



THIRD PARTY COMPLIANCE MANAGEMENT

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WHAT IS A THIRD PARTY

- Any person or entity that you hire who isn't your permanent employee is a third party to you.
- Typical third parties are -
 - Contract employees
 - Sub-Contractors
 - Agents
 - Lobbyists
 - Distributors
 - Resellers
 - Consultants
 - Freight forwarders/ Customs broker
 - Suppliers / Vendors
 - Joint venture partners, among others.
- What is important is that you are paying them to do something on your behalf.
- The new global expectation is that you know who they are, you have vetted them, and you are in control of the activities for which you hired them.

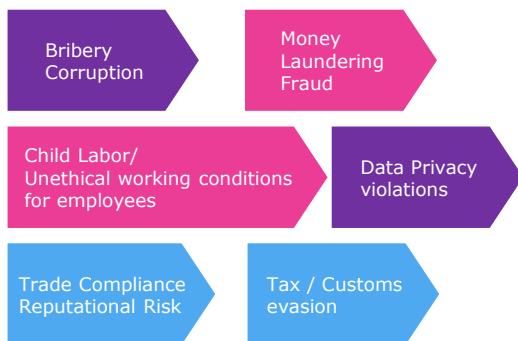
INITIAL QUESTIONS TO CONSIDER

- Does your company work with Third Parties and who are they?
- Does your Compliance Program cover Third Parties?
- Is your company third party of another company? What kind of compliance requirements has your customer imposed on your company ?

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THIRD PARTY RISKS

Potential Third Party Risks



Line of Defense

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Expected Outcomes

Company conducts business with individuals and organizations who comply with relevant legal requirements and commonly accepted ethical business standards

Compliance, Commercial & other terms formalized in the Contract

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THIRD PARTY COMPLIANCE – LEGAL REQUIREMENTS

Under many legal frameworks, organizations may indeed be held liable for acts of corruption by their third parties

A) US FOREIGN CORRUPT PRACTICES ACT (FCPA)

- Under the FCPA, an organization or individual may be held liable for making a payment to a third party while knowing that all or a portion of the payment will go directly or indirectly to a foreign official.
- According to US Department of Justice guidance issued on the FCPA, the term "knowing" includes *conscious disregard, deliberate ignorance and wilful blindness*.
- To avoid being held liable for corrupt third-party payments, the US Department of Justice encourages companies "to exercise due diligence and to take all necessary precautions to ensure that they have formed a business relationship with reputable and qualified partners and representatives".

B) UK BRIBERY ACT

- In its Adequate Procedures Guidance to the UK Bribery Act, the UK Ministry of Justice states that "a commercial organisation will be liable to prosecution if a person associated with it bribes another person intending to obtain or retain business or an advantage in the conduct of business for that organisation".
- An "associated person" is defined as an individual or entity that "perform services for or on behalf" of an organization.
- In the event of failure to prevent bribery by an associated person, the UK Bribery Act provides that it is a "defence" for an organization "to prove that [it] had in place adequate procedures designed to prevent persons associated with [it] from undertaking such conduct".

THIRD PARTY COMPLIANCE – LEGAL REQUIREMENTS

C) UNITED NATIONS CONVENTION AGAINST CORRUPTION

- Article 21. Bribery in the private sector "Each State Party shall consider adopting such legislative and other measures as may be necessary to establish as criminal offences, when committed intentionally in the course of economic, financial or commercial activities:
 - The promise, offering or giving, directly or indirectly, of an undue advantage to any person who directs or works, in any capacity, for a private-sector entity, for the person himself or herself or for another person, in order that he or she, in breach of his or her duties, act or refrain from acting.
 - The solicitation or acceptance, directly or indirectly, of an undue advantage by any person who directs or works, in any capacity, for a private-sector entity, for the person himself or herself or for another person, in order that he or she, in breach of his or her duties, act or refrain from acting."

D) NATIONAL CRIMINAL LAWS AND ADMINISTRATIVE OFFENCES ACTS

- EU criminal law on corruption is based upon OECD conventions such as the OECD Anti-Bribery Convention
- Prohibition of giving and receiving bribes in business dealings and in dealings with public officials
- Prohibition of bribing foreign public officials / EU public officials
- National Administrative Offences Acts can entail fines for the company concerned (e.g. in Germany the OWiG)
 - German Criminal Code (Strafgesetzbuch) - Bribery
 - Bribery can also be committed by an agent of the company.
 - An employee/director of the company can be held individually criminally responsible as perpetrator, inciter or accessory to corruption committed by the agent of the business.

EVALUATION OF CORPORATE COMPLIANCE PROGRAMS GUIDANCE BY DOJ

Organization of Revised Evaluation Guidance 2019	Original Evaluation Guidance: 11 Topics, 2017
I. Is the Corporation's Compliance Program Well Designed?	
A. Risk Assessment	Topic 5
B. Policies and Procedures	Topic 4
C. Training and Communications	Topic 6
D. Confidential Reporting Structure and Investigation Process	Topic 7
E. Third Party Management	Topic 10
F. Mergers and Acquisitions	Topic 11
II. Is the Corporation's Compliance Program Being Implemented Effectively?	
A. Commitment by Senior and Middle Management	Topic 2
B. Autonomy and Resources	Topic 3
C. Incentives and Disciplinary Measures	Topic 8
III. Does the Corporation's Compliance Program Work in Practice?	
A. Continuous Improvement, Periodic Testing and Review	Topic 9
B. Investigation of Misconduct	Topic 7
C. Analysis and Remediation of Any Underlying Misconduct	Topic 1



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EVALUATION OF CORPORATE COMPLIANCE PROGRAMS GUIDANCE BY DOJ

- Under third-party risk management, DOJ's Guidance reiterates many important principles emphasized by DOJ in prior guidance and enforcement actions.
- A well-designed compliance program should apply risk-based due diligence to its third-party relationships.
- In particular, DOJ stated that due diligence should reflect the size and nature of the company or transaction
- DOJ intends to focus on whether the company's third-party risk process corresponds to the nature and level of enterprise risk identified by the company
 - Whether the company adequately verifies the business rationale for using the third-party
 - That appropriate contract terms are included
 - Whether the company adequately considered and analyzed the compensation and incentive structures for the third parties
 - How the company monitors its third parties
 - Whether the company has secured audit rights and exercised those rights
 - Whether the company has conducted training of its third parties
- As to post-engagement monitoring, DOJ points to the need to use various tools such as "updated due diligence, training, audits, and/or annual compliance certifications.

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EVALUATION OF CORPORATE COMPLIANCE PROGRAMS GUIDANCE BY DOJ

RISK BASED AND INTEGRATED PROCESSES

- How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company?
- How has this process been integrated into the relevant procurement and vendor management processes?

APPROPRIATE CONTROLS

- How does the company ensure there is an appropriate business rationale for the use of third parties?
- If third parties were involved in the underlying misconduct, what was the business rationale for using those third parties?
- What mechanisms exist to ensure that the contract terms specifically describe the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered?

MANAGEMENT OF RELATIONSHIPS

- How has the company considered and analysed the compensation and incentive structures for third parties against compliance risks?
- How does the company monitor its third parties?
- Does the company have audit rights to analyse the books and accounts of third parties, and has the company exercised those rights in the past?
- How does the company train its third party relationship managers about compliance risks and how to manage them?
- How does the company incentivize compliance and ethical behaviour by third parties?

EVALUATION OF CORPORATE COMPLIANCE PROGRAMS GUIDANCE BY DOJ

REAL ACTIONS AND CONSEQUENCES

- Does the company track red flags that are identified from due diligence of third parties and how those red flags are addressed?
- Does the company keep track of third parties that do not pass the company's due diligence or that are terminated, and does the company take steps to ensure that those third parties are not hired or re-hired at a later date?
- If third parties were involved in the misconduct at issue in the investigation, were red flags identified from the due diligence or after hiring the third party, and how were they resolved? Has a similar third party been suspended, terminated, or audited as a result of compliance issues?

ENFORCEMENT ACTIONS DUE TO BUSINESS PARTNER NON-COMPLIANCE

Company	Business Partner Involved	Action By Business Partner	Government Officials Involved	Estimated Cost of Violation(s) Paid to Govt Authorities
Dow Chemicals (2010)	Contractors/ Consultants	Expediting product registration in India	Product Registration Board Officials	\$325,000(Fine)
Diageo (2011)	Consultant/ Lobbyist	Negotiations of tax and customs disputes resulting in favorable decisions- India, Thailand, South Korea.	Government Tax Officials	\$3,000,000 (Fine) \$13,300,000 (Indirect)
DePuy (JNJ) (2011)	Sales Agents, Distributors and Travel Agents	Bribing public doctors in several European countries (Greece, Poland) & paid kickbacks to Iraq to obtain 19 contracts under the UN Oil for Food Program.	Government hospital doctors and hospital administrators	\$21,400,000 (Fine) \$48,600,000 (Indirect)
Biomet (2012), (2017)	Distributors	Funnel bribes to government officials	Government hospital doctors, Customs officials	\$17,280,000 (Fine) \$5,750,000 (Indirect)
Smith & Nephew (2012)	Distributors	Funnel bribes to government officials (Greece)	Government hospital doctors	\$16,800,000 (Fine) \$5,400,000 (Indirect)
GSK (2014)	Travel Agents and Event Organizers	Organized fictitious conferences and overbilled for training sessions (China)	Government hospital doctors	\$500,000,000 (fines and penalties)
Anheuser-Busch InBev (2016)	Promoters	Improper payments to government officials in India	Government Tax and License officials	\$6,000,000 (Fine)

There is a clear trend in International Anti-Bribery legislation to make corporations liable for misconduct of their Third Parties if they do not apply a thorough level of scrutiny in the selection, approval and management process of their third parties

AB INBEV - FCPA SETTLEMENT

WHAT HAPPENED?

- Promoters had no experience or apparent knowledge of the beer industry or the regulation around distribution of beer.
- Promoters were paid excessive commission and reimbursements for promotional expenses.
- These commissions and reimbursements were used to pay government officials.

BENEFIT

- Generating beer orders from the state and operating excess brewing hours

WHAT WENT WRONG?

A) Due diligence was not conducted before engagement of promoters

- After engagement, employees completed and backdated due diligence forms
- Employees also modified responses to the due diligence forms
- Promoters were related to Government officials

B) Failing to Execute a Written Contract.

- In both cases, AB InBev failed to execute written contracts before engaging the promoters

C) "Wilful Blindness"

- AB InBev should have acknowledged and addressed the big red flag – why were these promoters being hired and what conceivable justification existed to support retaining the promoters?



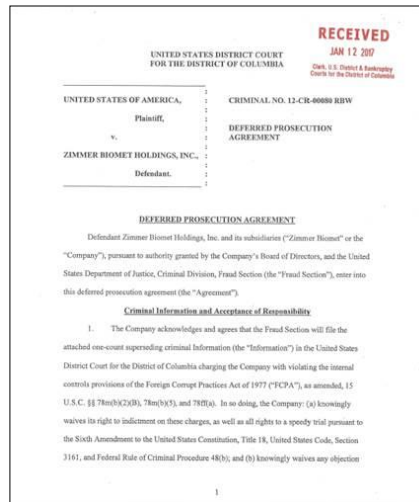
ZIMMER BIOMET - FCPA SETTLEMENT

Zimmer Biomet Holdings, Inc. has entered into a Deferred Prosecution Agreement (“DPA”) with DOJ for a three-year term in 2017.

WHAT HAPPENED?

The violations relate to actions by Biomet’s subsidiaries in Brazil and Mexico prior to the merger.

- In Brazil, Biomet allowed a distributor who had been terminated for making improper payments to HCPs to remain involved in Biomet’s business.
- **Adequate due diligence** was not conducted and Distributor continued to operate via business relation with another distributor (common major shareholder) – [Wilful Blindness](#)
- In Mexico, 3i Mexico used a customs broker [without contract](#) to import unregistered and mislabelled product into Mexico through Laredo, Texas. The customs broker’s sub-agents made improper payments to Mexican customs officials.



ZIMMER BIOMET - FCPA SETTLEMENT

WHAT WENT WRONG ?

A) Lack of oversight of distributor activities

- Businesses were not always aware of the activities of the distributors. For example, whether distributors were:
 - Paying for meals/entertainment of HCPs
 - Using third-party vendors to interact with government agencies
 - Training sub-distributors on Biomet policies and procedures

B) Ineffective contract maintenance and tracking

- Engagement before contracting
- Non-renewal of expired contracts

C) Lack of controls around payments to third parties

- For example, payments to third parties that were not consistent with the third party’s contract

ELEMENTS OF AN EFFECTIVE THIRD PARTY COMPLIANCE PROGRAM

A. Risk Assessment

- Whether the company adequately verifies the business rationale for using the third-party
- Risk/reward analysis should be performed

B. Due Diligence

- Draft Due Diligence Policy / SOP
- Performed prior to selection and periodically particularly when considering a renewal of a contract
- Could be performed Internally / by External firm / Combination of two
- “Red Flag” identification and resolution

C. Contracting

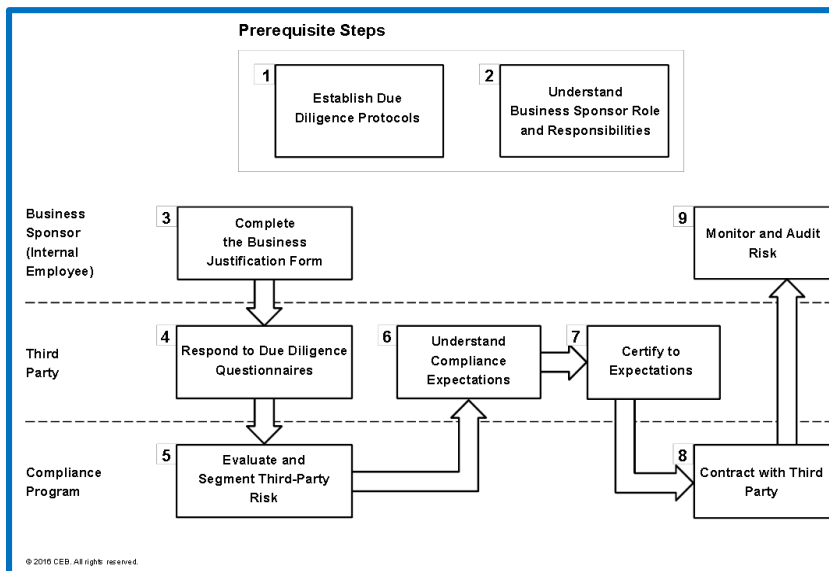
- Operational/ Commercial - Describe clear commercials, services and method of invoicing and payments
- Compliance - Certification to comply with ABAC and company compliance policies
- Right to Audit clause

D. Monitoring and Training

- Audits, Transaction testing, Unannounced visits/meetings,
- Compliance training, Annual certification programs
- Train those “responsible persons” on the compliance risks and how to manage those risks
- Share Compliance policies, code of conduct, manual

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TYPICAL DUE DILIGENCE PROCESS



STEPS

- ❖ There is a valid business need
- ❖ Business Sponsor completes the questionnaire
- ❖ Third Party completes the questionnaire
- ❖ Compliance Evaluates the questionnaire, looks for “Red Flags”
- ❖ Due Diligence completed and documented
- ❖ Contact with Third Party

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RED FLAGS

WHAT ARE RED FLAGS?

- ▣ Circumstances which indicate an increased risk of corruption
- ▣ Red flags can be cited by the government as evidence to demonstrate a company's "wilful blindness"
- ▣ Due diligence process has to identify and "resolve" all red flags

HOW TO RESOLVE/ MITIGATE RED FLAGS

- ▣ Internal Review by stakeholders (Legal, compliance, Procurement)
- ▣ External Consultation (DD Companies / law)
- ▣ Senior Management Decision
- ▣ Additional certifications
- ▣ Enhanced due diligence investigation
- ▣ Refresh due diligence

COMMON RED FLAGS

- ▣ CPI
- ▣ Suspicious or unusual compensation (high commission or fees) or payment arrangements
- ▣ Transactions in high risk countries
- ▣ Individuals or entities with questionable reputation, or known for, or previously accused of illegal or improper business practices
- ▣ Family connections to government officials
- ▣ Agents recommended by Foreign Officials
- ▣ Objection to anti-bribery contractual provisions
- ▣ Lack of transparency of ownership structure
- ▣ No significant experience relevant to the business or organization as a shell company with no meaningful presence
- ▣ Individuals who claim to have special relationship with a Foreign Official
- ▣ Requests for political or charitable contributions
- ▣ Vague scope of work or description of services

CHALLENGES - THIRD PARTY COMPLIANCE PROGRAM

- A. Performing Due Diligence on all Third Parties may be costly
- B. Lack of publicly available information
- C. Information not shared by Third Party
- D. Incorrect information shared by the Third Party
- E. Lack of understanding of Compliance principles by the Third Party
- F. Changes in Third Party ownership, nature of business operations not communicated to the company
- G. Difficulty in enforcing Right to audit clause
 - a. Confidentiality concern by the Third Party
 - b. Consolidated book of accounts for all customers/ suppliers

KEY TAKEAWAYS

- We operate in a Complex, Regulated and Dynamic environment and work with many Third Parties
- Clear trend in International Anti-Bribery legislation to make corporations liable for misconduct of their Third Parties if they do not apply a thorough level of scrutiny in the selection, approval and management process of their third parties
- Third Party Due Diligence is a **"Line of Defence"** for prevention of Commercial and Compliance Risk and is "Must"
- Due Diligence of Third Party **does not provide legitimacy to an illegal or unethical purpose**
- Right intent supported By the robust Due Diligence Process is a good defence
- Contracts with all relevant Commercial and Compliance terms in a MUST!
- Develop Due Diligence Policy And Procedure
- Provide Efficient And Effective Trainings to Third Parties
- Implement Auditing And Monitoring Of Due Diligence Process

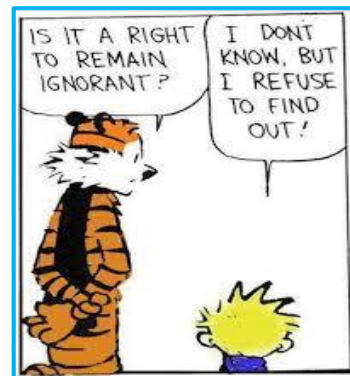
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KEY TAKEAWAYS

"Consider the possible range of 'foreign officials' covered by the FCPA. Some are obvious, like health ministry and customs officials of other countries. But some others may not be, such as the doctors, pharmacists, lab technicians and other health professionals who are employed by state-owned facilities."

*"Indeed, it is entirely possible, under certain circumstances and in certain countries, that **nearly every aspect** of the **approval, manufacture, import, export, pricing, sale and marketing** of a drug product [medical device, etc.] in a foreign country **will involve a "foreign official" within the meaning of the FCPA.**"*

...Quoting Lanny Breuer, Assistant Attorney General for U.S. Justice Department, Criminal Division, at the Pharmaceutical Regulatory and Compliance Congress forum, Washington DC, November 2009



**Willful
Blindness!
Ignorance is
not an excuse**

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