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What Are the Areas of FCPA Risk?

The *Resource Guide on the US Foreign Corrupt Practices Act* issued in 2012 by the US Department of Justice (DOJ) and Securities and Exchange Commission (SEC) stressed the importance of a risk assessment in complying with the FCPA. Compliance professionals know how important risk assessments are in developing and implementing effective compliance programs. They also know that "risk" is a moving target of external and internal factors and that assessing risk is a continual process of investigation, re-examination and adjustment.

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Categorizing Risk

The importance of effective risk assessment is evident in the *FCPA Resource Guide*, enforcement actions and settlements by DOJ and SEC. The sheer number of potential risk areas can be overwhelming, particularly for smaller companies still new to the challenges of constantly evolving global anti-corruption compliance.

The *2013 Global Risks* published by the World Economic Forum's Risk Assessment Network provides a useful system of three risk categories that some companies may find useful in focusing their resources for risk assessment. In the forward to the *2013 Global Risks Report,* Lee Howell, Managing Director of the Risk Response Network, notes, "... global risks are often diminished, or even ignored, in current enterprise risk management. One reason for this is that global risks do not fit neatly into existing conceptual frameworks.

Fortunately, this is changing. *The Harvard Business Review* recently published a concise and practical taxonomy that may also be used to consider global risks."* The three areas of risk:

1. **Preventable risks**, "... such as breakdowns in processes and mistakes by employees."
2. **Strategic risks**, "... which a company undertakes voluntarily, having weighed them against the potential rewards."
3. **External risks**, "... which the report calls 'global risks;' they are complex and go beyond a company's scope to manage and mitigate."

Even though external risks may be beyond a company's "... scope to manage and mitigate," understanding the global landscape is invaluable in corporate planning and growth, market entry and outsourcing. Assessing and addressing the remaining two – strategic and preventable risks – are corporate responsibilities.

* Kaplan, R.S., and Mikes, 2012. *Managing Risks: A New Framework. Harvard Business Review.*

TRENDS IN FCPA ENFORCEMENT

A review of 2012's FCPA enforcement actions and the joint DOJ/SEC FCPA Resource Guide points to several noteworthy trends. We have identified trends in four major areas that affect compliance and actions that compliance professionals can take to effectively address them.

1 – Learn Before You Fall:

Deferred Prosecution Agreements (DPAs) and Non Prosecution Agreements (NPAs) became the preferred enforcement strategy of DOJ and SEC in 2012 but they are not inevitable. In fact, according to Former US Assistant Attorney General Lanny Breuer, if a company wants to avoid pleading guilty or to convince us to forego bringing a case altogether, they must prove to us that they are serious about compliance. Our prosecutors are sophisticated. They know the difference between a real compliance program and a make-believe one." The Resource Guide identifies the "Hallmarks of Effective Compliance Programs," which serve as a roadmap for self-assessment and action. Equally valuable is a review of recent enforcement actions, which will not only identify the terms of the DPA or NPA but will also provide insight into the corporate actions that triggered DOJ and SEC interest in the first place.

2 – One Size Does Not Fit All:

Compliance must be tailored to address each organization's risk profile based on corporate size and structure, acquisitions and mergers, product lines, supply chains, third party entities, locations of operations and customs/import activities. Companies should realign their compliance programs to reflect their unique risks. Adequate resources must be allocated and metrics established to track training, testing, understanding and application of SOPs and policies.

Hallmarks of Effective Compliance FCPA Resource Guide

The FCPA Resource Guide issued by the US Department of Justice and the Securities and Exchange Commission identified the following "Hallmarks of Effective Compliance."

1. Commitment from senior management and a clearly articulated policy against corruption.
2. Code of Conduct and compliance policies and procedures.
3. Oversight, autonomy and resources.
4. Risk assessment.
5. Training and continuing advice.
6. Incentives and disciplinary measures.
7. Third party due diligence and payments.
8. Confidential reporting and internal investigations.
9. Continuous improvement: Periodic testing and review.
10. Mergers and acquisitions: Pre-acquisition due diligence and post-acquisition integration.

SUNSHINE AND THE AFFORDABLE CARE ACT

In February 2013, the Centers for Medicare and Medicaid Services (CMS) published the final regulation implementing the Sunshine provisions of the Patient Protection and Affordable Care Act of 2010 (ACA). The final rule takes effect on April 9, 2013.

The final rule imposes several requirements on "applicable manufacturers," CMS defines two categories of applicable manufacturers. The first is "an entity that is engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply." The second regulated entity is one "... under common ownership with an entity described above, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological and medical supply."

CMS imposes two important new requirements on regulated entities.

1 – Transfer of Value

Applicable manufacturers of products available under Medicare, Medicaid or the Children's Health Insurance Program (CHIP) must report certain payments or "transfers of value" they make to "covered recipients." Covered recipients are physicians and teaching hospitals. Reports must be submitted annually. CMS defines requirements related to how reports are to be made, which payments are excluded from the reporting requirements, and specific rules for research payments and indirect payments made through a third party.

2 – Ownership and Investment Interests

Applicable manufacturers must report information about ownership and investment interests. The new rule defines "ownership" and "investment interest" and applies to the ownership and investment interests held by physicians and their immediate family members.

The format for reporting is included in the rule as well as the data each report must contain. Payments for research are reported separately from other payments and use a separate format. The rule also provides new information about the publicly accessible website including the information from manufacturers that will be included and the process for delayed publication. Failure to report is addressed in details about allowable civil penalties.

A number of payments and transfers of value are excluded from the reporting requirement. Among them are samples, educational materials, some devices for evaluation, payments or transfers of value less than $10 (unless the aggregate exceeds $100 in a calendar year), items provided under warranty, non-medical services, discounts and rebates.

What Are the Areas of FCPA Risk? *(continued)*

The Guide and recent FCPA enforcement actions by DOJ and SEC provide a rough roadmap of some of the areas that deserve investigation into the risks they may pose to compliance with the FCPA. Some of the most significant areas of risk:

- **The organization's global footprint:** Corruption is not spread evenly across the globe. Transparency International confirms that inconsistency in its *2012 Corruption Perception Index* (http://www.transparency.org/cpi2012/results), which ranks 176 countries and territories on how corrupt their public sectors are perceived to be. Health Care companies are exposed to additional, industry-specific risks because of interactions with "foreign government officials" in the country's health care industry.
- **Interactions with health care professionals:** Most companies have policies governing employee interactions with governmental and regulatory officials. In many countries, those officials may be categorized as medical professionals, complicating both business and compliance. Pfizer, for example, entered into an agreement with a Croatian doctor who was also a professor at a government-funded university. Similarly, Eli Lilly's subsidiary in Poland made payments to a charitable organization founded and administered by the Director of the Silesian Health Fund, one of Poland's regional government health authorities.
- **Subsidiaries, mergers and acquisitions:** Corporate "relatives" pose liability to the parent company under the anti-bribery, books and records, and internal controls provisions of the FCPA. In its civil complaint against Eli Lilly, for example, the SEC alleged, "Eli Lilly and Company violated the Foreign Corrupt Practices Act in connection with the activities of its subsidiaries in China, Brazil, Poland and Russia. In its complaint against Pfizer, the SEC states, "This action arises from violations of the books and records and internal controls provisions of the FCPA by Pfizer relating to improper payments made to foreign officials in numerous countries by employees and agents of Pfizer's subsidiaries in order to assist Pfizer in obtaining or retaining business." Writing about accounting and internal controls, the SEC alleged that four Pfizer subsidiaries engaged in illegal transactions in eight countries. During the relevant period, the subsidiaries recorded false entries in their books and records, which were then consolidated into the books and records of Pfizer which, in turn, reported the results in its consolidated financial statements. According to the SEC, Pfizer failed to develop and maintain an effective system of internal controls that would detect and prevent the violations. In 2012 Pfizer and its subsidiary Wyeth (acquired by Pfizer in 2009) settled allegations by the SEC that they had both violated the FCPA's anti-bribery, books and records, and internal controls provisions. It is noteworthy that some of the violations alleged against Wyeth occurred before Pfizer acquired the company.

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- **Third parties:** Third parties – joint venture partners, agents, brokers, suppliers and distributors – all prevent risk of FCPA violations, but not all of them present the same degree of risk. The Resource Guide notes, "... performing identical due diligence on all third party agents, irrespective of risk factors, is often counterproductive, diverting attention and resources away from those third parties that pose the most significant risk." Identifying risk from a third party requires an analysis that incorporates multiple factors including the third party's relationship with the company (agent, distributor, joint venture partner, etc.), the volume of product sales or services attributed to the third party, the reliance of the company on the third party (is it the only supplier of a service or ingredient, for example), and the service provided (product sales, imports and customs, procurement of suppliers).

- **Training:** All global companies maintain training programs; not all of them are effective, either from an operational or compliance perspective. The FCPA Resource Guide emphasizes that training should be multi-faceted, covering "company policies and procedures, instructions on applicable laws, practical advice to address real-life scenarios and case studies." Equally important, the Guide makes clear that training should be designed for the target audience. Global training programs that distribute the same message to employees regardless of the individual's location, job function, vulnerability to corruption, culture or language are unlikely to achieve the necessary compliance results. A straightforward example comes from Orthofix, which entered into settlements with DOJ and SEC in 2012 to resolve allegations of violating the internal controls provision of the FCPA. Orthofix had a training program that it distributed to employees, including those of its Mexican subsidiary. The ineffectiveness of the training would have been quickly noted if employees were tested and test results were regularly monitored, not only by the subsidiary but also in the corporate compliance department. FCPA and country-specific anti-corruption training is essential for compliance. It must be relevant to the audience; reinforced through regular communications and multiple learning mechanisms; and regularly updated to keep it "new" and prevent disengagement.

Until recently, the FCPA was considered the world's primary anti-corruption law and DOJ was the primary enforcement agency. Without slighting the DOJ, which continues its aggressive enforcement of the FCPA, it's worth noting that the SEC is emerging as an enforcement power in its own right, now bringing civil actions even when the DOJ declines to lodge criminal charges. SEC's active enforcement of the FCPA's accounting provisions translates into increased risk for global companies and escalating pressure to proactively address those risk factors.

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