

Pharmaceutical Regulatory and Compliance Congress
Monitoring and Auditing of Third Parties
October 21, 2015

EY Survey

“Where business partnering relationships are in place, the risk of fraud, bribery and corruption substantially increases. Fifty-five percent of respondents believe risks are more likely to arise from third parties than from internal staff.

Monitoring and Auditing of Third Parties

Why the concern with third parties?

- Less control over their work
- Less visibility to their work and records
- May not have strong internal controls
- May be owned by a former employee
- May delegate work to a sub-contractor
- Incentives to engage in inappropriate behavior
- Direct interactions with government officials
- Easier for employees to deny knowledge of wrongdoing

Monitoring and Auditing of Third Parties

Johnson & Johnson Auditing Approach

- Separate group within Corporate Internal Audit that conducts only proactive FCPA audits and fraud investigations
- Proactive FCPA audits
 - Commercial audits of operating units
 - Distributors
 - Travel agencies
 - Clinical Research Organizations

Monitoring and Auditing of Third Parties

Overview of FCPA Audits

- 3 weeks on site
- 3 to 4 audit staff
- Local translators / auditors assist
- Work is totally separate from Financial audits
- Structured audit programs approved by Law Department
- Audit areas mapped to fraud allegations, FCPA trends, DOJ guidance, country risk, etc.
- Work consists of interviews and detailed transaction testing

Monitoring and Auditing of Third Parties

J&J Auditing Approach

Operating Unit
(2007)

Operating Unit
+ Distributors
(2011)

Operating Unit
+ Distributors +
Travel Agencies
(2014)

Operating Unit +
Distributors + Travel
Agencies + Clinical
Research
Organizations (2015)

Monitoring and Auditing of Third Parties

J&J Third Party Audit Approach

- First, audit the function / process at our operating unit
- Next, audit the third party

Do you have a list of all third parties?

Monitoring and Auditing of Third Parties

Auditing Third Parties

- Consider outsourcing or co-sourcing
- Biggest challenge: Do we have all of the third party's records and transactions? Have they withheld something?
- Interview management and staff
- Don't forget to audit sub-contractors; they may be even more of a risk

Monitoring and Auditing of Third Parties

Auditing Distributors

Possible Distributor Issues

- Cash to government officials; cash is generated through high margins, discounts, free goods, samples, rebates, credit notes, “special services,” promotional programs
- Sponsoring government officials for events and conferences
- Excessive or inappropriate entertainment
- Inappropriate payments to government officials

Risk may be higher if you have no physical presence in that market

Monitoring and Auditing of Third Parties

Auditing Distributors

- Areas to audit:
 - Payments
 - Expense Reports
 - Petty Cash
 - Free Goods
 - Samples
 - Promotional Programs
 - Shipping Records

Monitoring and Auditing of Third Parties

Auditing Distributors

Payments to HCPs for Congresses, travel, etc.

- May not be transparent – possibly not approved by your company
- Higher risk of inappropriate transactions when a third party is executing transactions on our behalf
- Possible inaccurate recording of transactions in books and records if we funded the payments through discounts or free goods and thus recorded them as a reduction of Sales instead of an Expense

Monitoring and Auditing of Third Parties

Auditing Distributors

Free Goods, Samples, Promotional Programs

- Trace transactions from your records to distributor records
- Were free goods, samples, and goods from promotional programs sold?

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Possible Travel Agency Issues

- Excess cash given to government officials
- Travel is extravagant (e.g., first class flights, resort location, luxury hotel, etc.)
- Approved travel is changed (e.g., side trips, etc.)
- Family and friends booked for travel

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Auditing a Travel Agency

Areas to audit:

- Training
- Payments, with heavy emphasis on supporting documents related to travel charges

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Possible Clinical Research Organization Issues

- Inappropriate site selection process
- CRO personnel not trained in compliance
- Payments not supported
- Work not performed
- Work performed, but at above FMV
- Capital equipment given or donated to CRO
- Overcharges for pass through costs
- Other payments by CRO for education, etc. not appropriate

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Audit Steps at CROs

- Training
- Policies and Procedures
- Details of clinical trials (milestones, etc.)
- Payments made by CRO
- Due Diligence on CRO third parties
- Customs agents and brokers
- Contract employees (flex staffing)

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Possible Next Steps at J&J

- Contract sales organizations
- Customs agents / brokers
- More reliance on data analytics

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Other Thoughts

- Review your business practices
 - How many distributors do you need?
 - Should they be prohibited from performing certain functions?
 - Should you use local travel agencies?
 - Should advance payments to vendors be permitted?

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Other Thoughts

- Enhance your oversight of third parties
 - Stricter policies
 - More personnel
 - More training
 - Ongoing or continuous monitoring of transactions

QUESTIONS?