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FCPA and Anti-Corruption for the Life Sciences Industry

Vetting Third Parties: How to Define and Execute Systematic, Risk-Based Third-Party Due Diligence

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Provisions of the FCPA Relevant to Third-Party Due Diligence

Antibribery provisions:

- Prohibit corrupt payment of anything of value
- directly, or indirectly with knowledge that the payment will be passed on
- to a foreign (i.e., non-US) government official
- for the purpose of
  - (i) influencing, inducing or otherwise affecting an official act, decision or omission thereof, or
  - (ii) securing an improper advantage
- in order to obtain or retain business.

Accounting provisions:

- Require companies to maintain accurate books, records and accounts and design and implement adequate internal controls.

The Knowledge Requirement: Why the Need for Due Diligence?

Under the FCPA, enforcement authorities can impose liability for payments made by a company to a third party "knowing" that all or a portion of the payment would be passed on to a government official:

- "firm belief"
- "substantially certain"
- "high probability"

The Knowledge Requirement: Why the Need for Due Diligence?

A company could therefore be liable under the FCPA even if:

- There was an offer, but no actual payment, and/or
- The company did not have actual knowledge of the payment or offer.

Third-Party Due Diligence: Negating the Knowledge Element

By conducting thorough due diligence on third parties, companies provide themselves with the best chance to avoid FCPA violations, and, should such violations arise as a result of acts by third parties, to negate the knowledge element.

Additional Reasons for Third-Party Due Diligence

- For issuers, due diligence is vital to satisfying the company's FCPA internal controls obligations.
- The US Sentencing Guidelines require companies to implement effective compliance programs based on their risk environment.
- The UK Bribery Act, which will become effective July 1, 2011, establishes a criminal offense of "failure to prevent bribery," and, similar to the FCPA, requires companies to devise and implement "adequate procedures" to prevent bribery.

Life Sciences Industry FCPA Risks

What are the key risk areas for life sciences companies?

Life Sciences Industry FCPA Risks

- Regulatory Approvals: Establishing operations, seeking product approval, seeking insurance reimbursements, and abiding by post-launch regulations may require significant interaction with local government and regulatory authorities in gathering all of the necessary approvals, licenses, and permits.
- Interactions with Healthcare Professionals and Institutions: FCPA risks arise in, among others, the contexts of detailing and promotional activities (including gifts, travel and entertainment, and funded site visits), consulting agreements (including lectures, article reviews, and roundtables), clinical trials, and grants (including research grants, conference/symposium sponsorship, and charitable and political contributions).

Life Sciences Industry FCPA Risks (cont'd)

- Mergers, JVs and Other Transactions: Mergers, JVs and other transactions create risks that liabilities for past conduct may be acquired or that ongoing compliance inadequacies at acquired companies will result in future liabilities.
- Other Risks: Interactions with other government officials such as patent officials, customs officials, tax authorities, health and safety inspectors, labor officials, environmental authorities, and others present additional risks.

Life Sciences Industry: Challenges and Conditions

Where are most life sciences companies today?

Common challenges:

- Knowing your business and risks
- Defining tools based on your risks
- Clearing your backlog
- Implementing a manageable process moving forward
- Executing on the process
- Keeping costs manageable while ensuring effectiveness and sustainability

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

Which third parties require due diligence?

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

Due diligence may need to be conducted for:

- acquisition partners
- joint venture partners
- sales representatives
- consultants, researchers
- agents of joint venture partners
- co-marketers, strategic alliance partners
- charities, foundations
- distributors
- customs clearance agents
- accountants, law firms, real estate firms
- security firms
- suppliers
- investigative firms hired to conduct due diligence

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

What information should companies obtain during the due diligence process?

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

Key diligence checklist:

- Business information (address, corporate structure)
- Beneficial ownership
- Relationships with governments and government officials
- Business references
- Prior investigations, bankruptcies, or reputational issues
- Services to be rendered, need for the services
- Qualifications and resources
- Compensation
- Identity of any third parties to be used by the third party
- Third party's compliance policies and/or program
- Life cycle of agreement/relationship

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

What should companies require from third parties to ensure compliance?

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

Depending on the circumstances, agreements with third parties often should include:

- An anti-corruption certification (and periodic subsequent certifications);
- A commitment to provide notification of material changes to the third party's compliance landscape;
- A commitment to provide FCPA training to relevant employees;
- A commitment to cascade anti-corruption controls and training to subcontractors;
- A specific and well-documented process for requesting and making payments;
- Termination rights; and
- Audit rights.

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

What red flags should the due diligence process be aimed at identifying?

Nuts and Bolts of Third-Party Due Diligence: Goals of an Effective Program

General red flags include:

- Insufficient experience or resources; unusual compensation;
- Unclear role or services;
- High-risk country;
- Close ties to government officials;
- Request for unusual payment arrangements;
- Reputational issues (past allegations of corruption, bankruptcies, etc.);
- Inability to contact business references; and
- Reliance upon government contacts rather than upon skill and resources.

Basics of an Effective Program

What are the fundamental building blocks of an effective risk-based third-party due diligence program?

Basics of an Effective Program

Fundamental building blocks:

1. Completion of risk assessment based on global, regional and local business practices.
2. Articulation of key risk factors.
3. Define scope of due diligence for each third party (or group of similar third parties) based on risk.
4. Identify and create materials (instructions, checklists, contracts).
5. Determination of responsibilities (legal, compliance, business, central v. local, etc.).
6. Development of systematized process – repeatable, scalable, auditable.
7. Creation of anti-corruption due diligence reports and analysis of findings.

Basics of an Effective Program

Completion of risk assessment based on global, regional and local business practices

Basics of an Effective Program

Completion of risk assessment. Systematically determine:

1. What are you selling? Where is it manufactured and by whom?
2. How are products and operations regulated?
3. How are they promoted and sold? How shipped?
4. How are products tested and approved?

For each:

1. What third parties are used?
2. Why are third parties used?
3. How are third parties used?
4. How are third parties compensated?

What controls are currently in place? What improvements will be needed based on your review?

Basics of an Effective Program

Risk assessment process. Depending on the size and uniformity of your business operations, a risk assessment may involve:

1. Visits to all or some of your operations.
2. Interviews of key personnel (sales, marketing, business development, medical, manufacturing, HR, government relations, finance, etc).
3. Review of existing policies and procedures.
4. Review of sample of due diligence files and contracts.
5. Review of data on third-party transactions.

DO NOT assume your business is the same in every region.

DO NOT assume what people tell you about the business is accurate – ask lots of people; verify with data

Basics of an Effective Program

Articulation of key risk factors

Basics of an Effective Program

Articulate key risk factors:

1. Identify types of third parties.
2. Identify nature of activities.
3. Identify potential risks.

Basics of an Effective Program

Define scope of due diligence for each third party (or group of similar third parties) based on risk

Basics of an Effective Program

- Categorize and/or grade third parties based on risk factors:
  1. Geography.
  2. Function.
  3. Interactions with government officials.
  4. Representative capacity.
  5. Quantification – numbers of transactions, values of transactions.
- Tailor process to risk level, for example:
  1. Low-risk – basic, minimal procedures (focused mostly on public sources).
  2. Medium-risk – enhanced procedures (collection of materials showing qualifications, financials; possibly interviews).
  3. High-risk – detailed and thorough review, possibly including site visits and creation of report by external vendor.

Basics of an Effective Program

Identify and create materials and processes (instructions, checklists, contracts)

Basics of an Effective Program

Possible materials/processes:

1. Internal information form.
2. Questionnaires for third parties.
3. Internet search.
4. Review of third party's financial, policies, marketing materials.
5. Interviews.
6. Site visits.
7. External diligence reports (public source or enhanced).
8. Agreements.
9. Annual certifications.
10. Audit procedures.

Create detailed but understandable instructions for internal personnel who must apply the processes in the real world.

Basics of an Effective Program

Determination of responsibilities

Basics of an Effective Program

Who will collect/analyze/approve? Possibly a combination of:

1. Legal.
2. Compliance.
3. Business.
4. Procurement.
5. Finance.
6. Local, regional or global resources.

Basics of an Effective Program

Development of systematized process – repeatable, scalable, auditable

Basics of an Effective Program

Systematized process:

1. Uniform standards for assessment of risk and application of procedures – including addressing red flags when they arise.
2. Exceptions to uniform standards for local needs can be accepted where appropriate but should be approved centrally.
3. Standard process for collecting, analyzing, approving and – importantly – maintaining relevant materials (diligence information collected, internal discussions/rationales/approvals, contract with third party, any subsequent certifications or audit results, etc.).
4. Periodic audits to ensure compliance with process.

Basics of an Effective Program

Creation of anti-corruption due diligence reports and analysis of findings

Basics of an Effective Program

Document your process:

1. Keep copies of all materials collected.
2. Document the analysis that was done.
3. Document all approvals and resolutions of red flag issues.
4. Track the individuals involved in the process.

Good documentation allows:

1. Ability to assess any changes that may occur during the relationship.
2. Ability to easily analyze a third party when that party is proposed for another function or by another business unit.
3. Ability to justify decisionmaking if reviewed by an enforcement authority or other party.

Questions and Answers

Any questions before we proceed to the hypotheticals?

Hypotheticals

BioPharm, a US life sciences company, wants to hire a representative named Ivan Graftsky to help secure regulatory approval for a product it hopes to distribute in Belastonia (a country with a poor Transparency International rating). BioPharm conducts due diligence on Graftsky and checks his references. The reports are generally good, but BioPharm uncovers a newspaper article from five years ago that links Graftsky to a bribery scandal that occurred in the province of Omura. Can it proceed in hiring this representative?

Hypotheticals

BioPharm retains Graftsky and, several years into the relationship, the company receives a call from Graftsky saying he will need more money to “get the job done.” He has not signed an FCPA compliance certification since he executed his initial contract several years ago. When BioPharm asks him if he is paying bribes, he says, “Of course not, but you know what kind of place this country is.” What should BioPharm do?

Hypotheticals

BioPharm conducts a further investigation of Graftsky's operations. BioPharm concludes that it will terminate its relationship with Graftsky pursuant to a clause in the contract that authorizes termination if the company has reason to believe corrupt payments were made or promised. BioPharm also decides not to pay Graftsky any commissions due under the contract, for fear that he might use all or some of the money to make an improper payment. Graftsky sues BioPharm, claiming breach of contract and defending his innocence and honor. How should the company handle this?