# Lessons Learned from the Recent FCPA Enforcement Action Against Medical Device Company Smith & Nephew

In the latest major FCPA enforcement action against the medical device industry, on February 6, 2012, Smith & Nephew Inc. (Smith & Nephew) and its British parent company, Smith & Nephew plc (S&N plc) agreed to pay a total of US$22.2 million to settle violations of the Foreign Corrupt Practices Act (FCPA)[1] alleged by the US Department of Justice (DOJ) and Securities and Exchange Commission (SEC). According to the criminal information and deferred prosecution agreement filed in connection with this case, between 1998 to 2008, Smith & Nephew paid up to US$9.4 million in bribes to publicly employed Greek health care providers to induce the purchase of its products. Smith & Nephew allegedly sold its products to a distributor at full price and then transferred the amount of the distributor discount to off-shore shell companies controlled by the distributor. The distributor then allegedly paid "cash incentives" to publicly employed health care practitioners. The government further alleged that Smith & Nephew then recorded the payments as "marketing services," and that S&N plc incorporated these records into its books, even though no services were actually performed.

The agreements impose a US$16.8 million criminal fine on Smith & Nephew and US$5.4 million in disgorgement of profits and prejudgment interest on S&N plc. The deferred prosecution agreement with the DOJ also requires that Smith & Nephew continue to implement and develop its compliance program and requires Smith & Nephew to retain an independent compliance monitor for 18 months to review its anti-corruption compliance program. In addition, S&N plc agreed to the entry of a court order permanently enjoining further violations of certain sections of the FCPA.

The US government's enforcement actions against Smith & Nephew directly arise out of its broader investigation into alleged corruption in the medical device industry. Although

1 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 recordkeeping and internal accounting controls. These accounting provisions were designed to operate in tandem with the anti-bribery provisions of the FCPA and 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).

## Contacts

Keith M. Korenchuk
+1 202.942.5817

Samuel M. Witten
+1 202.942.6115

Dawn Y. Yamane Hewett
+1 202.942.6278

this case is neither the first nor the largest settlement of FCPA violations involving the healthcare industry, it is yet another cautionary tale as to why every life sciences and medical device company covered by the law must assess the risks of its possible government interactions and maintain and implement robust corporate compliance programs to prevent violations of anti-corruption laws.

## Background

Smith & Nephew is a wholly owned subsidiary of London-based Smith & Nephew plc, a maker of orthopedic, endoscopy, and wound-care products. Because S&N plc trades on the New York Stock Exchange, it is an "issuer" within the meaning of the FCPA, and accordingly, is required to make and keep detailed and accurate books, records, and accounts of its assets and its subsidiaries. S&N plc operates through a number of other subsidiaries, including one in Germany, Smith & Nephew gmbh (S&N gmbh), which was also implicated in the charges. The global annual sales of Smith & Nephew plc and its subsidiaries were nearly US$4.3 billion in 2011.[2]

Like many countries around the world, Greece has a national healthcare system. Most of Greece's hospitals are publicly owned and operated, and the health care providers employed at these public hospitals provide health care services in their official capacities. Therefore, the US government considers these publicly employed health care providers "foreign officials" as defined in the FCPA.[3]

Since the 1970s, Smith & Nephew and S&N gmbh sold their medical devices through a local Greek distributor, which sold the devices to health care providers and hospitals. Under the standard arrangement, the distributor bought the products at a discounted price, and sold the products at full "list" price for a profit. In addition, Smith & Nephew and S&N gmbh covered a certain portion of the Greek distributor's marketing expenses.

2 Smith & Nephew, About Us, At a Glance, *available at*: http://global.smith-nephew.com/master/about_us_at_a_glance_1201.htm.

3 15 U.S.C. § 78dd-2(h)(2)(A).

According to the documents filed by the US government in its enforcement actions, beginning around 1997 or 1998, Smith & Nephew and S&N gmbh allegedly altered the standard arrangement so that the Greek distributor would purchase the products at full list price, and Smith & Nephew and S&N gmbh would pay the amount of the distributor discount to three off-shore companies controlled by the distributor. Smith & Nephew and S&N gmbh would then record these payments in their books as "marketing services," but instead of legitimate marketing services, the Greek distributor would use the money to provide cash incentives to government-employed health care providers to encourage their purchase of Smith & Nephew and S&N gmbh products.

Documents produced to the government revealed that a number of Smith & Nephew executives allegedly were aware of the corrupt payments.[4] Very early in the relationship, the Greek distributor emailed the Greek sales manager at Smith & Nephew in the US to ask for the payment of invoices, because "[w]e have many outstanding payments to surgeons."[5] The payments continued, even though they were detected by an internal audit and an in-house counsel noted that paying surgeons to use Smith & Nephew products was "[n]ot legal or ethic[al]; but universal."[6] A few years later, the Greek distributor wrote to both the Greek sales manager and the Vice President for International Sales in the United States, stating "I absolutely need this fund to promote my sales with surgeons, at a time when competition offers substantially higher rates. [The off-shore shell company]'s only reason for being is the need for cash incentives, a real pain in the neck but unavoidable fact of Greek life."[7] The Greek distributor continues by stating, "[i]n case it is not clear to you, please understand that I am paying cash incentives right after each surgery … ."[8]

4 Deferred Prosecution Agreement Attachment A: Statement of Facts, *United States v. Smith & Nephew, Inc.*, No. 1:12-cr-00030 (D.D.C. Feb. 6, 2012) (DPA).

5 *US Securities & Exchange Comm'n v. Smith & Nephew plc*, Case 1:12-cv-00187, (D.D.C. Feb. 6, 2012), ¶ 16 (*SEC v. S&N plc*).

6 DPA ¶ 16; *SEC v. S&N plc* ¶ 15.

7 DPA ¶ 22; *SEC v. S&N plc* ¶ 19 (emphasis original).

8 *Id.*

Smith & Nephew commenced a thorough investigation and voluntarily disclosed information to the government about potentially corrupt incidents to the government. The agreement announced on February 6, 2012 acknowledges Smith & Nephew's thorough self-investigation of the underlying conduct, its cooperation with the government's investigation, and the remedial efforts and compliance improvements undertaken by the company.[9]

## FCPA Enforcement Trend: Industry-Wide Enforcements

Enforcement of the FCPA is steadily growing, and in the past few years, both the DOJ and SEC have opened investigations into entire industries. The government began with investigations into the customs clearance and permitting practices across the oil and gas services sector, which ensnared global logistics firm Panalpina World Transport[10] and six of its oil and gas services customers, Shell, Transocean, Pride, Tidewater, Noble, and GlobalSantaFe.[11] Together, the seven companies paid US$236.5 million to settle FCPA-related charges with the US government based in part on payments to customs officials in Africa.[12] In 2007, the DOJ and SEC turned their attention to the orthopedic medical device industry and corrupt payments to government-employed health care providers in Greece. A number of medical device makers, including Smith & Nephew, Biomet Inc., Stryker Corp., Zimmer Holdings Inc., Wright Medical, and Medtronic Inc. began internal investigations of potentially corrupt activities and disclosed these investigations to the government. Kara Novaco Brockmeyer, the Chief of the FCPA Unit of the US Department of Justice's Criminal Division, stated that "[t]he SEC will continue to hold companies liable as we investigate the medical device industry for this type of illegal behavior."[13]

The government is expected to maintain its strategy of investigating entire sectors. In 2010, Cheryl Scarboro, then-Chief of the SEC Enforcement Division's FCPA Unit, warned that the SEC "will continue to focus on industry-wide sweeps, and no industry is immune from investigation."[14] DOJ Assistant Attorney General Lanny A. Breuer explained that a major reason the Justice Department is able to take such an industry-wide approach is because "one way in which corporations obtain credit for their cooperation is by providing [the government] with information about their competitors and their clients."[15]

This cooperation has led to significantly decreased fines in several recent enforcement actions. Last year, for example, the DOJ and SEC settled with Johnson & Johnson (J&J) for alleged payments made by its subsidiaries to doctors and hospital administrators in Greece, Poland, and Romania, as well as kickbacks under the United Nations' Oil for Food Program in Iraq.[16] According to both the DOJ and SEC, the US$78 million fines that J&J received were substantially discounted due to its cooperation. The DOJ further explained that J&J's extensive cooperation with the government "has played an important role in identifying improper practices in the life sciences industry."[17] Notably, this comment about Johnson & Johnson's cooperation

9 Department of Justice, Medical Device Company Smith & Nephew Resolves Foreign Corrupt Practices Act Investigation, Feb. 6, 2012, *available at*: http://www.justice.gov/opa/pr/2012/February/12-crm-166.html.

10 Deferred Prosecution Agreement, *United States v. Panalpina World Transp., (Holding) Ltd.*, No. 10-00765 (S.D. Tex. Nov. 4, 2010).

11 Department of Justice, Oil Services Companies and a Freight Forwarding Company Agree to Resolve Foreign Bribery Investigations and to Pay More Than $156 Million in Criminal Penalties, *available at*: http://www.justice.gov/opa/pr/2010/November/10-crm-1251.html; Securities & Exchange Commission, SEC Charges Seven Oil Services and Freight Forwarding Companies for Widespread Bribery of Customs Officials, Nov. 4, 2010, *available at*: http://www.sec.gov/news/press/2010/2010-214.htm.

12 Securities & Exchange Commission, SEC Charges Seven Oil Services and Freight Forwarding Companies for Widespread Bribery of Customs Officials, Nov. 4, 2010, *available at*: http://www.sec.gov/news/press/2010/2010-214.htm.

13 SEC Charges Smith & Nephew PLC with Foreign Bribery, Feb. 6, 2012, *available at*: http://www.sec.gov/news/press/2012/2012-25.htm.

14 SEC Charges Seven Oil Services and Freight Forwarding Companies for Widespread Bribery of Customs Officials, Nov. 4, 2010, *available at*: http://www.sec.gov/news/press/2010/2010-214.htm.

15 Assistant Attorney General Lanny A. Breuer Speaks at the 24th National Conference on the Foreign Corrupt Practices Act, National Harbor, Md., Nov. 16, 2010, *available at*: http://www.justice.gov/criminal/pr/speeches/2010/crm-speech-101116.html.

16 Keith M. Korenchuk, Kirk Ogrosky, Samuel M. Witten, and Benjamin H. Wallfisch, Arnold & Porter LLP, "Advisory: J&J Agrees to Pay US$78 Million to Settle Allegations of Payments Made to European Healthcare Providers," (April 2011), *available at*: http://www.arnoldporter.com/public_document.cfm?id=17469&key=8J1.

17 Department of Justice, Johnson & Johnson Agrees to Pay $21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations, April 8, 2011, *available at*: http://www.justice.gov/opa/pr/2011/April/11-crm-446.html.

may mean more enforcement actions in the industry are on their way.

## Special Anti-Corruption Considerations in the Medical Device Industry

The enforcement actions against Smith & Nephew and S&N plc illustrate the compliance risks for all life sciences and medical device manufacturers that sell their products abroad. In countries with nationalized health care systems, governments run the vast majority of hospitals. The health care providers in those public hospitals are thus government employees, and the US government has clearly taken the position that these health care providers are government officials under the FCPA.[18] This localization of government procurement poses particular risks for life sciences companies and medical device manufacturers who sell their products, either directly or indirectly, to health care providers. In a competitive marketplace, all companies want to market their name brand to persuade more customers to purchase their products. When those customers are government officials, simple purchases are considered government procurement decisions that fall under the ambit of the FCPA. Thus, a company that sells its products in countries with national health care systems may have interactions with thousands of different publicly employed health practitioners, and each interaction carries a risk of corruption. The Smith & Nephew case arose in Greece, with its many government doctors with procurement authority, but could arise in any system with a similar structure. The concerns might be even higher in large and growing markets such as China, Brazil, India, and Russia, as well as other developing countries where corruption risk may be endemic. The UK Bribery Act, which also prohibits commercial bribery in addition to bribery to government officials, expands a company's potential liability because procurement decisions, even by private health care practitioners, could present corruption concerns that could expose covered companies to UK prosecution as well.[19]

The Smith & Nephew case also demonstrates that companies are liable not only for their own direct actions, but also for the actions of their third parties.[20] Because many life sciences and medical device manufacturers sell their products through local distributors who have significant interactions with procurement decision-makers, it is particularly important to maintain appropriate control over distributors and ensure that they comply with all applicable anti-corruption laws, including the FCPA, the UK Bribery Act, as well as national and local anti-corruption laws.

While the risks associated with distributors have been documented, there has been much less attention paid to the risks presented by other types of third parties such as research organizations conducting clinical trials; customs, shipping, and freight forwarders; marketing and other consultants; and event coordinators, to name just a few examples. Simply turning a blind eye to the corruption risks posed by one's third parties does not absolve oneself of liability. Even if a company does not have actual knowledge of corrupt payments, the knowledge requirement of the FCPA can be satisfied by "willful blindness," or "consciously disregarding a high probability" of violations of the FCPA.[21] Thus, companies would be wise to implement a robust anti-corruption compliance program, with clear policies and procedures, training, monitoring, and internal controls.

18 15 U.S.C. §§ 78dd-1(f)(1)(A) ("The term "foreign official" means any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.").

19 2010 UK Bribery Act, *available at*: http://www.legislation.gov.uk/ukpga/2010/23/pdfs/ukpga_20100023_en.pdf. For a detailed analysis of the law, 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; and Arnold & Porter LLP, "Advisory: UK Bribery Act 2010: An In-Depth Analysis," (May 2010) *available at*: http://www.arnoldporter.com/public_document.cfm?id=15833&key=23D1.

20 Keith M. Korenchuk, Samuel M. Witten, and Dawn Y. Yamane Hewett, Anti-Corruption Compliance: Avoiding Liability for the Actions of Third Parties, Financial Fraud Law Report, July/August 2011, *available at*: http://www.arnoldporter.com/resources/documents/Arnold&PorterLLP_FinancialFraudLawReport_July-August2011.pdf.

21 1998 Amendments to the FCPA, House Conference Report No. 100-576, *available at*: http://www.justice.gov/criminal/fraud/fcpa/history/1988/tradeact-100-418.pdf.

## Conclusion

The recent enforcement action against Smith & Nephew sends yet another clear message to medical device and life sciences companies to review and consider their government interactions and corruption risks that may be present in their business practices. As discussed above, life sciences and medical device manufacturers confront enhanced corruption risks when operating in countries with government hospitals and publicly employed health care practitioners. Furthermore, any interaction with a government official could present corruption risks, and government interactions may exist in seemingly innocent transactions, such as donations to charitable organizations[22] and engagement of third parties, as well as more obvious interactions, such as direct hosting of, and gifts to, government officials. Life sciences and medical device manufacturers should routinely assess the special corruption risks inherent in their industry and develop and implement robust compliance programs to mitigate those risks.[23]

22 Keith M. Korenchuk, Samuel M. Witten, and Dawn Y. Yamane Hewett, Arnold & Porter LLP, "Advisory: Anti-Corruption Compliance: Special Considerations for Charitable Contributions by Company Giving Programs and Foundations," (June 2011) *available at*: http://www.arnoldporter.com/public_document.cfm?id=17625&key=16F1; *see also* Keith M. Korenchuk, James P. Joseph, Samuel M. Witten, and Andras Kosaras, Guarding Against Anti-Corruption Problems in Overseas Philanthropic Activities, Taxation of Exempts, Nov./Dec. 2011, *available at*: http://www.arnoldporter.com/resources/documents/Arnold&PorterLLP_TaxationOfExempts_November-December2011.pdf.

23 Keith M. Korenchuk, Samuel M. Witten, and Dawn Y. Yamane Hewett, Arnold & Porter LLP, "Advisory: Building an Effective Anti-Corruption Compliance 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.

*If you have any questions about any of the topics discussed in this Advisory, please contact your Arnold & Porter attorney or any of the following attorneys:*

**Keith M. Korenchuk**
+1 202.942.5817
Keith.Korenchuk@aporter.com

**Samuel M. Witten**
+1 202.942.6115
Samuel.Witten@aporter.com

**Dawn Y. Yamane Hewett**
+1 202.942.6278
Dawn.Yamane.Hewett@aporter.com

### *Global Anti-Corruption Team*

**Marcus A. Asner**
+1 212.715.1789
Marcus.Asner@aporter.com

**John P. Barker**
+1 202.942.5328
John.Barker@aporter.com

**James W. Cooper**
+1 202.942.6603
James.W.Cooper@aporter.com

**John A. Freedman**
+1 202.942.5316
John.Freedman@aporter.com

**Drew A. Harker**
+1 202.942.5022
Drew.Harker@aporter.com

**Kathleen J. Harris**
+44(0)20 7786 6100
Kathleen.Harris@aporter.com

**Richard L. Jacobson**
+1 202.942.6975
Richard.Jacobson@aporter.com

**Keith M. Korenchuk**
+1 202.942.5817
Keith.Korenchuk@aporter.com

**Arthur Luk**
+1 202.942.5393
Arthur.Luk@aporter.com

**John N. Nassikas III**
+1 202.942.6820
John.Nassikas@aporter.com

**Kirk Ogrosky**
+1 202.942.5330
Kirk.Ogrosky@aporter.com

**Philippe A. Oudinot**
+1 202.942.5736
Philippe.Oudinot@aporter.com

**Christopher S. Rhee**
+1 202.942.5524
Christopher.Rhee@aporter.com

**Mara V.J. Senn**
+1 202.942.6448
Mara.Senn@aporter.com

**Claudius O. Sokenu**
+1 212.715.1787
Claudius.Sokenu@aporter.com

**Craig A. Stewart**
+1 212.715.1142
Craig.Stewart@aporter.com

**Michael D. Trager**
+1 202.942.6976
Michael.Trager@aporter.com

**Baruch Weiss**
+1 202.942.6819
Baruch.Weiss@aporter.com

**Charles R. Wenner**
+1 202.942.6974
Charles.Wenner@aporter.com