

The U.S. Foreign Corrupt Practices Act (FCPA): How to Minimize Your Risk

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Thank you for your interest in PharmSource®. We are pleased to provide this white paper, which delivers valuable insights on the U.S. Foreign Corrupt Practices Act (FCPA) and practical advice on implementing a strong FCPA compliance program. PharmSource ADVANTAGE online service (www.pharmsource.com) is the industry's most respected outsourcing information web portal for serious consumers of information on contract drug development and manufacturing. We are dedicated to providing incisive reporting and analysis through our two publications – Bio/Pharmaceutical Outsourcing Report and Emerging Markets Outsourcing Report. This service also includes full access to PharmSource's highly regarded database of contract service providers, where subscribers can search for and compare hundreds of companies from around the world that serve the pharma industry.

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703-383-4903

FCPA Enforcement on the Rise as Offshoring Grows

Late in 2008, the German electronics giant Siemens was fined USD 800 million to settle corruption charges brought by the U.S. Department of Justice—the largest penalty ever levied under the U.S. Foreign Corrupt Practices Act (FCPA).

Corruption is ubiquitous in human society. Today, most Western countries have laws that prohibit corrupt practices by companies working within their borders. In the United States, the FCPA “prohibits a U.S. issuer or domestic concern from directly or indirectly paying or giving a gift of any value to a foreign official in order to obtain or retain business, or secure any improper business advantage.” The FCPA has an anti-bribery component, policed by the Department of Justice (DoJ), that criminalizes offering, authorizing or giving a “thing of value” to a foreign official anywhere in the world in order to obtain or retain either business or an improper business advantage. The U.S. Securities and Exchange Commission (SEC) enforces specific accounting practices for all companies with publicly traded stock in the United States. These practices and standards help eliminate slush funds and off-the-book transactions that might fund bribery.

Corruption is policed less well in many emerging markets. In fact, some countries perceived as being the most corrupt are among those where it's most popular to do business. Transparency International ranks the world's countries in order of perceived corruptness—out of 150 countries, for example, Brazil, China and India are all ranked at 72 (Denmark, Finland and New Zealand, all seen as least corrupt, are ranked first). In some cases, bribery and other forms of corruption are common business practices; thus, U.S. companies must be particularly careful to articulate and comply with their own anticorruption policies when doing business in these areas.

Increased Global Scrutiny of FCPA Violations

Diligence among U.S. companies to avoid corruption is especially important today, as FCPA enforcement has intensified due to an increasingly outsourced business environment, increased media exposure of corruption and more rigorous policing of corruption overseas. As a result of this trend:

- ◆ Enforcement authorities are focusing more closely on joint venture relationships and their extended implications.
- ◆ Both the SEC and DoJ have added staff, and the Federal Bureau of Investigation (FBI) has dedicated a new task force to FCPA investigations.

- ◆ Federal U.S. authorities now receive more support for their enforcement efforts from foreign governments—the result of a new global convention adopted by the 30 countries of the Organization for Economic Cooperation and Development, making corporate bribery illegal and providing U.S. investigators with access to secret bank accounts and foreign tax records.

Interpretation of FCPA Regulations for the Bio/Pharma Industry

The FCPA is interpreted fairly broadly; for example, enforcement authorities are concerned not only with people offering bribes, but with any kind of exchange that benefits a company in terms of tax liability, customs tariffs or other local obligations. The legal definition of “foreign official” is also very broad and extends to a political party or party officials, any candidate for foreign political office, any officer or employee of a foreign government, a public international organization, or any department or agency of the same, as well as any person acting in an official capacity. This last category is of particular significance to the pharmaceutical industry. “In most of the world, the state is heavily involved in medical care,” says Tom Johnson, a partner at Covington and Burling, LLP. “Employees of state-owned hospitals, clinics and universities should be viewed as foreign officials, and enforcement authorities might even view doctors working for organizations such as the UK’s National Health Service as foreign officials as well. Physicians employed by government institutions such as hospitals and who also have private practices are more difficult to categorize, and companies should make those decisions

on a case-by-case basis.” In many countries the state has a broad reach, and companies doing business overseas must keep this in mind.

“The FCPA covers officials with state-owned business enterprises and, in Asia and the Middle East in particular, the state touches many employees that U.S. companies are not used to thinking of in terms of foreign officials,” notes Leslie McCarthy, director of corporate development at The STEELE Foundation, who has a particular focus on FCPA practices. “This is where the need for comprehensive compliance programs and effective due diligence come in. Perhaps your local partner works for a company whose principal’s wife is the Minister of Energy, or perhaps your in-country agent is doing what he thinks is best to ‘smooth’ the import/export process. ... These are very risky situations and unless you vet your third parties carefully, a company can end up in trouble very quickly.”

Companies are advised to be careful. Punishment for violating the FCPA includes fines and imprisonment, suspension of a person’s or firm’s right to do business with the federal government or ineligibility to receive export licenses, and/or being barred from the securities business and participation in agency programs. The United States Sentencing Commission notes, “Criminal liability can attach to an organization whenever an employee of the organization commits an act within the apparent scope of his or her employment, even if the employee acted directly contrary to company policy and instructions. An entire organization, despite its best efforts to prevent wrongdoing in its ranks, can still be held criminally liable for any of its employees’ illegal actions.” With enforcement on the rise, companies must be more vigilant. ■

Table 1: FCPA and the Pharmaceutical Industry

Of special concern to companies in the pharmaceutical industry and working abroad are these challenges:

- ◆ Healthcare providers are a de facto part of the government in some countries and, while they often cannot be vetted at great depth, they do need to be accounted for and educated about the company’s FCPA position.
- ◆ Sales and marketing divisions are often the public face of the company overseas, and their staff members need to be trained carefully in compliance with FCPA guidelines.
- ◆ International clinical trials typically require a government interface; who that is and how the role is handled is of special importance.
- ◆ All relationships with government officials can be challenging and must be carefully conducted with an understanding of FCPA provisions as well as the local culture and customs that might result in conflict.
- ◆ Grants and foundations, specifically how their money is distributed and by whom, must be reviewed carefully to ensure that recipients are credible entities.

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Compliance Programs Key to Mitigating Corruption Risk

Compliance programs are at the core of companies' best strategies for minimizing the risk of FCPA violations—but companies must be careful to follow best practices established by the DoJ Sentencing Guidelines, which note, "An established compliance and ethics program that follows the key elements of the Sentencing Guidelines will further serve to demonstrate to enforcement authorities a good-faith commitment to compliance."

"There are three keys to a good compliance program," notes McCarthy.

"These include an articulated compliance policy, a training program, and identifying and performing adequate levels of due diligence on third parties." In addition, she recommends implementing an effective disciplinary and incentive system, creating a mechanism for reporting violations, and having a well-documented record of compliance efforts in case of public scrutiny. "Companies need to show their seriousness of intent when complying with the FCPA," McCarthy says.

For example, a multinational company with sales reps in Asia and Eastern Europe might look to save money by training its reps to vet the resellers and distributors with whom they work. What's wrong with this picture? "Because your sales team has vested relationships with agents overseas, they also have an interest in having them approved," McCarthy says. "Your reps are also vulnerable because they might have friendships with their contacts and be persuaded of the efficiencies of letting the locals conduct business in their own way. Finally, they are not experienced investigators. The DoJ regards these third parties as direct extensions of your U.S.-based company. Without an independent process, your internal process is open to the possibilities of corruption, compromise and sloppiness."

A credible compliance program must be consistent, reinforce anti-corruption standards and be diligently implemented companywide and from region to region. Due diligence on third parties must exhibit a solid understanding of the culture,

customs, communication styles and relationships that guide your third-party agents, resellers, partners, distributors and other intermediaries. In detail, a compliance program must include:

- ◆ Risk assessments that measure the likelihood and severity of possible violations and direct compliance resources based on those assessments.
- ◆ A clearly defined corporate compliance and ethics policy that emphasizes the company's commitment to upholding both FCPA and foreign anti-corruption and anti-bribery laws. The policy must also clearly define compliance standards, procedures and controls to be executed by all employees at all levels, including external partners and third parties.
- ◆ A compliance officer whose primary job function is to command necessary resources and respect to ensure that the job gets done. This role should have a direct line to the CEO and the Audit Committee and be free from undue influence or intimidation. Visible support from senior management must exist for the compliance and ethics program.
- ◆ Reinforcement of the company's compliance priorities from the top ranks down and out into the field, including regular training and audits/certification, and newsletters and other forms of communication for ongoing awareness of FCPA procedures and standards.
- ◆ A systematic and consistent due diligence effort to vet third parties, incorporating investigative best practices, secure documentation retention and appropriately tiered levels of inquiry, all based on clearly articulated standards and risk assessment.
- ◆ Clear-cut warranties and representations to accompany all business partnerships abroad, including any agents acting on any level for the company.

"...it is far easier to start a compliance program before commencing work overseas than it is to implement one retroactively, but it is also far more cost-effective to implement and run a compliance program than it is to be involved in any kind of FCPA investigation, which not only is costly but can have devastating effects on a company's reputation and business."

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- ◆ Regular audits and reviews to examine internal accounting controls; the accuracy of books, records and expense reports; and any signs of corrupt practices.
- ◆ Ongoing education and training, both internally and for third parties, to promote understanding of the company's ethical standards and its legal expectations surrounding FCPA compliance.
- ◆ An effective system for reporting and responding to questions and breaches in the field, including well-established channels for reporting suspected violations of the compliance program or any other suspected illegal conduct under FCPA. There should also be a system to prevent retaliation against any employee who raises questions or reports a concern.
- ◆ A system for imposing effective and consistent discipline for anyone, including managers, who fails to take reasonable steps to prevent and detect violations.
- ◆ A system of incentives to promote commitment to the company's compliance and ethics program.
- ◆ A system for responding appropriately to violation reports to ensure that investigations are conducted professionally and root causes of violations are addressed in order to prevent recurrence.
- ◆ Appropriate background checks to ensure that authority is not delegated to those who have shown they will not respect the law or support the company's compliance and ethics program.
- ◆ Steps to promote a culture of compliance and ethics.

McCarthy notes that it is far easier to start a compliance program before commencing work overseas than it is to implement one retroactively, but it is also far more cost-effective to implement and run a compliance program than it is to be involved in any kind of FCPA investigation, which not only is costly but can have devastating effects on a company's reputation and business. As more multinationals enforce compliance programs overseas, however, it is hoped that local corruption standards will begin to change and that some countries now perceived as very corrupt will begin to enforce compliance from within, as has been happening more rigorously in Europe. This will certainly level the playing field for all countries and companies doing business in markets perceived today as being more corrupt. ■

Increased Scrutiny Makes Compliance Programs Critical for Pharma

There are significant incentives for companies to invest in a comprehensive compliance program. FCPA fines remain very high and penalties are increasing. For example, after a mishandled payment of USD 70,000, one company had to spend tens of millions of dollars just on the remediation around the investigation, exclusive of any fines. The costs of mitigating even a small infraction can be significant, so compliance programs are a critical investment for companies of all sizes. "There has never been a more critical time to have a compliance program in place," says Jonathan Kellerman, Principal, Pharmaceutical & Life Sciences Advisory Services Group, PricewaterhouseCoopers.

The Office of the Inspector General (OIG) of the United States has collected more than USD 4 billion in fines for FCPA violations to date, and the pharmaceutical industry in particular is a target of intense FCPA scrutiny in both the U.S. and abroad.

Compliance Standards Amidst Economic Challenges

Companies are being warned by regulatory agencies not to weaken compliance standards in the current economic crisis. In a December 2008 letter to CEOs of SEC-registered firms, Lori Richards, SEC Director, Office of Compliance Inspections and Examinations, emphasized that "even with the current financial crisis, corporate cost-cutting measures should take into account the need to maintain adequate compliance programs and internal financial control systems." Anticipated Congressional legislation will add USD 110 million in funding for enforcement actions concerning financial fraud and corruption, and additional audit teams are being put together by enforcement agencies.

At a time when companies are looking to cut costs, experts predict that the trimming of corporate compliance programs will happen and will have a detrimental effect on companies. The next three years will see "several currently reputable, large U.S. companies and individual corporate

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managers under investigation for fraud, corruption and other criminal and civil violations,” writes Sharle Brown, Partner and Chair, FCPA, Foreign Corruption and Corporate Compliance Practice for DLA Piper, all because they “did not fight the tendency of managers and business units to shortcut legal compliance, internal controls and due diligence procedures designed to prevent and detect financial crimes, particularly violations of the U.S. Foreign Corrupt Practices Act.”

FCPA Compliance Programs Face Global Challenges

Implementing and maintaining FCPA compliance programs can be challenging at any time, especially in emerging markets. In many of these countries, notes Kellerman, “facilitation payments” are a standard way of doing business—paying to expedite visas, having supplies delivered on time and getting other daily operating tasks accomplished. Complying with FCPA by not making these payments can have a significant impact on a company’s business model in these regions, and companies must find a way around this obstacle. Often, U.S. companies find themselves trying to avoid any corrupt practices, while other local companies or third parties are not so mature or farsighted.

Another significant challenge focuses on the actual implementation of compliance programs worldwide. “There are resource issues here,” Kellerman notes. “Especially in emerging markets, daily FCPA oversight is critical for due diligence and monitoring of third parties. FCPA compliance programs must be implemented, administered and maintained. Yet too often, designated compliance officers must wear multiple hats.”

“Any compliance program must be consistent, reinforce anticorruption standards and be diligently implemented companywide and in all regions,” agrees McCarthy.

First Step: Risk Inventory

As we’ve seen in the two previous sections of this paper, compliance programs require companies to have in place corporate anticorruption policies and procedures as well as training vehicles for employees and third parties. The heart of the compliance program, however, is identifying and mitigating external risk.

McCarthy notes that the often-paralyzing first step of a compliance program is to identify all the third parties with which your company has a relationship. First, however, you need to know what constitutes a third party—see Table 2 for examples.

Table 2: Indications of a Credible Due Diligence Program

- ◆ Resellers, distributors, channel partners, manufacturers, licensing representatives, sales and marketing consultants, export agents, and joint venture and acquisition targets and affiliates undergo routine and renewable vetting.
- ◆ Documents are securely retained to ensure that corporate compliance activity is fully archived and readily available to legal and regulatory bodies.
- ◆ A tiered approach is used to provide companies with multiple levels of due diligence, each of which is determined on a cost-effective, case-by-case basis and based on risk assessment.
- ◆ Background questionnaires and anticorruption declarations (these can be automated) are used to provide constant notifications and transparency in managing third parties and a starting point for further due diligence.
- ◆ Automated renewals are conducted to ensure that third-party status remains up-to-date.
- ◆ Clearly articulated processes are put in place for identifying, reporting and decision-making related to the discovery of “red flag” indicators.
- ◆ The education and training components of a compliance program are incorporated into an established due diligence process, systematizing a corporate commitment to disseminating and tracking relevant FCPA-related information and materials on an ongoing basis.

Then you must identify all these representatives and intermediaries and anyone else outside the company with whom you do work.

Once that is done, companies should do a risk inventory. This is a systematic calculation of risk that looks at many risk factors for each category of third party. Which intermediaries are most at risk for corruption? What is their relationship to any government entity? What are the modes of payment? What is the overall level of risk in the industry? What is the level of risk in the region? In turn, this overall assessment of the level of risk tells you what level of due diligence you need to do for each third party in order to mitigate its specific risk level.

Second Step: Due Diligence

Now companies need to go ahead and conduct due diligence. What does this mean? FCPA best practices for this are not set out officially, but it is advisable to use a framework that meets or exceeds professional investigative standards and expectations, says McCarthy, whose company currently has active investigations in more than 95 countries around the world.

Kellerman agrees. "If authorities need to investigate, the presence of a serious and consistent due diligence process for third parties provides evidence of a credible best effort to prevent FCPA violations," he says, "as does a companywide compliance education program."

Table 3: How to Identify Red Flags

Due diligence is done to uncover red flags that can indicate that further investigation is needed or that there is a high risk that the subject in question is engaged in unethical or corrupt activities. The following questions will help you to identify red flags:

1. Has the subject cooperated in completing a due diligence questionnaire and other relevant disclosures?
2. Who are the subject's social and business associates?
3. What is known about past social relationships, and to what extent are they connected to government officials?
4. Have any recommendations to use this third party originated among government officials?
5. Has the third party ever held office, been an official in a political party or been connected with government officials? Is this foreign representative actually qualified for the work he or she is to perform for your company?
6. Does he or she sit on government healthcare-related committees or organizations or on hospital boards?
7. Is he or she in a position where payments to him or her might influence purchasing or prescribing behavior?
8. What is the service being requested? Is compensation commensurate with market rates or is it disproportionate to the job being done? If there is a payment involved, where is it going? Does the third party request money to be sent offshore? Is the payment to be made in the name of the corporation or to some other individual or relative of the individual? Is the payment to be in cash or a cash equivalent? Does he or she want goods and services in lieu of monetary payment?
9. Have any unusual payment patterns or financial arrangements emerged?
10. Are the types of representations and warranties from the third party contractually binding and appropriate? Has the third party been properly notified of and educated on FCPA, your company's anticorruption commitment and other anticorruption laws?
11. Has the subject committed to financial transparency and full disclosure of expenses, corporate licensing, history and other accounting?
12. What is his or her financial history?
13. Has the subject agreed to produce documentation and be audited?
14. Has a place of business been confirmed and staffing determined to be proportionate to remuneration for services?
15. Are there legal issues in the public record, such as complaints, or has that person been sued?

A set of repeatable procedures establishes a credible due diligence process; ensures a valid, testable outcome; and leverages proven methods to minimize unforeseen errors or complications. This will represent a good-faith effort on the part of a company to prevent violations. In addition, says Kellerman, successful due diligence on third parties requires a solid understanding of the culture, customs, communication styles and relationships that guide business practices in each particular region. A credible due diligence program will address several key risk points (see Tables 2 and 3).

“Remember that it is not enough to set up a compliance program—it is also critical to keep the program up-to-date, including due diligence efforts, and to keep up with standard industry practices,” says McCarthy.

Outsourcing Due Diligence

Companies can undertake due diligence themselves or outsource both risk profiling and due diligence investigations completely or on a case-by-case basis. Both McCarthy and Kellerman note that it is common for companies to outsource due diligence efforts, first to remain unbiased and second to put these activities into the hands of experts. “Tasks can be outsourced country by country as needed,” says Kellerman. “And it is important to use an unbiased intermediary who can get at the right level of detail.”

McCarthy adds, “Protect yourself by not allowing individuals with a vested interest in the outcome, such as sales and marketing reps working within the country or with a subject, conduct the investigation.”

There are two basic types of due diligence: research and field investigation. Which type is needed depends on the level of risk for the subject of the investigation. Here, The STEELE Foundation’s model for each is presented as an example of what thorough due diligence processes involve for each type.

- ◆ **Global Database Investigation:** This is a very basic due diligence investigation that involves searching databases, international records and media sources in English and the local languages. Analysts then synthesize the findings and put them into context to identify red flags and other concerns according to FCPA guidelines.
- ◆ **Enhanced Due Diligence:** This involves an in-the-field investigation on a primary subject (typically a company) and one principal to ensure that the company is not misrepresenting itself. This process

is used for any third parties that appear to present a serious risk. Investigators work hard to identify sources that can confirm a company’s legitimacy and whether there has been any involvement with corrupt activities such as bribery, money laundering or organized crime.

Why is outsourcing due diligence useful? “Some records have to be pulled locally and by hand,” says Kellerman. “Trained investigators can do that easily and know where and how.” In China, for example, private investigators must be Chinese nationals. Even local law firms in China must contract out their investigations to local investigators.

“It’s easy to be fooled,” says McCarthy, “but trained inves-

tigators and consultants know most of the tricks, as well as have the advantage of being unbiased. For example, we had one company that paid a marketing consultant in China USD 250,000 for staff and operating costs. The field investigation found that the guy was doing business out of his mother-in-law’s apartment on his cell phone—no staff, no operations. There’s no real way to know that unless you look for it on the ground. He had a business address, stationery, all the trappings of a real company.”

How does this work? Consulting firms such as The STEELE Foundation conduct all manner of risk mitigation procedures and consulting, including FCPA risk inventories, due diligence, and research and field investigations worldwide.

“The United States is increasing its push to investigate FCPA and financial fraud violations by raising enforcement budgets and adding personnel. In addition, there is an increased risk of investigation right now in the pharmaceutical sector, based on the frequency with which the United States and other local regulators are conducting investigations.”

STEELE also provides companies with technology and tools for case management, security and archiving of records. Accounting firms such as PricewaterhouseCoopers (PwC) provide similar services. "We can work both sides of the problem," says Kellerman, "helping companies to set up compliance programs and conduct due diligence as well as assisting them if they are being investigated by regulatory authorities." PwC provides due diligence, third-party audits, profiling of third parties and risk profiling.

How much does it cost? Due diligence can be affordable even for small companies. As an example, STEELE charges USD 275 for a basic Global Database Investigation, and has a menu of services and flat fees for field investigations country by country worldwide.

Compliance Is Key

The United States is increasing its push to investigate FCPA and financial fraud violations by raising enforcement budgets and adding personnel. In addition, there is an increased risk of investigation right now in the pharmaceutical sector, based on the frequency with which the United States and other local regulators are conducting investigations. Interactions between healthcare company officials and anyone related to any government or government agency are undergoing intense scrutiny. A strong corporate compliance program not only helps a company avoid FCPA violations but, in the case of any investigation or inquiry, the right compliance program and accompanying comprehensive due diligence indicate a level of good faith critical to regulatory agencies. ■

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