

Mini Summit IX: What is next in global compliance

CBI conference in Brussels

12 May 15 | Moderator Andy Bender

The panel

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Angelique Lee-Rowley, Esq., Vice President, Associate General Counsel and Compliance Officer Spectrum Pharmaceuticals, Inc.; Former Director, Compliance, Siemens Healthcare, Irvine, CA, USA; angelique.lee-rowley@sppirx.com

Abdul Luheshi, MBA, Vice President, Health Care Compliance, Johnson & Johnson, Former Co-chair, Asia Pacific Pharma Congress, London, UK; aluheshi@its.jnj.com

Nathalie Raynaud, Corporate Compliance Director, Global Compliance & Business Integrity Department, Sanofi, Paris, France; nathalie.raynaud@sanofi.com

Andy Bender, MS, MBA, President and Founder, Polaris, New York, NY, USA (Moderator); abender@polarismanagement.com

Topics by speaker

Nathalie Raynaud: emerging / re-emerging Compliance topics such as human rights, interaction with public officials who are not HCP, lobbying/advocacy activities, free competition matters, and compliance for animal health

Angelique Lee-Rowley: will be speaking how Compliance Officer/Dept. evolving from “police” to valued business partner; integrating “compliance” into normal business operations & engaging employees with fun & relevant information. Good segway between this and Abdul Luheshi’s.

Abdul Luheshi: The evolution of compliance from control-based to ethics-based, and the integration of controls into existing business processes. (slides)

Peter Dieners: has developed two topics:

- New developments in the area of penal law
- Risk management affecting the boards of companies

Andy Bender: trends in global transparency reporting

Trends in Global Compliance

From “Police” to Valued Business Partner

By Angelique Lee-Rowley

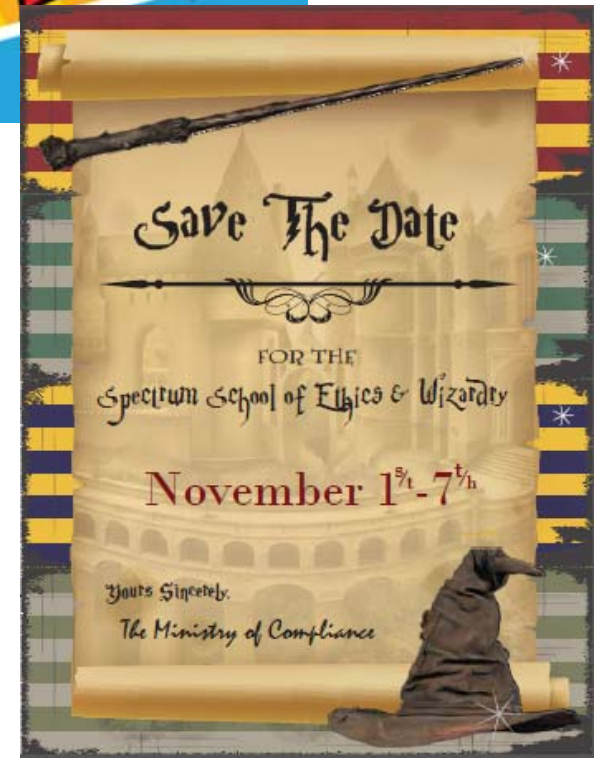
Traditional Compliance Allocation of Time



Strategic “Business Partner” Approach



Example: Corporate Compliance & Ethics Week



Compliance

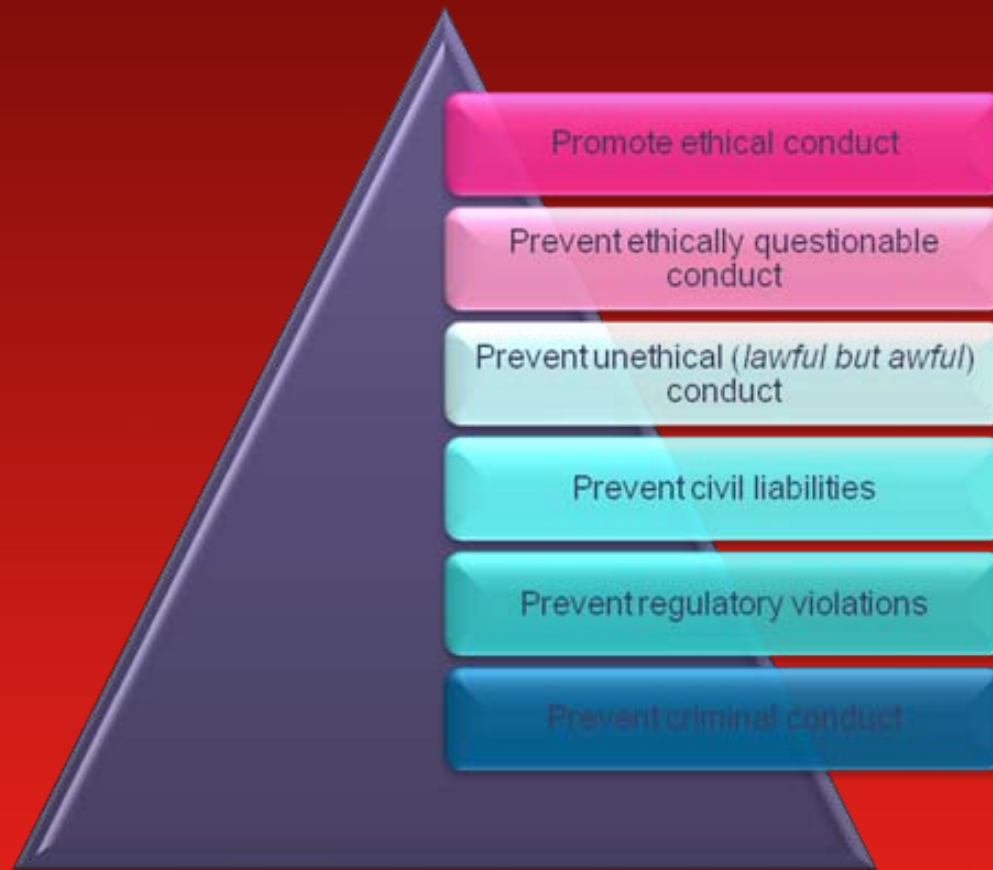
- Is about doing what is required by LAW and RULES

Ethics

- Is about doing what is RIGHT

BY OFFICERHOLDER
VIOLATIONS
STITUTES
DEFINED \approx GOOD
POLITICAL
COST \approx DIFFICULT
CORRUPTION
TAKE
ACT
REPRESSION
WILL

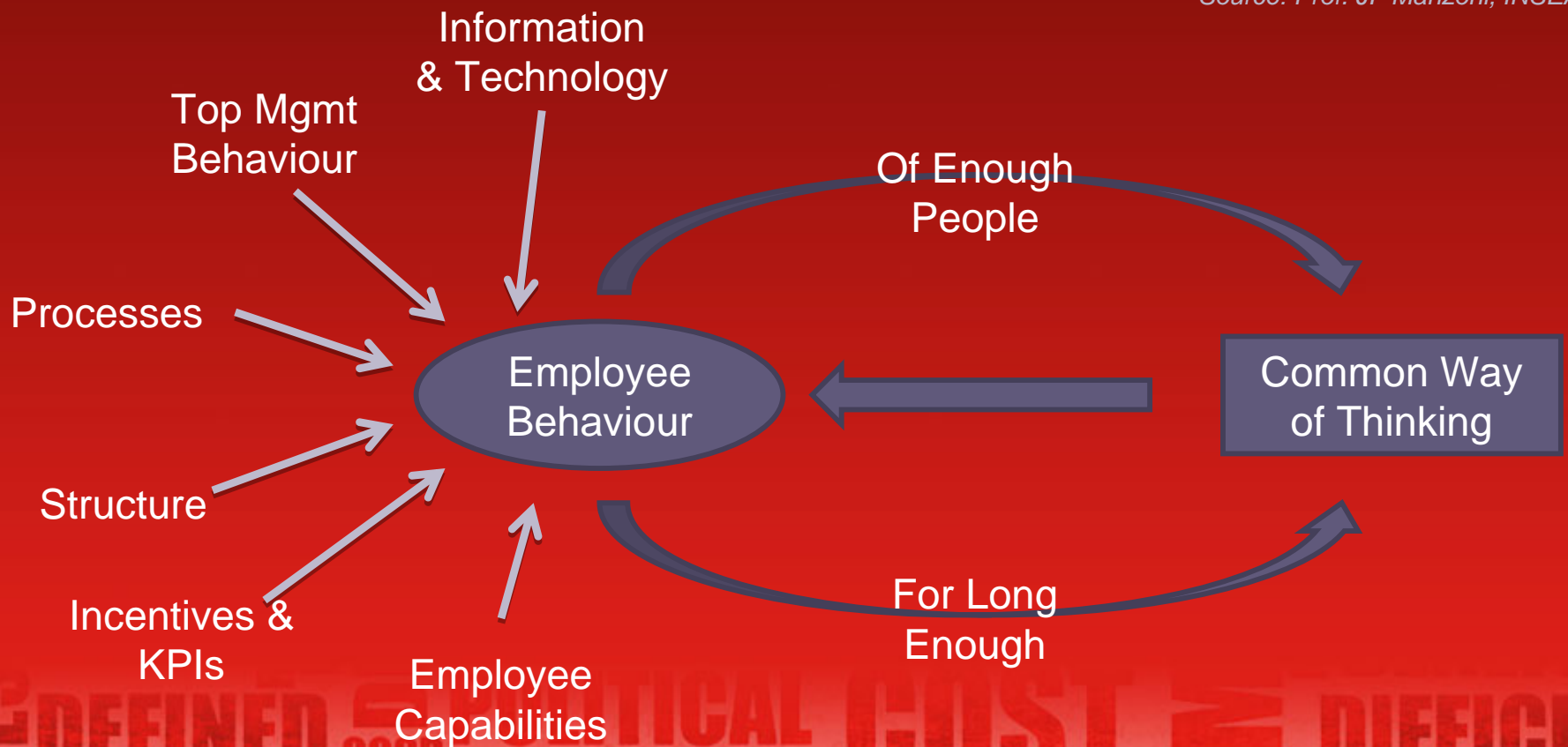
Compliance Program Hierarchy of Objectives



BY OFFICERHOLDER VIOLATIONS STATUTES DEFINED GOOD POLITICAL COST DIFFICULT
CORRUPTION TAKE ACT REPRESSION
ILLEGAL

‘Culture is a common way of thinking which drives a common way of acting’ (Goffee & Jones, 1998)

Source: Prof. JF Manzoni, INSEAD



BY OFFICERHOLDER
VIOLATIONS
STITUTES
DEFINED GOOD
CORRUPTION
TAKE
COST ≥ DIFFICULT
ACT
REPRESSION
ILL

Follow up questions

- 1. Why do most compliance programs have limited success in preventing non-compliance?**
- 2. How can training and communications be adapted to be more effective?**
- 3. Is it fair that compliance leads to increased bureaucracy and if so how should we manage it?**
- 4. How can business leaders and line managers affect the compliance of their organisations?**
- 5. Are today' compliance officers well equipped to deal with the evolution of the compliance function?**

What is next: after Aggregate spend

By Andy Bender

Ensuring FMV payments of reported spend

- KOL tiering updates

Conducting background checks on HCPs and HCOs that companies are reporting on

- Need for risk based methodology

Monitoring spend policies

- Validation of contracts and services provided
- Validation of spend caps
- Missing consent

Spend entry process validation – audit of the spend entry policies and procedures

- Incomplete and inaccurate data entry (internal and by third parties)
- Need for training and certification
- Cross border validation
- Processes for spend notification and validation by HCPs and HCOs

Larger companies are investing in spend capture systems (HCO and HCP), collection of data before spend is incurred

Next frontier: LatAM and Far East, integration of global spend systems

Other important compliance trends (I)

By Peter Dieners

New developments in the area of penal law: The German government is currently planning to include a further provision into the German Penal Code in order to cover commercial bribery with respect to private practitioners. Until today only employed clinic physicians in public and private hospitals are covered under the existing anti-corruption and commercial bribery legislation. The governments would now also like to include self-employed physicians under the commercial bribery legislation. This new law will have many impacts (e.g., more investigations, need for proactive mitigation measures etc.).

Risk management affecting the boards of companies: I see an increasing risk for legal entities and their board or management team members to be held liable for compliance infringement due to a lack of organizational preventive measures. Without the proper infrastructure and documentation in place, personal criminal and civil liability as well as substantial administrative fines may be imposed on management and the company.

Other important compliance trends (II)

By Peter Dieners

This increasing risk is due to a changed attitude of the courts and prosecution authorities to target organizational deficiencies with a specific view to the compliance management system and the underlying organizational measures. Any deficiency in the organizational set-up opens the way for cartel, tax and prosecution authorities to impose the aforementioned substantial liabilities and fines. Based on our experience from many cases, improvement is often needed in establishing a clear delegation of compliance related duties, a thorough assessment of compliance related risks and well-documented records that reflect that such compliance measures have been established and implemented. This is particularly true for complex group structures, such as matrix structures, in which reporting lines and instruction channels, which are required under the applicable corporate law, differ from those that are actually used in practice.

Without these safeguards in place, companies will find it difficult to dispute organizational default allegations. In our experience, we have found that presenting a defense is sometimes almost impossible due to a complete absence of documented processes and delegation of duties. In that respect, having solid practices and processes in place alone is not sufficient if these mechanisms are not documented and implemented in a way which satisfies the respective legal and formal prerequisites.

Questions regarding Transparency guidelines within the EU: Peter Dieners

- **What is the intention and mind of the transparency codes and guidelines?**
- **Why do we have transparency laws in some EU member states and transparency codes in other EU member states?**
- **Which countries are covered under mandatory disclosure legislations?**
- **What is the different between the EFPIA Disclosure Code and the national transparency codes of the national/local pharmaceutical associations in the EU member states and which one(s) have to be considered by local companies?**
- **Which kind of payments have to be disclosed on basis of the EFPIA Disclosure Code and what is the period for such disclosure after the payment has been granted? Where have the payments to be disclosed and for which period?**
- **Which legal requirements exist to obtain the consent of the HCP even if the national code stipulates for the disclosure of the relevant transfer of values? What happens if the HCP does not grant such consent?**