

Corrupt practices in the US and UK healthcare industries



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www.practicallaw.com/4-384-1742

With increasing frequency, US regulators are aggressively pursuing enforcement actions against foreign companies and the activities of subsidiaries of US companies outside the US, in relation to practices that violate laws prohibiting corruption. The focus on such companies and activities by the US Securities and Exchange Commission (SEC) and the Department of Justice (DOJ) is nowhere more evident than DOJ's current investigation of BAE Systems' Al Yamamah arms deal with the Saudi Arabian government. This is despite a lengthy investigation by the UK Serious Fraud Office, which was halted following the UK Government raising national security concerns. The decision to halt the investigation was initially successfully challenged in the UK High Court by pressure groups which want it to be reopened. The High Court ruled that the Serious Fraud Office's decision was unlawful. However, the House of Lords eventually overruled this in July 2008.

The impact of this heightened enforcement activity is particularly acute in relation to the pharma, biotech and medical device industries, because the regular business of companies in these industries involves contact with public hospitals and government health services that can create risks of infringing anti-corruption legislation. The extra-territorial effect of the US laws prohibiting corruption are evidenced by recent enforcement actions against pharma and medical device companies. In 2005, for example, the SEC and DOJ alleged that Diagnostic Products Corporation used its Chinese joint venture to channel US\$1.6 million (about EUR1.1 million) of improper payments to doctors and laboratory officials who controlled purchasing decisions at state-owned hospitals. The company was fined US\$4.7 million (about EUR3.3 million).

Against this background, this article:

- Examines the relevant UK legislation and the US Foreign Corrupt Practices Act.
- Identifies high-risk areas for the healthcare industry.
- Suggests potential solutions to the problems that can arise.

UK LEGISLATION

The bulk of the UK laws are between 90 and 120 years old and prosecutions involve evidentiary difficulties in:

- Establishing payment flows.
- Distinguishing between legitimate and illegal payments.
- Calling on witnesses from other jurisdictions.

- Proving the necessary elements (for example, that a principal approved an agent's actions).

In addition to common law offences relating to misconduct in public life and embracery, the UK has a growing body of legislation prohibiting corrupt practices. The Public Bodies Corrupt Practices Act 1889 (1889 Act) provides that anyone who corruptly offers, solicits or receives, any advantage as an inducement or reward for a public body doing or failing to do anything, is guilty of a misdemeanour.

The Prevention of Corruption Act 1906 (1906 Act) prohibits any agent "corruptly" accepting or attempting to obtain for anyone, any consideration as an inducement or reward for doing or failing to do any act in relation to his principal's affairs. As with the 1889 Act, a person "corruptly" giving or agreeing to give or offering the consideration will also be guilty. A conviction under the 1906 Act is punishable summarily by up to six months' imprisonment and/or a fine, and on indictment by a term of imprisonment not exceeding seven years and/or a fine. The 1906 Act was intended to extend the crime of corruption beyond the public sector and into the private sector. The 1906 Act also goes further than the 1889 Act in that it does not just cover particular matters or transactions, but also any inducements that can be viewed as encouraging favourable treatment. Neither the 1889 Act nor the 1906 Act define "corruptly". In the leading case of *Cooper v Slade (1858 6 HL Cas. 746)*, the majority view was that "corruptly" meant "purposely doing an act which the law forbids as tending to corrupt".

The Prevention of Corruption Act 1916 introduced a presumption that any consideration received by an official in the public sector from a person who holds or seeks to obtain a contract from the public body represented by the official was a corrupt payment.

More recently, the Anti-Terrorism, Crime and Security Act 2001 (2001 Act) amended the laws mentioned above to apply to public bodies and their agents located outside the UK and who have no connection with the UK. The 2001 Act also makes it possible for the UK authorities to prosecute a prohibited act committed by a UK national or entity while outside the UK.

There is also relatively new legislation in this area in the form of the Fraud Act 2006 which creates three new offences:

- Fraud by false representation.
- Fraud by failing to disclose information.
- Fraud by abuse of position.

The legislation was enacted in 2007 and the resulting case law has been limited. For example, one case involved identity theft, and another involved the falsification of documents by an employee at a logistics company to ensure that a package was not screened at Heathrow Airport. As such, it seems that the new legislation is not been used to prevent corruption despite the fact that it has great potential to do so. However, the UK Home Office is due to review the operation of the Fraud Act in 2010, and it is hoped that further light will be shed on the issue when this occurs.

US FOREIGN CORRUPT PRACTICES ACT

Prohibitions

In comparison, the US Foreign Corrupt Practices Act (FCPA) prohibits the offer, payment, promise, or authorisation of the giving of money or anything else of value, “corruptly”, to a foreign official for purposes of assisting in obtaining or retaining business, or directing business to, any person. A “foreign official” is defined as:

- Any officer, employee or other party acting on behalf of any foreign government (or any department, agency, or instrumentality of a foreign government, or of a public international organisation);
- A foreign political party (or official of it); or
- A candidate for foreign political office.

This has been interpreted broadly. Employees of “public international organisations” (like the World Health Organisation) can count as “foreign officials”, as can employees of government health services, and the SEC has taken enforcement actions based on payments to employees of the World Bank.

A corrupt purpose of “assisting in obtaining or retaining business” includes a broad range of both direct and indirect activities, for example:

- Influencing an act or decision of a foreign official in his official capacity;
- Inducing that person to do or omit to do an act in violation of his official duties;
- Securing any improper advantage; or
- Inducing that person to use his influence with a government or instrumentality of a government to affect an act or decision by the government or instrumentality.

In addition, the FCPA prohibits payments or offers to any third party, while knowing that all or a portion of the payment will ultimately be made to a foreign official for the same purposes. In other words, a person or entity subject to the FCPA cannot circumvent its restrictions by making a prohibited payment indirectly through a third party such as an agent or representative. “Knowing” in such circumstances is defined broadly to include actual knowledge, as well as knowledge that such a payment is likely to occur; even ignoring indications of trouble or “red flags” can lead to liability.

Significantly, US authorities can attempt to enforce the prohibitions of the FCPA against individuals and companies not based in the US, as well as the foreign subsidiaries of US companies, under a variety of theories:

- Companies which are not domiciled in the US but which trade American Depository Receipts on a US stock exchange count as “issuers” and are therefore subject to the FCPA.
- Non-US subsidiaries (and their employees) can violate the FCPA in their capacity as agents for their US parent companies.
- Even those foreign companies that do not count as “issuers” of securities can violate the FCPA if they take an act “in furtherance” of an illicit payment while within the US. The DOJ takes a very broad view of this “territoriality” jurisdiction, interpreting the FCPA to apply when a foreign company simply causes an act to be done within the US by anyone acting as its agent. For example, initiating a wire transfer from a US bank might be sufficient for US authorities to assert jurisdiction under the FCPA.

US authorities have increasingly used all these theories in bringing cases against foreign entities. Since 2001, there have been at least three enforcement actions against foreign companies, as well as at least ten other actions against non-US subsidiaries, for violations of the FCPA. Several of these cases have involved companies in the healthcare industry.

Exceptions and defences

An exception to the FCPA allows for “facilitating payments” to expedite or to secure the performance of a “routine governmental action”. This exception covers actions ordinarily performed by a government official, such as obtaining permits, processing visas, providing mail, phone, and power services, scheduling inspections, and similar actions. It specifically does not cover a decision to award new business or to continue business with a particular party. Accordingly, it may be legal to pay an official to perform some official function faster, but not to make a different substantive decision.

The FCPA also provides for an affirmative defence where activity otherwise prohibited by the FCPA is explicitly permitted under the written laws or regulations of the foreign official’s country. In practice, this defence is very narrowly construed and not applicable where such payments are merely customary. A second affirmative defence is available when the payment was made as a reasonable and bona fide expenditure, such as travel or lodging expenses, directly related to the promotion of products or services or in execution of a contract with a foreign government.

Books and records provisions

In addition to the anti-bribery prohibitions, the FCPA contains record-keeping and internal accounting control provisions applicable to companies subject to US securities laws. These provisions require that companies make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; and that they maintain an effective system of internal accounting controls.

Comparison of US and UK legislation

As can be seen, there is overlap between the UK and US legislation in relation to the prevention of corrupt practices. However, there are some differences. The main substantive difference is that the UK legislation does not provide an exception for the payments described above as “facilitating payments” (*see above, Exceptions and defences*).

The practical differences between these jurisdictions are illustrated by the number of investigations and prosecutions and their resulting sanctions. Over the past five years, there has been a significant increase in the level of US enforcement activity. In 2003, the SEC and DOJ together brought only two FCPA cases, but since 2006 they have brought over 30 enforcement actions. More importantly, recent enforcement actions have resulted in massive criminal and civil fines. DOJ recently announced its largest ever criminal penalty (US\$26 million (about EUR18.2 million)) against Vetco International Ltd., and the SEC and DOJ together obtained a record US\$44 million (about EUR30.1 million) combined criminal and civil penalty against Baker Hughes, Inc.

In contrast, the UK has yet to successfully prosecute a company for breach of its anti-bribery laws.

For companies with any form of presence or activity in the US, the impact of the UK authorities’ failure to investigate and prosecute this type of conduct may be illusory rather than real. These companies could still face the risk of investigation and prosecution in the US, as illustrated by the US DOJ’s investigation into the BAE deal.

HIGH RISK AREAS FOR HEALTHCARE COMPANIES

For healthcare companies there are certain areas that can be particularly problematic.

Government flashpoints

Interactions between pharmaceutical, biotech and medical device companies and government decision makers frequently occur in connection with product testing, registration and licensing, manufacturing, and sales and marketing. It is critical to monitor company-government interactions at each of these junctures for potentially improper activities.

Healthcare providers as “foreign officials”

In many countries, hospital administrators, physicians, nurses and other healthcare professionals that are employed by government hospitals wear “two hats” under US law. Under the relevant UK legislation, these healthcare professionals can also be considered agents of the foreign public bodies. The SEC/DOJ have consistently considered such healthcare professionals to be “foreign officials” under the FCPA. As a result, dealings with these healthcare professionals could be subject to both US and UK legislation.

Healthcare companies should therefore be aware that benefits provided directly or indirectly to these individuals create potential exposure. The following all present risks for healthcare companies:

- Contracts for research and development and clinical trial research.

- Consulting contracts.
- Expert reports supporting product registrations.
- Post-registration patient research.
- Speaking engagements.
- Charitable grants.
- Promotion and sales efforts.

Use of agents and consultants

Companies can be held responsible for the improper conduct of their agents and consultants. Contracts with agents and consultants should address anti-corruption compliance. However, the bottom line is that companies entrusting their businesses to agents should always know their partners.

SOLUTIONS

There are no “silver bullets” that will magically bring companies into compliance with anti-corruption laws. However, there are steps that can be taken to educate employees’ about their obligations under these laws and manage the ways in which business is conducted.

Anti-corruption compliance programme

An anti-corruption compliance programme is a useful first step in avoiding problems. Such a programme should include a:

- Clearly articulated corporate policy.
- Designated corporate official with oversight responsibilities.
- Committee review of foreign agents and contracts.
- Zero tolerance policy for wrongdoing.

Employees should also be made aware of their responsibilities with regular training and certifications.

Due diligence for joint ventures and partnerships

The US DOJ has issued some guidance about entering arrangements with partners (this advice is directed at US Companies, but can be applied more generally). In particular, there are two recommendations:

- “Companies are encouraged 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.”
- “Such due diligence may include investigating potential foreign representatives and joint venture partners to determine if they are in fact qualified for the position, whether they have personal or professional ties to the government, the number and reputation of their clientele, and their reputation...”

This advice can be found at www.usdoj.gov/criminal/fraud/docs/dojdocb.html.

Companies should have auditable trails of the steps that they have taken to comply with anti-corruption legislation. For example, they should retain formal proposals to and investigations of joint venture partners.

Contractual provisions

Contracts with joint venturers and partners should contain provisions designed to provide some assistance in insulating companies from liability under anti-corruption laws. Some provisions that companies should think about include:

- Withdrawal rights.
- Representations or evidence of a firm policy covering compliance with the FCPA and related laws.
- Veto rights for selection of agents.
- Legal opinions of local counsel.
- Conditions on capital infusions.

Provisions requiring regular and independent audits may also be useful in ensuring agents do not engage in corrupt practices or that any inappropriate practices are identified quickly and terminated.

REPUTATIONAL ISSUES

If a company is prosecuted for an offence under anti-corruption laws, negative consequences for its business will almost surely follow. The public and companies with which it deals may be wary of the company's business practices and both goodwill and share price could suffer. Even if there is little publicity in the mainstream press, the

company will have to declare any fines it has had to pay in its accounts and this could cause problems with shareholders and with any future merger plans. Company officers and employees can also be prosecuted which can lead to fines and possible imprisonment. Such action would undoubtedly have significant financial consequences and could cause irreparable harm to the employees' careers.

CONCLUSIONS

Compliance programmes for all employees, together with due diligence on potential partners and contractual safeguards with joint venturers and partners, can help insulate a company from potential liability. There is no substitute, however, for vigilance in relation to companies' activities in markets where corrupt practices are common.

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