funding by companies can be complex & problematic (forex issues)
- Detailed & itemised budgeting for proper accounting & transparency

Reference Guidance Documents

- Foreign Corrupt Practices Act (FCPA)

  http://www.fcpa.us/
- Pharmaceutical Research and Manufacturers of America (PhRMA)

  http://www.phrma.org/
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

  http://www.ifpma.org/
- European Federation of Pharmaceutical Industries & Associations (EFPIA)

  http://www.efpia.org/Content/Default.asp?
- Japan Pharmaceutical Manufacturers Association (JPMA)

  http://www.jpma.or.jp/english/