

## J&J Agrees to Pay US\$78 Million to Settle Allegations of Payments Made to European Healthcare Providers

On April 8, 2011, in another example of vigorous enforcement of anti-bribery laws around the world, Johnson & Johnson (J&J) agreed to pay a total of US\$78 million in settlement agreements with the US Department of Justice (DOJ), the US Securities and Exchange Commission (SEC), and the United Kingdom's Serious Fraud Office (SFO) in connection with payments allegedly made by J&J subsidiaries to doctors and hospital administrators in Greece, Poland, and Romania, as well as asserted kickbacks under the UN's Oil for Food Program in Iraq. The DOJ and SEC settlements involve allegations that J&J violated the US Foreign Corrupt Practices Act (FCPA).<sup>1</sup> The SFO settlement resulted in a Civil Recovery Order under the Proceeds of Crime Act 2002. The case was brought under existing UK bribery law and not the new UK Bribery Act, which will not enter into force until July 1, 2011.

As part of the settlements, J&J will pay US\$48.6 million in disgorgement and prejudgment interest to the SEC, a US\$21.4 million criminal fine to the DOJ, and a US\$8 million fine to the SFO. J&J also entered into a three-year Deferred Prosecution Agreement (DPA) with the DOJ that requires J&J to implement certain compliance measures and provide reports to the government about its compliance program.

This settlement is the latest in a recent string of major FCPA settlements involving large multinational companies such as Tyson Foods, Alcatel-Lucent S.A., and Siemens AG.

<sup>1</sup> The FCPA prohibits a broad range of persons and businesses—including US and foreign issuers of securities registered in the United States—from making a corrupt payment to a foreign official for the purpose of obtaining or retaining business for or with, or directing business to, any person. These provisions also apply to foreign persons and companies that take any act in furtherance of such a corrupt payment while in the United States. 15 U.S.C. § 78dd-1.

The FCPA also requires companies with securities listed in the United States to meet its provisions on record-keeping and internal accounting controls. These accounting provisions were designed to operate in tandem with the anti-bribery provisions of the FCPA, require companies covered by the law to make and keep books and records that accurately and fairly reflect the transactions of the company, and to devise and maintain an adequate system of internal accounting controls. 15 U.S.C. § 78m(b)(2).

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Although the J&J settlement is not the largest such settlement, it is the first recent major settlement primarily involving payments to foreign healthcare professionals and hospitals, a major compliance risk for healthcare companies doing business abroad. In many European countries, doctors and other healthcare professionals are employed by hospitals that are government-owned and operated, and the government has taken the position that these healthcare providers are therefore “foreign officials” under the FCPA.<sup>2</sup> The anti-bribery provisions of the FCPA prohibit paying, giving, offering, promising, or authorizing the paying or giving of money or “anything of value” directly or indirectly to a foreign official with the intention of improperly influencing or inducing any act or decision of such an official, or securing an improper advantage, in order to obtain or retain business or direct business to another person.

## Background

J&J is a medical products company that markets pharmaceuticals and medical devices around the world. According to the allegations by the US and UK governments, J&J subsidiaries in Greece, Poland, and Romania made payments to government-employed physicians and hospital administrators in exchange for the procurement of J&J products or to reward loyal physicians. These payments allegedly focused on J&J’s surgical implants, such as artificial hips and knees. In all three countries, most hospitals are publicly owned and operated, and doctors who work at those hospitals are government employees, thereby potentially implicating the FCPA.

## Greece

Between 1998 and 2006, DePuy and DePuy subsidiaries are alleged to have paid approximately US\$16.4 million to Greek distributors, a significant portion of which the government maintains was used to pay cash incentives to government-employed doctors in Greece. According to the

DOJ complaint, DePuy earned more than US\$24.2 million in sales as the result of these payments to doctors.

DePuy, a maker of surgical implants, allegedly began making illegal payments in 1997, before it was acquired by J&J in 1998. DePuy contracted with a Greek company to serve as the exclusive distributor of DePuy’s medical devices in Greece. According to the allegations, DePuy sold its surgical products to the Greek distributor at a significant discount, and the distributor used the difference in price to pay “commissions” to publicly employed doctors who agreed to use DePuy implants. After J&J acquired DePuy, the government claims that J&J executives decided to stop payments to one Greek distributor, but that J&J continued paying “commissions” to Greek physicians via another avenue.

J&J acquired DePuy in 1998, after DePuy had already made a series of payments to a Greek distributor that the government alleges were for the purpose of obtaining business in Greece. After the acquisition, the government contends that J&J’s Policy on Business Conduct—which prohibited bribes, required accurate books and records, and dictated controls over payments to third parties—also applied to the DePuy organization. However, the government asserts that J&J’s oversight of the DePuy operations was inadequate and that J&J did not move quickly enough to ensure that DePuy’s arrangement with the Greek distributor complied with J&J’s policy.

In December 2009, a former DePuy executive, Robert John Dougall, was charged by the SFO with corruption in a case that had been brought to the attention of UK prosecutors by the DOJ. The executive pleaded guilty and was sentenced to a year of imprisonment.<sup>3</sup>

<sup>2</sup> 15 U.S.C. § 78dd-2(h)(2)(A).

<sup>3</sup> *British Executive Jailed for Part in Greek Healthcare Corruption*, SFO Press Release (Apr. 14, 2010), available at: <http://www.sfo.gov.uk/press-room/latest-press-releases/press-releases-2010/british-executive-jailed-for-part-in-greek-healthcare-corruption.aspx>. The indictment was brought under Section 1 of the Prevention of Corruption Act 1906.

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## Poland

J&J Poland was alleged to have earned more than US\$4.3 million from sales related to illegal payments between 2000 and 2006. According to the allegations, J&J Poland paid government-employed Polish doctors pursuant to services contracts, but the contracts were a sham and the doctors provided no services. Instead, the government asserts that these contracts were a mechanism for J&J Poland to make payments to doctors or to influence members of government committees that made healthcare purchasing decisions for government-owned hospitals. The government claims that J&J Poland also spent approximately US\$7.6 million for publicly employed doctors and hospital administrators to travel to medical conventions in Poland and abroad.

## Romania

Between 2002 and 2007, J&J Romania allegedly paid local distributors to deliver cash to publicly employed doctors and sponsored travel for doctors who agreed to prescribe J&J products. In some cases, the government claims that J&J Romania employees worked with distributors to deliver cash to government-employed doctors, ranging from 3-5 percent of sales value. The government further asserts that these payments were funded through discounts to the distributors, and that in late 2007, J&J Romania began sponsoring travel for government-employed doctors to attend medical conferences in exchange for promises to prescribe J&J products.

## UN Oil for Food Program

The UN Oil for Food Program was created after international trade sanctions were imposed on Iraq following its invasion of Kuwait in the 1990s. Under the program, Iraq was allowed to use the proceeds from crude oil sales to purchase humanitarian goods—food, medicine, and infrastructure supplies. The program has been associated with corruption. Iraqi officials required companies seeking contracts to sell humanitarian products to pay 10 percent kickbacks on each contract. Two J&J subsidiaries allegedly paid US\$850,000 to the Iraqi government in order to obtain 19 contracts under the program between 2000 and 2003.

## J&J's Cooperation with the Government Investigation

As reflected in public statements by the US government, J&J cooperated with the government investigation, made a voluntary disclosure to DOJ, conducted a thorough internal investigation, and reported all its findings to the government. The DPA explicitly recognized that “J&J’s cooperation during this investigation and its substantial assistance in investigations of others has been extraordinary.”<sup>4</sup> As a result, J&J paid a criminal fine to DOJ that was a 25 percent reduction from the bottom of the fine range specified by the US Sentencing Guidelines.<sup>5</sup>

## FCPA Enforcement Trends

This settlement serves as another example of vigorous enforcement of US anti-bribery laws. The DPA in this case has many of the same features as other recent DPAs in terms of the anti-corruption compliance program expected by the US government of companies covered under the FCPA.<sup>6</sup> The DPA contains language nearly identical to DPAs that have been agreed to by the DOJ in settlements with other companies. J&J is required:

to adopt new or to modify existing internal controls, policies, and procedures in order to ensure that it maintains: (a) a system of internal accounting controls designed to ensure that J&J makes and keeps fair and accurate books, records, and accounts; and (b) a rigorous anticorruption compliance code, standards, and procedures designed to detect and deter violations of the FCPA and other applicable anticorruption laws.<sup>7</sup>

<sup>4</sup> Deferred Prosecution Agreement, *SEC v. Johnson & Johnson*, No. 1:11-cv-00686, at 3 (D.D.C. Apr. 8, 2011) (J&J DPA).

<sup>5</sup> *Id.* at 5.

<sup>6</sup> For a discussion of recent DPAs, including the striking similarities in the language used by the DOJ in each case, see: Arnold & Porter LLP, “Advisory: Building an Effective Anti-Corruption Compliance Contacts Program: Lessons Learned from the Recent Deferred Prosecution Agreements in Panalpina, Alcatel-Lucent, and Tyson Foods,” (March 2011) available at: [http://www.arnoldporter.com/public\\_document.cfm?id=17347&key=1H3](http://www.arnoldporter.com/public_document.cfm?id=17347&key=1H3).

<sup>7</sup> J&J DPA at 31.

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The J&J agreement also contains other key elements found in other recent DPAs, including:

- appointing a Chief Compliance Officer and heads of compliance within each sector and corporate function;
- developing and implementing detailed requirements for gifts, hospitality, and travel policies and procedures;
- establishing an internal mechanism to handle complaints and reports of potential corruption;
- conducting risk assessments and audits;
- implementing new procedures for acquisitions and dealings with third parties; and
- conducting training.

## FCPA in the Healthcare Context

This settlement also illustrates the special risks that healthcare companies face when promoting their products abroad. In many countries, physicians making purchasing decisions are government employees, and drug and device companies may have interactions with thousands of different physicians. Any payments or potential inducements to government-employed doctors should be carefully examined from a compliance perspective, as well as the activities of third parties who sell or distribute devices or drugs to doctors and hospitals. This case also demonstrates that the government takes the view that the FCPA applies not only to cash payments but also to other gifts or transfers that might be considered inducements. For example, the allegations against J&J included claims that J&J sponsored physician travel to medical conferences.<sup>8</sup>

The DPA in this case also includes an explicit warning that the government believes an FCPA conviction—like convictions under the Anti-Kickback Act<sup>9</sup>—can result in exclusion from participation in US federal healthcare programs.<sup>10</sup> For companies and their executives, the threat

of exclusion from participation in Medicare and Medicaid can be a significant bargaining chip for the government in cases like this.

## UK Enforcement Action

On the same day as its settlement with US authorities, J&J paid a US\$8 million settlement to the SFO in relation to the bribery allegations involving DePuy's activities in Greece. The SFO and DOJ were closely coordinated in investigating this case; DOJ informed SFO of the allegations regarding DePuy's conduct in Greece since DePuy International is incorporated and headquartered in the UK.<sup>11</sup>

In addition, this settlement came under the existing domestic legal regime relating to corruption. British authorities will have a much stronger and more modern enforcement tool when the UK Bribery Act and its regulations become effective on July 1, 2011.<sup>12</sup>

## Conclusion

The concurrent US and UK settlements in the J&J case teach a series of valuable lessons:

- Global compliance program development, enhancement, and implementation are now global standards of care. The risks of ineffective compliance efforts, once largely focused on compliance with US healthcare regulatory matters, are now a major global concern. Compliance risks are greatest in geographic locations where corruption risks are believed to be high.
- US and British authorities are working closely together and continue to bring aggressive anti-corruption actions. Companies must now consider a global response to governments during the investigation process.

<sup>8</sup> *Id.* at 23, 25.

<sup>9</sup> 42 U.S.C. § 1320a-7b.

<sup>10</sup> See, 42 U.S.C. § 1320a-7(a) (requiring mandatory program exclusion for felony convictions relating to healthcare fraud).

<sup>11</sup> *DePuy International Limited ordered to pay £4.829 million in Civil Recovery Order*, SFO Press Release (April 8, 2011), available at: <http://www.sfo.gov.uk/press-room/latest-press-releases/press-releases-2011/deputy-international-limited-ordered-to-pay-%C2%A34829-million-in-civil-recovery-order.aspx>.

<sup>12</sup> See, Arnold & Porter LLP, "Advisory: UK Government Issues Guidance on the Bribery Act," (March 2011) available at: [http://www.arnoldporter.com/public\\_document.cfm?id=17392&key=10C0](http://www.arnoldporter.com/public_document.cfm?id=17392&key=10C0).

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- Healthcare companies operating in global markets should be especially concerned about managing the risks associated with interactions with government-employed physicians or other healthcare providers who are in a position to make procurement decisions.
- Ongoing risk assessment, compliance program evaluation, and remediation are important activities for global businesses.
- The risks of executive liability for engaging in misconduct or failing to exercise effective oversight continue to increase.

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*We hope that you have found this Advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:*

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