

CORRUPTION

Mitigating corporate corruption in the healthcare industry

BY PAULINE RENAUD



Over the last few years, an increasing number of international healthcare companies have faced litigation under the Foreign Corrupt Practices Act (FCPA). The most high-profile of these cases was arguably that of Siemens AG, Europe's largest engineering conglomerate, with significant healthcare operations, which agreed to pay a record \$800m in fines and disgorgement of profits after an investigation into allegations of serious bribery under the FCPA. In addition, other major cases are currently being investigated, and it is thought that the healthcare industry will continue to face legal scrutiny going forward. Indeed, officials at the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) have reportedly said that the pharmaceutical industry would be a particular focus in 2009, arguing that corruption risk tends to be higher in the sector than in many others. This seems to be due to a combination of factors, including the objectives set by the DOJ and the SEC, the ongoing effects of the financial crisis, and the general nature of the healthcare sector, which has close ties to government. As such, companies must take care to ensure compliance with the FCPA.

Healthcare companies susceptible to violations

The FCPA was passed in 1977 to address both the transparency requirements provided

under the Securities Exchange Act of 1934 and the rising issue of the bribery of foreign officials. But FCPA enforcement has intensified in recent years, with US regulators increasing their scrutiny of various sectors, and doling out significant fines and penalties. This has been notable in the pharmaceutical and medical devices industries, where several companies are currently being investigated for violations of the FCPA and other anti-kickback and fraud abuse statutes. A number of previous investigations have resulted in a fine, and the penalties are getting more severe. "Recent FCPA enforcement activity trends towards increased financial penalties for corporations and a prosecutorial focus on individuals," says Kimberly Egan, a partner at DLA Piper LLP. "In 2008, 60 percent of FCPA prosecutions were of individuals. In addition, the SEC Deputy of Enforcement, Scott Friestad, said that the financial penalties that the Commission expects to see in 2009 'will dwarf the disgorgement and penalty amounts that have been obtained in prior cases'." This may be partly due to the increased cooperation between US regulators and foreign governments in the pursuit of such investigations, which increases the success rate of enforcement.

Of course, several other factors are also notable here, not least the ongoing effects of the financial crisis. For example, as competition

increases, it is likely that the number of employees making corrupt payments to obtain sales will also increase, as will the likelihood of them getting caught. This is reflected in the figures – at the end of 2003, the US recovered about \$1.8bn for the year from the healthcare sector via judgements and settlements. But today, it is reportedly more like tens of billions of dollars – a significant increase. However, the nature of the industry and the developments impacting it are also important parts of the equation. A significant number of customers and business partners associated with US healthcare companies are employed by public healthcare systems in various countries, and since many of these individuals qualify as 'foreign officials' under the FCPA, any payment made to influence their business decisions may be considered a bribe in violation of the Act. "US regulators view all employees of government healthcare institutions – from the most senior executives to the most junior employees – as foreign officials within the meaning of the FCPA," explains Gary DiBianco, a partner at Skadden Arps Slate Meagher & Flom LLP. "Accordingly, improper payments or other benefits made to such individuals, in the eyes of the regulators, run afoul of the FCPA," he says. Furthermore, the definition of 'foreign officials' is often broader in countries such as China, Russia and Mexico, including not only members of the Ministry of Health, but also other bureaucrats such as doctors, nurses and any other staff, thereby exacerbating the risk of litigation for companies.

Clearly, the potential vulnerabilities of the healthcare industry are numerous and varied. As such, pharmaceutical and healthcare companies run a great risk of breaking the law when marketing and distributing their products, notes Doug Tween, a partner at Baker & McKenzie LLP. "Payments for product registration, placement on hospital formularies, clinical trial outcomes, treatment protocols, or the writing of prescriptions could be considered a corrupt payment under the FCPA. Even making contributions to an official's favoured charity can run afoul of the FCPA, as Schering Plough found out in 2004," he says. Furthermore, many healthcare compa- ▶▶

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nies operate in foreign countries via a local agent, and US regulators stipulate that even if an incriminated payment has been made by a third party in a foreign country, the company will still be subject to an FCPA enquiry.

Naturally then, the increased litigation has had an impact on a number of large companies. Besides Siemens, whose fine was one of the largest ever delivered, other global brands have also been found guilty of committing various forms of corporate corruption. For example, AstraZeneca received a document request from the SEC in 2006 that related to the company's operations in Italy, Croatia, Russia and Slovakia. According to a 2008 filing, the group has responded to the SEC's request, but the outcome of its investigation is as yet unknown. Similarly, Eli Lilly turned over documents relating to its Polish subsidiary a few months ago. Again, that investigation is ongoing. "Also, in June last year, AGA Medical settled a US DOJ investigation by agreeing to a \$2m criminal fine and retention of a corporate compliance monitor," adds Mr DiBianco. "According to the settlement papers, AGA

Medical employees allegedly made corrupt payments to Chinese healthcare professionals to secure sales. AGA also, allegedly, made payments through its local Chinese distributor to employees of the State Intellectual Property Office in exchange for patent approvals." He adds that it is likely that some of the issues outlined in this settlement will be echoed in future prosecutions and settlements.

Difficulties, exceptions and obligations

Recent developments in the healthcare industry may have an impact on FCPA enforcement actions going forward. Often cited is the contraction of the pharmaceutical sector, which could potentially encourage FCPA compliance in these companies – or conversely, stimulate the US government's wish to extract large penalties from erring healthcare giants. In addition, the Obama administration's efforts to overhaul the US health insurance system will also be relevant. The developments are likely to affect the Medicare/Medicaid landscape, and could therefore change the conditions for debarment proceedings.

But Ms Egan warns that a more immediate effect will be felt from the fact that an increasing number of pharmaceutical companies are sending their clinical trials to countries with public health systems – and if the legal and cultural customs are not a good fit with those in the US, FCPA compliance can be a real problem. "Many Latin American countries prohibit pharmaceutical companies from contracting with or paying employees of state-owned institutions directly, including study investigators, which means that companies must contract with the institution itself. As a practical matter, pharmaceutical companies often find that clinical trial payments made to institutions directly never reach the participating investigators or study personnel, which can affect a pharmaceutical company's ability to recruit experienced investigators," she says. The danger here is that companies in this position may find that they have violated the FCPA without even realising it.

However, there are some limited exceptions to the FCPA, which allow otherwise impermissible payments to be made to doctors and scientists employed by public institutions, notes Ms Egan. Examples include payments to low-level state employees for facilitating permits, or payments for bona fide business expenses, such as business travel, under certain specific conditions. But healthcare companies need to

be aware of their other statutory obligations before taking the plunge. "There are two other US fraud statutes that apply specifically to the healthcare industry and that can be implicated in foreign corruption investigations," explains Ms Egan. "The Anti-Kickback Statute and the 'Stark Act' limit financial arrangements between clinical trial sponsors and any clinical investigator who offers medical services under the Medicare and Medicaid programs, or who treats patients who are covered by those programs, regardless of whether those medical services are provided in the US or overseas." She further explains that the Anti-Kickback Statute is intended to discourage healthcare companies from providing financial incentives to investigators to encourage them to recommend certain medicines to Medicare/Medicaid patients. And under the Stark Act, physicians are prohibited from referring Medicaid and Medicare patients to health services where the physician has a financial relationship.

Failure to comply with any of these statutory obligations can have severe consequences for both individuals and companies. Violating the terms of the Stark Act can result in fines of up to \$15,000 for each service billed to Medicaid, plus twice the reimbursement claimed. Furthermore, intentional fraud can result in a \$100,000 fine and exclusion from the Medicare and Medicaid programs. Under the FCPA, violations by an individual can result in a five-year-imprisonment and a criminal fine of \$250,000. In addition, a company can be fined up to \$2m. But in the case of wilful violation, an individual can be imprisoned for up to 20 years, fined \$5m and be excluded from Medicare and Medicaid programs. Companies can face a fine of up to \$25m. "The DOJ can also seek restitution, and the SEC may seek disgorgement of a company's profits on contracts secured as a result of corrupt payments," adds Mr Tween. "Of course, these penalties can be expanded in cases with multiple counts of conviction, or in certain other circumstances. In addition to monetary damages, a company can also suffer reputational damages, suspension or debarment from government contracting, an inability to receive ITAR export licences. In addition, DOJ frequently requires the imposition of a corporate compliance monitor as a condition of any settlement." Indeed, the imposition of a third-party monitor is becoming an increasingly common aspect of anti-corruption settlements. ▶▶

Mitigating risks

In light of the increasingly severe penalties involved, businesses are advised to take a series of steps in order to limit corporate corruption risks. This is particularly crucial when operating in emerging markets. Firstly, companies should have a thorough understanding of the incidence of corruption in the countries where they operate, and of the nature of the relationships between foreign government officials and employees. They should also make sure they have an effective FCPA compliance program in place for any employee dealing with employees of state-owned healthcare institutions in foreign countries. "It is important to tailor compliance policies and training to particular geographies in which a company operates," asserts Mr DiBianco. "Thus, for example, companies should understand that the business environment and climate in China is different from that in Eastern Europe, and that each environment presents particular risks. Among other areas, companies should focus on assessment of their marketing, sponsor-

ship, travel, gift and entertainment practices, as these have been a focus of recent settlements," he says. Businesses should also translate their code of conduct into the languages of the countries they operate in, ensuring that it is disseminated among employees.

Furthermore, reporting mechanisms can also be implemented to allow individuals to report potential FCPA violations. Thorough due diligence should be conducted on third parties, and on expenditures by agents, and consultants should be subject to frequent audits, especially in high-risk countries. Mr Tween adds that compensation systems that potentially provide an incentive to make fraudulent payments should be prohibited. In addition, healthcare companies should require "prior approval for anything that is, or could be construed as, a payment to a foreign official – particularly gifts and entertainment expenses – in order to assess the payment's reasonableness and connection to a bona fide business purpose, and ensure that such payments, if made, are fully and accurately docu-

mented in the company's books and records," says Mr Tween. Also, "facilitating payments" to foreign officials permitted under the FCPA should be carefully monitored and prohibited where necessary.

Compliance with the FCPA and other anti-corruption legislation is clearly becoming increasingly important for healthcare companies. This is for a number of reasons. The risks of violation are numerous, and US regulators are intensifying their scrutiny of healthcare businesses in light of the financial crisis and the sector's vulnerability to widespread corruption. But external risk is only half the story, and companies are advised to take a closer look at their internal anti-corruption programs so as to identify and tackle their weak points. Furthermore, it is vital that this process is ongoing, in order to keep up with the shifts that the healthcare industry is currently experiencing. Only then can healthcare companies be assured that they are doing everything necessary to mitigate the threat of corporate corruption in their businesses. ■



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Kim's Consumer Product Safety Commission work includes counseling to clients who import, distribute or manufacture products intended for use by US consumers. She advises on the intersection between CPSC, FTC and FDA regulation of particular products and counsels on the special consumer protection concerns related to Chinese suppliers. She has published on Chinese supply chain issues as they affects toys, food items, and pharmaceuticals and has conducted webinars for industry groups on the same topics.

Kim's food work has included risk management planning and strategic assessments related to obesity claims, litigation analyses in connection with an acquisition of a company manufacturing dietary supplements, advice on FDA's food additive and food contact regulations, advice on FDA's GRAS ("Generally Regarded as Safe") regulations, general advice on food safety issues, product recalls, and supply chain rationalization.

Kim's work for pharmaceutical and biotechnology clients work covers all aspects of new drug development around the world. Her experience includes preclinical and clinical trial development, clinical data review, Data Safety Monitoring Board and Adjudication Board issues, FDA and EMEA approval of new molecular entities or line extensions, drug labeling issues, promotional issues, HIPAA and other patient privacy issues, data disclosure obligations, study subject compensation issues, informed consent and payment to physician regulations, Advisory Committee and Oral Explanation preparations, and WHO policies. She also provides strategic advice to pharmaceutical companies on compliance with Good Clinical Practices and ICH guidelines and

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Kim's litigation matters have included a wide variety of complex commercial litigation, including mass tort and product liability matters in the food, pharmaceutical, asbestos, silica, and medical device industries, as well as insurance coverage litigation, trade secret and business tort litigation, and contract disputes. Ms. Egan focuses on scientific and regulatory fact development, witness preparation, jury testing and expert strategy.

Kim is Chairman of the Board of Friends Together for Sudan, an organization that helps women and girls in the Darfour region of Sudan achieve meaningful access to education. She also provides pro bono support to organizations engaged in life sciences research in the former Soviet Union and elsewhere in the developing world.