



National Pharma AudioConference

An Update on FCPA Enforcement in the Life Sciences Industry -
Compliance Considerations

Ted Acosta
Global Leader – Life Sciences
Fraud Investigation & Dispute Services
Ernst & Young

Increased emphasis on proactive compliance measures

Key Laws and Standards/Guidance on proactive compliance measures:

- *FCPA*
- *UK Bribery Act*
- *OECD Good Practice Guidelines*

➤ *Enforcement – More frequent*

- *United States*
- *Poland*
- *Germany*
- *Italy*
- *United Kingdom*
- *Serbia*
- *Korea*
- *China*

Key Elements of a Robust Anti-Corruption Program

- Anti-Corruption Risk Assessment
- Anti-Corruption Policy
 - ▶ Stand-alone corporate anti-corruption policy
 - ▶ Policies around gifts, meals, entertainment, charitable donations, facilitation payments and other
 - ▶ Policies on retaining high risk third parties and the activities they perform
- Anti-Corruption Training
- Anti-Corruption Focused Financial Controls
 - ▶ e.g., extra controls around expenses/transactions (honoraria, margins, sponsorships and financial support, employee/contractor expense reimbursement)
- Anti-Corruption Due Diligence on Business Transactions (e.g., M&A, joint ventures)
- Monitoring/Auditing
 - ▶ Anti-corruption audits
 - ▶ Compliance certifications (employees and third parties)
 - ▶ Data analytics
 - ▶ Internal reporting mechanisms (e.g., hotlines)
- Periodic reassessment

What are other life sciences companies doing?

- Anti-corruption risk assessments

- ▶ Gap analysis – current program versus risks
- ▶ Recommendation for improvement of existing policies

- Implementation of anti-corruption policies and training of employees

- Third party due diligence

- ▶ Policies around how to retain new third parties
- ▶ Procedures around how to conduct due diligence on existing third parties

Third party due diligence

Why does it matter?

- Inappropriate payments are often paid indirectly through third parties. Willful ignorance is not an excuse. The standard is “known” or “should have known”.

What are best practices?

- Ethics and compliance programs focusing on third parties, including the following elements:
 - ▶ Documented due diligence procedures in regard to retaining, and regular oversight of, third parties;
 - ▶ e.g, background checks, questionnaires, interviews, identification and resolution of ‘red flags’
 - ▶ Informing the third parties of the anti-corruption policies of the company; and
 - ▶ Seeking commitment of compliance from the third parties.
 - ▶ Explicit mention of “FCPA,” company policies and other standards in contracts
 - ▶ Right to audit

Goal?

- Getting to know the third parties with whom you do business is an important part of anti-corruption policy.
- Goal is to obtain “reasonable level of confidence” that your third parties will not engage in corruption or other improper business activity that could cause legal, financial or reputational damage to your Company.

Third party due diligence – cont'd

Approach:

- *Due Diligence of current third parties*
- *Due diligence of future third parties*
- *FCPA contractual provisions*
- *Annual certification & post-contract due diligence*
- *Training*

Third party due diligence – cont'd

Key Considerations:

- *Cost*
- *Accessibility of information*
- *Availability of Company resources*
- *100% assurance is not obtainable*
- *Rewards need to be balanced with risk and appropriate safeguards that can be applied to mitigate risk*
- *Business decisions that will need to be made as a result of the due diligence (e.g., what if third party does not want to sign the anti-corruption language in the updated contract)*

Thanks

*Ted Acosta
Ernst & Young
5 Times Square
New York, NY 10036*

*+1 212 773 3022
ted.acosta@ey.com*