Evolution of Compliance

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Food for Thought

- **Perceptions** of Compliance then and now.
- What are the **Shareholders & Company's expectations**?
- Shifting priorities from a back office "support function" to a business critical Stakeholder



MNC Life in Compliance – International Markets



What has changed



- *Increased* regulation, legislation, enforcement actions, prosecutions, audits, news scandals, M&A activity, a Financial Crisis (2008), and the China GSK scandal in 2013 (which had a domino effect)....
- In the international markets, Compliance has moved quickly (last 5 years) from a traditional low profile "approval" function to a true "business partner" working with Finance, Internal Audit, Legal & Investigations.

Risk Management = Internal Controls Wheel



Life Sciences – High "Sector Risk" in APAC

- Highly-regulated industry;
- Many "government" (FCPA) touchpoints;
- Intense scrutiny and "industry probes" by external agencies;
- Charitable donations & "grants" are a source of keen focus for both Pharma & Devices;
- Inter-agency cooperation in investigations & enforcement is on the rise.



Number of FCPA Enforcement Actions by Region (2005 to Present*)



FCPA Enforcement Actions in China

Since 2002, the DOJ and the SEC have brought enforcement actions against 46 corporations across a variety of sectors relating to business activities in China:

Automotive

• Daimler AG, 2010

Aircraft

- Nordam Group, Inc., 2012 Cosmetics/Personal Care
- Avon Products (China) Co., Ltd, 2014
- Nu Skin Enterprises, 2016 Mining/Energy
- Maxwell Technologies, 2011
- BHP Billiton, 2015

Finance

• JPMorgan, 2016

Gaming

• Las Vegas Sands, 2016

Healthcare/Life Sciences

- Diagnostic Products Corp., 2005
- AGA Medical, 2008
- Biomet, Inc., 2012
- Pfizer/Wyeth, 2012
- Eli Lilly, 2012
- Bruker Corp., 2014
- Mead Johnson Nutrition, 2015

- Bristol-Myers Squibb, 2015
- SciClone Pharmaceuticals, 2016
- Novartis AG, 2016
- AstraZeneca, 2016
- GlaxoSmithKline, 2016 Infrastructure
- Schnitzer Steel Industries, 2006
- Watts Water Technologies, Inc., 2011
- General Cable, 2016

Manufacturing

- Control Components, Inc., 2009
- InVision Technologies, 2004
- York International, 2007
- Siemens AG, 2008
- ITT Corporation, 2009
- Avery Dennison, 2009
- Diebold, Inc., 2013
- Tyco, 2012
- Keyuan Petrochemicals, Inc., 2013
- Nortek Inc., 2016

- Johnson Controls, 2016 Technology
- Paradigm BV, 2007
- Faro Technologies, 2008
- RAE Systems, Inc., 2010
- Rockwell Automation, 2011
- IBM Corp., 2011
- PTC Inc., 2016
- Akamai Technologies Inc., 2016 Telecommunications
- Alcatel-Lucent, 2007
- UTStarcom, Inc., 2009
- Veraz Networks, Inc., 2010
- QualcommInc., 2016 Tobacco
- Alliance One International, 2010

No. 1: In the past decade, conduct in China has been the source of the largest number of enforcement actions. In 2016, a majority of enforcement actions involved alleged bribery in China.

Effective Compliance Program – Best Defense

Mitigation: Establishing an Effective Compliance Program

The greatest bulwark against corruption risk is an effective compliance program. Such programs are increasingly necessary in an age where U.S. and local enforcement agencies are increasingly scrutinizing internal controls when making enforcement decisions.

"Basic elements" the DOJ and the SEC consider when evaluating compliance programs:

- Tailored to Risks Faced by the Company
- Clear Compliance Policies
- Targeted Compliance Training
- Culture of Compliance Tone and Messaging
- Third-Party Due Diligence
- Confidential Reporting of Misconduct

- Evolves with the Business and Market Risks
- Stern Consequences For Violations
- Sufficient Compliance Resources
- Independence of Compliance Function
- Financial Controls and Monitoring

Building Effective Global Compliance Officers

Improving the capabilities of Compliance Officers:

•Built upon the **Coy's strategy**, resourcing (reach) & program design (realistic or not)

- •Focus on critical driver's of business performance
- •High value placed on a CO's ability to analyze **risk & offer workable solutions**
- •Emphasize transfer of knowledge, mentorships and "IP sharing"
- •Embed past lessons into training & highlight "individual accountability"
- •Carefully listen to the "message" not the messenger when issues raised

This need is intensifying today as Life Sciences Companies face many new challenges:

Digitization and artificial intelligence,
increasing leverage to use data as a competitive weapon,
Potential new technology competitors.

These technology-driven shifts create an **imperative** for most organizations to change, which in turn demands more and better Leaders up and down the line.

Future Fit



Given the **pace of change** today, the most important driver in fostering an internal ethical mindset is "**culture**" – this should drive change-enabling leadership development.

Translate the Compliance Strategy into a leadership model specific to its **needs** & **aspirations** – repeat the Coy's aspirations as often as possible to reinforce msg.

High EQ: Enhance the ability of COs to adapt to different situations and to adjust their behavior in different situations. This is something that requires a high degree of **self-awareness and a learning mind-set**.

Promote, support and instill a sense of courage and pride in "far flung COs" who intelligently challenge the status quo in a selfless manner, when seeking to find positive change. These are your real advocates and change-makers.

When **Leaders fully appreciate** that their committed COs are the "Keepers of the Realm", then fewer problems are likely to arise. **#1 Positive continual influence to the Top**!

Be an Authentic & Brave Leader



im Rider / South Bend Tribune