The Tenth International Pharmaceutical Compliance Congress
Overview of the Anti-Corruption Landscape
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General Framework

- Higher expectations as to the ethical integrity of business activities
- Globalization of business activities ("high risk jurisdictions" and "emerging markets")
- More expansive reach of national laws with extraterritorial reach (FCPA, UK Bribery Act)
- Greater complexity of compliance systems as consequence of financial crisis
- Legal entities becoming subject of criminal investigations
Board members are increasingly subject to very intense scrutiny.

Several precedents have created high awareness regarding board member responsibilities, due to the breach of the duty to ensure a suitable compliance management system.

Responsibilities defined in countless:
- national statutory law provisions
- industry standards
- court decisions
- regulations and regulatory provisions

Exposure of board members not only in prominent cases with high public attention but part of the ordinary course of actions.
- Example: Civil law litigation against former board members for damages as a consequence of criminal investigations.
Complex Group Structures

Regular corporate structure

- Holding Level
- Group company
  - Corporate organ
  - Employees

Matrix-structure

- Holding Level
- Matrix-company
  - Corporate organ
  - Employees
- Other group company
  - Matrix-manager

Instruction Rights
Directive Rights
Reporting Obligations
Complex Group Structures: Risks

Matrix Structures: Reporting lines / instruction channels, as required under company law, differ from those that are actually used in practice.

Problem: Actual instruction channels and reporting lines often lack a legal binding basis.

Deficient delegation of instruction and directive rights in the matrix companies vis-à-vis matrix managers may cause the following liabilities:
- Personal liability of board members of individual companies
- Personal liability of board members on group-level
- Personal liability of active staff members within matrix structure
- Liability of individual companies and of ultimate parent company
“Compliance Governance” and risk mitigation

- To minimize exposure, board members have to establish and maintain an adequate Corporate Governance Organisation and functioning Compliance Management System
- Legal Instrument Organisational Guideline
- "Corporate Responsibilities and Corporate Compliance: A Resource for Health Care Boards of Directors"
  - Published by the Office of Inspector General of the U.S. Department of Health and Human Services and the American Health Lawyers Association in Spring 2015
  - Recommendations for board members “to ask the right questions”
  - Expected to become a sector-related benchmark
International Observations and Trends: Commercial bribery covering (private) HCPs

- Example: New German law governing commercial bribery for HCPs
- Will enter into force end of May/June 2016
- Previous anti-corruption law only covered government officials/privately employed clinic physicians
- The new law requires infringement of unfair competition law as part of an “unlawful agreement“ to prescribe drugs/medical devices, etc.
- Healthcare organizations need to carefully screen their interactions with (private) HCPs (e.g., cost-free provision of equipment, non-interventional studies, congress invitations, etc.)
International Observations and Trends: The role of industry codes of conduct

- Increasing importance of industry codes of conduct
- Public prosecutor are increasingly considering them as „safe-harbors“
- Healthcare organizations need to make sure that industry codes of conduct are properly implemented and binding for all employees
- Compliance with industry codes of conduct are increasingly subject of internal audits and investigations (otherwise this may be interpreted as a lack of oversights by the boards)