US and PRC anti-bribery laws: regulation, risk and prevention in the life sciences industries

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With the dramatic increase in globalisation in the 21st century, businesses are facing a corresponding increase in corruption concerns when expanding overseas. In the US, the number of bribery related enforcement actions initiated by the Securities and Exchange Commission (SEC) and Department of Justice (DOJ) in the last seven years has far exceeded the total number of such enforcement actions initiated in the first 23 years after the Foreign Corrupt Practices Act (FCPA) was first adopted. These actions have been marked by record corporate fines and penalties and the imposition of independent monitors, as well as a notable willingness by US prosecutors to pursue enforcement actions against foreign based companies that violate the FCPA.

Beyond US regulation of corruption, many jurisdictions around the world have adopted equally stringent anti-bribery laws and are enforcing those laws against companies doing business within their borders. Multilateral anti-bribery initiatives such as the OECD Anti-Bribery Convention (OECD Convention) and the United Nations Convention Against Corruption (UN Convention) have prompted widespread anti-corruption initiatives and promise an increase in both unilateral and multilateral corruption investigations over the coming years.

Against this backdrop of increased anti-bribery enforcement, multinational companies are aggressively pursuing new opportunities in emerging markets such as China. But while China's booming economy provides significant commercial opportunities, it can also foster an environment of corruption. In the 2005 Transparency International Corruption Perceptions Index (a ranking of the countries most prone to public corruption) China was ranked near the bottom, indicating a widespread perception of "rampant corruption". The significant corruption risk of doing business in China is further heightened by severe domestic anti-corruption laws and actual, though somewhat uneven, enforcement of those laws.

This chapter examines:

- The relevant anti-bribery laws of both the US and China applicable to companies in the life sciences industry, including a summary of the FCPA and the People's Republic of China (PRC) anti-bribery laws and life sciences-specific laws.
- Specific corruption risks faced in emerging markets such as China where the public healthcare systems are largely controlled by the government.
- Best practices for anti-bribery compliance for life sciences companies, to reduce the risk of corruption violations when doing business in these markets.

FOREIGN CORRUPT PRACTICES ACT

Anti-bribery provisions

The 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 (*15 U.S.C. § 78dd*).

A "foreign official" is defined as (*§§ 78dd-1(f)(1)(A), 78dd-2(h)(2)(A)*):

- 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).
- A candidate for foreign political office.

A corrupt purpose of "assisting in obtaining or retaining business" includes a broad range of both direct and indirect activities that include (*§§ 78dd-1(a); 78dd-2(a); 78dd-3(a)*):

- 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.
- 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 (*§§ 78dd-1(a)(3), 78dd-2(a)(3), 78dd-3(a)(3)*). 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 "turning the other cheek" can lead to liability (*§§ 78dd-1(f)(2), 78dd-2(f)(3), 78dd-3(f)(3)*).

Exception and affirmative defences

An exception to the FCPA allows for "facilitating payments" to expedite or to secure the performance of a "routine governmental action" (*§§ 78dd-1(b), 78dd-2(b), 78dd-3(b)*). 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 the like. It specifically does not cover a decision to award new business or to continue business with a particular party. Therefore, it may be legal to pay an official to perform some official function faster, but not to make a different substantive decision (*§§ 78dd-1(f)(3), 78dd-2(h)(4), 78dd-3(f)(4)*).

The FPCA 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 (*§§ 78dd-1(c)(1), 78dd-2(c)(1), 78dd-3(c)(1)*). 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/internal controls

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 (*15 U.S.C. § 78m(b)(2)*).

Jurisdictional reach

The FCPA was designed to regulate conduct occurring outside the US, and its scope can encompass foreign activities of both US and non-US companies. The Act specifically applies to entities subject to US securities laws or "issuers;" "domestic concerns" which generally include US persons and US companies; and "persons other than issuers or domestic concerns" when such person commits any "act" in furtherance of corrupt payments "while in the territory of the United States" (*§§ 78dd-1, 78dd-2, 78dd-3*). The Act also applies to "agents" of both issuers and domestic concerns including those operating entirely outside of the US (*see Dooley v United Technologies Corp., 803 F. Supp. 428, 440 (D.D.C. 1992), stating that the FCPA covers foreigners who act as agents for domestic concerns*).

PRC ANTI-BRIBERY LAWS

In early 2006, the PRC embarked on a nationwide campaign to crack down on corruption and commercial bribery in the burgeoning Chinese economy. While the PRC's anti-bribery efforts are underway in numerous sectors, no sector has likely received as much attention as the life sciences industry. The recent conviction and execution of Zheng Xiaoyu, the former head of the State Food and Drug Administration for taking bribes to approve substandard drugs clearly signals that the government intends to aggressively enforce the PRC's anti-bribery laws and regulations in the life sciences and public health sector.

PRC commercial bribery law and regulations

In the PRC, corruption in the commercial context is governed by laws and regulations that impose civil, administrative, and criminal penalties for acts constituting "commercial bribery".

The PRC Anti-Unfair Competition Law of 1997 (PRC Competition Law) and the Provisional Regulations on the Prohibition of Commercial Bribery (Commercial Bribery Regulations) prohibit commercial bribery, which is defined as the "offer of bribes in the form of property or other methods by a business operator to another party in a transaction, or of having an interest [in] a transaction for the purpose of selling or purchasing products or services".

According to a *Reply regarding commercial bribery issued by the State Administration of Industry and Commerce* (SAIC), an essential element of commercial bribery is the creation of adverse effects on fair competition. The Commercial Bribery Regulations further specify that the term "property or through other methods" given to an entity or individual, includes, but is not limited, to:

- Cash (Renminbi Yuan (CNY) or other currencies).
- Commercial products (for example, tobacco, liquor, jewellery).
- Cash paid under the guise of a commission, consultancy, remuneration, marketing, endorsement or promotional fees, or reimbursement of expenses.
- Notes of value (for example, stocks, debentures, purchase coupons).
- Provision of entertainment, travel, or opportunities to study abroad.

Commercial bribery can rise to the level of a criminal offence prohibited by the PRC Criminal Code if, in return for improper benefits, an organisation offers tangible property of "large value" to government agencies or state-owned enterprises, companies, or institutions (collectively, SOEs) (Note that offering bribes to organisations other than government agencies and SOEs will not trigger criminal liabilities); state-employed personnel; or non-state-employed personnel. The Criminal Code defines the term "large value" to be an offer by an organisation of more than CNY200,000 (about US$26,500); or less than CNY200,000 but more than CNY100,000 (about US$13,300), if one or more aggravating factors apply.

On 8 July 2007, the Supreme People's Court (SPC) and the Supreme People's Procuratorate issued a joint opinion clarifying the government's position on commercial bribery crimes. The *Opinions on Several Issues Regarding Applicable Laws for Handling Criminal Cases of Accepting Bribery* (SPC Opinions) marks the most comprehensive judicial interpretation of various types of bribes since the issuance of the PRC Criminal Code. According to the SPC Opinions, numerous new types of bribes disguised as legitimate commercial transactions are expressly prohibited, including:

- Accepting free shares of corporate stock accepting bribes

under the guise of joint establishment of companies or other investments.

- Accepting a "salary" under the guise of a nominal job.
- Securing benefits while in a government position but accepting the property after leaving.

Life sciences industry-specific laws in China

The PRC has adopted several measures aimed specifically at combating corruption in the life sciences industry.

Prohibition of commercial bribery relating to purchase and sale of drugs. Drug manufacturers, drug trading enterprises, and medical care entities are prohibited from offering "off-the-contract" and "off-the-book" kickbacks during the purchase and sale of drugs. "Off-the-contract" and "off-the-book" kickbacks refer to payments the amount and type of which are neither provided in the relevant purchase and sales contracts nor recorded in account books (*see Rules of Financial Administration on Prohibition of "Off-the-book Funds," established by the Financial Institutes, issued by the Ministry of Finance on 16 June 2005, effective from 1 July 2005*).

Drug manufacturers and drug trading enterprises and their agents are also prohibited from offering property or other improper benefits to personnel or staff of medical care entities in exchange for sales of medicines or improper influence on doctors' medical prescriptions. The term "property or other improper benefits" includes cash payments, commercial products, tours, reimbursements, and other items.

Blacklist of drug enterprises found to engage in commercial bribery. Drug manufacturers, drug trading enterprises, and their agents can be placed on the official PRC Commercial Bribery Blacklist, which is published on the website of the relevant provincial health authorities, if both of the following apply:

- They have provided any property or other benefits to the management personnel, medical staff, or drug purchasing staff of the medical care entities where such enterprises' drugs, medical equipment, or medical consumables are used.
- If these activities are determined to be crimes of bribery by competent People's Courts, handled as bribery cases by relevant discipline inspection and supervision authorities, or punished by other competent authorities.

Medical care entities are prohibited from purchasing drugs, medical equipment, or medical consumables from any entity on the blacklist for a period of two years after the date on which the entity was placed on the backlist. (*See Provisions on the Establishment of a Recording System for Commercial Briberies in Purchasing and Selling Drugs, issued by the Ministry of Health on 19 January 2007.*)

Prohibitions against drug officials' acceptance of bribes. Officials from the State Administration of Food and Drug and its local delegates and officials are prohibited from engaging in the following:

- Attending banquets or recreational, fitness, or tourism activities that may affect the impartial execution of their official duties.
- Holding shares of stock in drug enterprises in breach of PRC law or in a disguised or concealed form.
- Claiming personal reimbursements or accepting lecture fees, consulting fees, cash, payment vouchers, expensive gifts, or securities from drug enterprises.

Officials in breach of these requirements are subject to disciplinary sanctions or, in serious cases, criminal liability.

Prohibitions against doctors' acceptance of bribes. Doctors are prohibited from soliciting and accepting illegal kickbacks or otherwise seeking improper benefits from manufacturers or trading enterprises for medical devices or drugs. Doctors who engage in such prohibited conduct, or who accept illegal kickbacks in exchange for encouraging patients to purchase drugs or medical devices from specific pharmaceutical enterprises, will fail the regular review and be suspended from practice for three to six months for training purposes. Doctors who fail the post-training review will have their medical licences revoked by the competent health authorities.

Prohibitions against evaluation committee's acceptance of bribes. When a drug procurement is conducted through a bidding process, members of the bid evaluation committee are prohibited from committing the following actions:

- Meeting the bidder in private or accepting visits, gifts, and banquets that are sponsored by drug manufacturing and trading enterprises in a manner which may impair the fairness of the bidding process.
- Soliciting or accepting money, property, or other benefits from drug manufacturing and trading enterprises.
- Pursuing personal interests by taking advantage of his or her position for the benefit of his or her spouse, children, or friends.

Evaluation committee members who commit any of the preceding actions will have their membership in the committee cancelled and will be subject to penalties imposed by the competent authorities.

PUBLIC CORRUPTION RISK AREAS

Frequent interactions with government officials raise potentially acute corruption risks for multinational medical device, pharmaceutical and other life science companies. Illicit payments are often masked as legitimate transactions, and low-level sales and marketing staff may have performance-related quotas and personal financial incentives that run counter to compliance objectives. Given these risks, companies must develop preventative safeguards to ensure that its *bona fide* programmes are not abused by individual employees and agents, particularly in emerging markets or countries with bad track records on corruption such as China.

FCPA ENFORCEMENT ACTIONS

Syncor International Corporation

In 2002, the SEC and DOJ brought charges against Syncor International Corporation, alleging that Syncor's foreign subsidiaries in Taiwan, Mexico, Belgium, Luxembourg, and France had made at least US$600,000 (about EUR439,400) in illicit payments to doctors employed by publicly controlled hospitals (*SEC v Syncor Int'l Corp., SEC Lit., Release No. 17887 (10 December 2002), available at http://www.sec.gov/litigation/litreleases/lr17887.htm (last visited 3 September 2007)*).

In particular, the alleged illicit payments included:

- Improper fees paid to doctors for referrals of patients to medical imaging centres owned and operated by Syncor's subsidiary.
- A personal loan to a doctor that was never repaid.
- Reimbursement of personal expenses incurred by doctors.
- Inflated or fictitious invoicing arrangements with doctors.
- Physician support payments in the form of sponsorships for attending educational seminars (including registration fees, travel, lodging, and meals) and gifts of computers, furniture and medical supplies.
- Direct gifts, including cash wire transfers, computers, digital cameras, wine, wristwatches, and travel.

Such payments, the government alleged, were made for "the purpose and effect of influencing the doctors' decisions so that Syncor could obtain or retain business with them and the hospitals that employed them". To settle the case, Syncor paid a US$500,000 (about EUR366,000) civil penalty and agreed to retain an independent consultant to review and make recommendations to the company's FCPA compliance policies and procedures. Syncor Taiwan also pleaded guilty to criminal FCPA violations and paid a US$2 million (about EUR1.46 million) penalty.

Schering-Plough

In 2004, Schering-Plough Corporation agreed to settle an enforcement action with the SEC and pay a US$500,000 (about EUR366,000) civil penalty for alleged FCPA violations (*In re Schering-Plough Corp., Exchange Act Release No. 49838 (9 June 2004), available at http://www.sec.gov/litigation/litreleases/lr18740.htm (last visited 3 September 2007)*).

The SEC alleged that between 1999 and 2002:

- Schering-Plough's Polish subsidiary made US$76,000 (about EUR55,700) in improper payments to a charity whose founder and president was the director of a regional Polish governmental health authority.
- The charitable contributions had been made to induce the director to influence purchasing decisions by the health authority in Schering-Plough's favour, a conclusion it reached in large part because the payments were falsely justified on documents submitted to the company's finance department.

Public officials

Physicians, hospital administrators, researchers and other professionals in the life sciences industry are frequently employed by public healthcare systems and therefore qualify as "public officials" under the FCPA and other anti-bribery laws. Because these individuals make a variety of decisions on a daily basis, such as prescribing drugs for patients, that could assist a company with "obtaining or retaining business", any benefit offered or given to such individuals could come under scrutiny as possibly made with corrupt intent.

In addition to routine sales and marketing activities, life sciences companies are frequently affected by numerous other decisions typically made by regulators and other government officials. Officials who act in a public capacity within the public healthcare system exercise the authority to make critical decisions with regard to product registration, authorised pricing, levels of reimbursement for specific prescription drugs, placements on hospital formularies, and the administration of clinical trial and treatment protocols.

Commercial opportunities for corruption

To further complicate matters, life sciences companies also commonly encounter situations in which they legitimately provide benefits to individual physicians for non-corrupt purposes which creates significant challenges when investigating and preventing potential bribery violations. In many instances, it is difficult to distinguish between legitimate activity and corrupt payments; the difference often comes down to the intent of the individual conferring the benefit (that is, whether they have a corrupt purpose).

Promotion of products. In the normal course of promoting the sale of products to physicians and other customers who may also be considered public officials, life sciences companies often engage in promotional activities that include providing benefits such as meals, entertainment, free product and goodwill gifts. These benefits generally constitute "something of value" provided to a foreign government official for the purposes of US and PRC anti-bribery laws (*see above, Foreign Corrupt Practices Act* and *PRC anti-bribery laws*). Companies must carefully regulate these activities to ensure that benefits are not provided with the expectation of a "quid pro quo" or the understanding that the official will improperly assist the company in obtaining or retaining business in return for the gift. These risks are magnified when companies use third party agents in foreign jurisdictions to act as sales representatives, distributors and brokers where the company may not have direct supervision over the actions taken by the agent on their behalf.

FCPA ENFORCEMENT ACTIONS CONTINUED

Diagnostic Products Corporation

In 2005, the SEC and DOJ brought enforcement actions against Diagnostic Products Corporation (DPC) alleging that the company used its Chinese joint venture to funnel improper payments to doctors and laboratory officials (*In re Diagnostic Products Corp., Exchange Act Release No. 51724, 2005 WL 1211548 (20 May 2005)*). Specifically, the government alleged that from 1991 through 2002, DPC:

- Used its joint venture to make improper commission payments to doctors and laboratory employees who controlled purchasing decisions at state-owned hospitals.
- That these payments, which totalled about US$1.6 million (about EUR1.17 million) and were mostly made in cash or by wire transfer, were recorded as legitimate expenses in the joint venture's books and records.

Once the payments were discovered, DPC instituted a compliance programme and stopped commission payments. DPC ultimately paid a US$2.7 million (about EUR1.98 million) civil penalty and a US$2 million (about EUR1.46 million) criminal fine to settle the FCPA charges. In addition, DPC agreed to retain an independent compliance consultant to review the company's FCPA policies for three years.

Micrus Corporation

In 2005, the DOJ entered into a non-prosecution agreement with Micrus Corporation, a US medical device company, for alleged violations of the FCPA. As part of its agreement with DOJ, Micrus agreed to pay a US$450,000 (about EUR329,600) penalty and retain a compliance monitor (*US v Micrus Corp., Press Release (2 March 2005), available at http://www.usdoj.gov/opa/pr/2005/March/05_crm_090.htm (last visited 3 September 2007)*). Specifically, the DOJ alleged that:

- Micrus paid more than US$105,000 (about EUR76,900) to doctors employed at hospitals owned and operated by the foreign governments of France, Turkey, Spain, and Germany in return for the hospitals' purchases of Micrus's products.
- Micrus disguised these payments as stock options, honoraria and commissions.

Additional pending investigations

In October 2005, Bristol-Myers Squibb disclosed that the SEC was conducting an investigation into the activities of the company's German pharmaceutical subsidiaries and its employees and agents in connection with potential FCPA violations. The matter is still pending and was including in Bristol's 31 December 2006 10K report.

In February 2007, Johnson & Johnson announced that the company had voluntarily disclosed to the DOJ and SEC that certain foreign subsidiaries may have made improper payments to government officials in connection with the sale of medical devices in two small-market countries. (*See Press Release (12 February 2007), available at http://www.jnj.com/news/jnj_news/20070212_192452.htm;jsessionid=FTQESWCJRQJS2CQPCB3WU3QKB2IIWTT1 (last visited 3 September 2007).*) In connection with this announcement, the company's chairman for Medical Devices & Diagnostics retired, noting that "he had 'ultimate responsibility by virtue of [his] position' for those subsidiaries that were the subject of the disclosure."

Consultancies. Distinguishing between legitimate expenditures and improper benefits becomes particularly difficult in circumstances where government officials are hired as consultants to perform certain legitimate services for companies for whom they may also be customers or regulators. As shown in the *Micrus, DPC,* and *Syncor* matters (*see box, FCPA enforcement actions*), fees for service arrangements such as speaking engagements, preparation of written articles or reports, market research, feedback and other services pose opportunities for abuse because they offer a potentially legitimate pretence for what may, in fact, be the provision of an illicit benefit.

Such engagements with public officials must be handled with particular care to rebut a presumption of impropriety. The relationships should be defined in written agreements which specify the services provided and provide for reasonable and not excessive market-based compensation. Consultancies should be avoided in situations where the particular government official is involved directly or indirectly in making decisions with respect to the company's products. All consulting arrangements must also conform to local laws and ethics rules.

Research, education and philanthropic donations. In addition to promoting the sale of products and services in the life sciences industry, companies often confer benefits in connection with educational programmes, grants and charitable donations to hospitals and physicians. For example, to assist in promoting the medical community's knowledge of important information such as the efficacy of pharmaceutical products or treatment programmes, manufacturers often provide legitimate financial and other support to sponsor physicians to attend medical conferences and to provide valuable training opportunities. Companies may also finance clinical studies and other medical research, as well as provide expensive medical equipment to clinics and hospitals.

While these expenditures are important from a social responsibility perspective, they also create opportunities for the improper channelling of benefits to government officials. The *Schering-Plough* settlement (*see box, FCPA enforcement actions*) clearly demonstrates the SEC's commitment to aggressively penalise even indirect benefits conferred in the charitable donations context. In this instance, the payments were made to a legitimate charity and not directly to a government official. Nevertheless, the SEC looked behind the transactions, asserting that the company "[m]anager did not view the payments to the Foundation as charitable, but as 'dues' that were required to be paid for assistance from the Director."

Companies must be careful when conducting such programmes to insulate the decision-making on how to distribute these benefits from the business units tasked with sales and marketing. Safeguards should be implemented to ensure that legitimate philanthropic activities not become fronts for providing individuals with benefits in exchange for an improper business advantage.

BEST PRACTICES FOR ANTI-BRIBERY COMPLIANCE

As recent cases indicate, in today's enforcement environment, a robust anti-bribery compliance programme is a must for multinational life sciences companies. Entities doing business in high risk jurisdictions such as China should adopt best practices to enhance compliance with the FCPA and domestic anti-bribery laws and regulations.

Comprehensive written policy, procedures and training

Effective compliance begins with a comprehensive, written anti-corruption policy as the foundation for a larger set of procedures including:

- Publication of an anti-bribery policy statement and related procedures and guidelines preferably translated into the local language.
- Mandatory training of high-risk employees and third party agents on no less than an annual basis.
- A hotline mechanism for reporting violations, preferably on an anonymous basis and outside of employees' own business units.

Third party agents

The use of third party agents, representatives or consultants in countries like China is often necessary and customary, but it also creates a high risk for vicarious liability for illicit payment activity. To guard against this risk in agent relationships, mandatory procedures should include:

- A thorough due diligence process before engaging a foreign agent to act on the company's behalf focused on the source of the agent's referral, qualifications for the engagement, disclosure of ownership or familial relationships to foreign government officials, and disclosure of any prior corruption charges or investigation.
- Written agency agreements that include anti-bribery representations and warranties.
- Monitoring of foreign agents through periodical training, the retention of the right to audit the agent's books and records, and annual compliance certifications.

Business hosting, gifts and entertainment

Since conducting business in high-risk jurisdictions like China often involves interaction with state-owned or controlled entities in a commercial capacity, employees are often put in a position where hosting or entertaining government officials is required for the success of the commercial relationship. While a limited amount of benefit can be legitimately conferred on a government official in connection with a *bona fide* business activity, such expenditures must be monitored to ensure that they are reasonable in scope and appropriately documented. Companies should:

- Provide detailed guidance to employees on appropriate hosting, gift and entertainment practices within their local jurisdictions.
- Establish internal controls procedures that require pre-authorisation from the corporate legal or compliance department before such expenditures can be offered or made.
- Document the *bona fide* purpose and amounts of such expenditures.

Monitoring and audit functions

The most effective compliance programmes not only implement comprehensive safeguards at the initiation of the programme, but continue to evaluate its effectiveness through ongoing auditing and monitoring of their programme by:

- Including an FCPA component as part of regular corporate audits to confirm adequate internal controls, accurate books and records entries and general adherence to compliance procedures.
- Creating mechanisms to track issues and share important compliance information with legal and compliance personnel and representatives from the relevant business units tasked with compliance responsibility.
- Regularly sharing compliance information with employees through topical web chats, formal and informal training modules and informational bulletins targeting specific identified risks or new best practices.

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