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## Ratting Out The Competition: New DOJ Strategies

Law360, New York (March 28, 2012, 1:13 PM ET) -- In a speech given Nov. 12, 2009, in front of an audience of large pharmaceutical and device company attorneys, compliance officers and executives, Lanny Breuer, assistant attorney general in the U.S. Department of Justice Criminal Division's Fraud Section stated that the application of the Foreign Corrupt Practices Act to the pharmaceutical industry would be "one area of criminal enforcement that will be a focus for the Fraud Section in the months and years ahead."<sup>[1]</sup>

Sure enough, within several months, more than five pharmaceutical and device companies reported in their 10-K filings that they had received "letters of inquiry" from the DOJ as well as from its civil partner in FCPA enforcement, the U.S. Securities and Exchange Commission. Unbeknownst to those pharmaceutical and device companies at the time, the letters were a product of a unique agreement that the Fraud Section had extracted from a major player in the pharmaceutical industry to help root out foreign corruption in the industry in exchange for a lighter criminal penalty.

Enforcement of the FCPA has grown exponentially in the last five years.<sup>[2]</sup> In the years between 2005 and 2010, the DOJ brought more cases than it had done in the 30 years since the FCPA's enactment.<sup>[3]</sup> Thus far, the DOJ has made good on its promise to "pursue guilty pleas or, if necessary, indictments against corporations — when the criminal conduct is egregious, pervasive and systemic, or when the corporation fails to implement compliance reforms, changes to its corporate culture, and undertake other measures designed to prevent a recurrence of the criminal conduct."<sup>[4]</sup>

Obviously, rigorous enforcement combined with limited resources requires prosecutors and regulators to be innovative and efficient in their investigative methodologies. As evidenced by the "letters of inquiry" referenced above, the Fraud Section has begun to utilize several innovative investigative techniques to proactively induce compliance and voluntary disclosures of FCPA violations from the health care industry.<sup>[5]</sup>

As an alternative to using its traditional investigatory and prosecutorial techniques to root out international corruption by individuals and corporations on a case-by-case basis, the Fraud Section is testing whether requiring cooperating companies to reveal potentially corrupt industry-specific practices is more efficient to root out international bribery schemes.

In the pharmaceutical industry, that example is embodied in the Johnson & Johnson deferred prosecution agreement (J&J DPA).<sup>[6]</sup> With resolutions like the J&J DPA, both the criminal and civil enforcement agencies are laying the foundation for a rapid succession of investigations, prosecutions, monetary settlements and convictions — all initiated by the health care industry players themselves.

After examining key components of the J&J DPA, we focus on how the cooperation requirements in that document intersect with the proactive investigatory techniques that the government is using to draw out allegations of fraudulent activity in particular

industries.

These letters of inquiry, as well as the efficiencies created through cooperative relationships with international enforcement partners, demonstrate the DOJ's commitment to finding efficient and effective means to investigate potentially corrupt practices by the health care industry overseas. Upon discussing the implications of these techniques briefly, we will elaborate upon some best practices for preventing and detecting FCPA violations.

## **Johnson & Johnson's Deferred Prosecution Agreement**

### *Background*

Announced in April 2011, the three-year DPA and \$21.4 million criminal penalty between the DOJ and J&J came out of the company's voluntary self-disclosure and extensive self-investigation of FCPA violations committed by its subsidiaries, employees and agents.[7]

The criminal disposition addressed "improper payments by J&J subsidiaries to government officials in Greece, Poland and Romania in violation of the Foreign Corrupt Practices Act (FCPA) and kickbacks paid to the former government of Iraq under the United Nations Oil for Food Program." [8] J&J, as a manufacturer and seller of medical devices, drugs and consumer health care products, was a prime target for the FBI and the DOJ, given the company's size and the agencies' explicitly stated interest in ferreting out corruption in the pharmaceutical industry.

### *Factors That Helped J&J Avoid Increased Liability*

The J&J DPA enumerates the key considerations taken into account by the DOJ in arriving at the ultimate criminal penalty and compliance requirements for J&J. Specifically, the DOJ viewed the following factors as mitigating J&J's culpability for the FCPA violations:

- its voluntary and timely self-disclosure of the conduct to law enforcement;
- its engagement in thorough self-investigation and reporting throughout the course of the investigation subsequent to the self-disclosure;
- its undertaking of remedial measures and compliance improvements to address the conduct; and
- its cooperation with law enforcement, the SEC and "multiple foreign enforcement authorities, including significant assistance in the industry-wide investigation." [9]

### *The J&J DPA Industry-Wide Cooperation Provisions*

The broad, "industry-wide" cooperation provisions differentiate the J&J DPA from most others. Moreover, the fact that J&J was given "additional credit" for such cooperation provides an unusual incentive for health care companies and business in other unique sectors to assist the government in broad industry-specific investigations.

Obviously, the DOJ's insistence that J&J "continue to cooperate in investigations of other companies and individuals in connection with industry-specific business practices overseas in various markets" is a powerful tool that should alarm the pharmaceutical industry as a whole.[10] Other companies in the same sector as J&J, and especially competitors, should understand that any dirty laundry is likely to be exposed and the best way to address these issues is to take affirmative steps to isolate and correct any potential problems, ensure that the company's compliance systems adequately prevent recurrence and take whatever disclosure steps are appropriate.

## **DOJ'S Use of Proactive Investigative Techniques**

*"Letters of Inquiry"*

FCPA investigations and resolutions traditionally consume large chunks of agency and prosecutorial resources. Historically, the FCPA Unit of the Fraud Section has not been characterized as "proactive" in their conduct of FCPA investigations as most cases evolved through the self-reporting process.

More recently, however, the Fraud Section has developed innovative proactive investigative techniques to keep particular industries and industry executives on their toes. Ultimately, these methodologies will seek to ensure that target international corporations, desiring to resolve criminal and regulatory investigations short of trial, prevent a repeat of such conduct in the future within their own company and also ferret out known industry-specific malfeasors.

One such proactive technique is the use of "letters of inquiry." These letters are the most informal correspondence the DOJ may issue — compared to subpoenas or summonses. But, like these more formal documents, the letters request information about areas of interest for the DOJ's investigative activities.

The use of these "letters of inquiry" allow investigation of large swaths of industry-specific conduct that the government has reason to believe is potentially illegal with the investment of minimal investigatory resources. Of course, this approach, prior to any self-reported conduct or any substantial investigation, permits the DOJ to efficiently target a much grander scale of potential industry-specific misconduct.[11]

This practice seems to have been particularly useful in the health care sector. According to 10-K filings submitted to the SEC, several targets have received these agency requests in the past year — among them Merck & Co. Inc., AstraZeneca PLC, Eli Lilly and Co., Baxter International Inc., SciClone Pharmaceuticals Inc., and Bristol-Myers Squibb Co. ("BMS"). All of these companies received inquiries from the DOJ and the SEC in connection with an industry-wide bribery investigation into practices thought to be common in the pharmaceutical industry.[12]

According to a Financial Times article, as of January 2012, a Pfizer Inc.-DOJ FCPA settlement is close at hand, and probes are ongoing against GlaxoSmithKline, Merck, Baxter, BMS, Eli Lilly, and AstraZeneca.[13] Smith & Nephew, a medical device company mentioned in the same Financial Times article as a DOJ target, entered into a DPA with the DOJ as of Feb. 3, 2012 and will pay a criminal penalty of \$16.8 million to the DOJ and \$5.4 million in disgorgement of profits to the SEC.[14]

*Cooperation with International Authorities and Conventions*

It is important to note that the J&J DPA was complemented by a U.K. Proceeds of Crime Act of 2002 settlement, and that the DOJ acknowledged the "significant assistance" provided by the law enforcement authorities of Greece, Poland and the U.K.[15] By developing better cooperative relationships and dividing up investigatory responsibilities with partner economic fraud becoming more "friendly" with the fraud or economic crime enforcement agencies of foreign countries, the U.S. prosecutors will be able to more efficiently allocate investigatory resources.[16]

Moreover, from an industry perspective, although global resolutions result in larger payouts from the health care industry defendants, global resolutions ultimately provide more closure and assurance against future prosecutions by other countries.

Finally, the DOJ is demonstrating its long-arm approach by continually seeking[17] to implement and enforce the Council of the Organization for Economic Co-operation and Development Convention on Combating Bribery of Foreign Public Officials in International

Business Transactions.[18]

For instance, President George W. Bush signed Executive Order 13259 in March 2002, which designates the European Union's organizations and Europol as "public international organizations" and makes bribery of officials from these organizations a violation of the FCPA.[19] These actions should further cause international companies to evaluate their FCPA risk profile and consider the consequences a multinational investigation of their business operations.

## **Lessons for Nontargeted Health Care Companies**

The health care sector is closely observing the government's activities and the industry's actions provide valuable lessons on how to best manage FCPA risk, even if the government has not initiated direct contact with a company yet. Clearly, companies that have not yet been targeted or contacted by the DOJ are paying attention to the enforcement climate.

The press release associated with the announcement of the J&J DPA and criminal penalty stated that J&J "cooperated extensively with the government and, as a result, has played an important role in identifying improper practices in the life sciences industry." [20] This statement is a sotto voce warning that the government is aware of the common practices in the industry, and that it has developed the experience to quickly identify improper conduct and be less forgiving in criminal resolutions of corporations that feign ignorance or rely on the widespread nature of the conduct within a particular industry.

As such, the J&J DPA serves as an invaluable guide for companies concerned about potential FCPA violations — its provisions provide a practical guide for corporate executives, counsel and compliance officers on how to structure internal monitoring and investigative structures to detect and prevent FCPA violations.

At minimum, every company should have an authentic, comprehensive, risk-based FCPA compliance policy that is accepted and adhered to from the bottom to the top of the corporate hierarchy. One can only speculate how large and severe the J&J penalties would have been had it not self-disclosed.

Finally, companies that implement rigorous FCPA compliance practices may be able to avoid illegal conduct altogether if they take advantage of the DOJ's FCPA Opinion Procedures.[21] By testing the DOJ's view of a particular business practice before its implementation, a company will be able to better manage its risk, and garner even more credit for its active compliance should a rogue violation should arise.

## **Conclusions**

The health care sector had ample warning that the DOJ's deluge of FCPA investigations and resolutions was coming. What they may not have known was that the government would be requiring suspect competitors to act as "Junior G-men" to help police the industry. But, even though the new era of FCPA enforcement is here, companies can and should now redouble their efforts to take advantage of the not-so-subtle cues given by the DOJ to guide their own internal compliance practices and manage their FCPA risk.

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[1] Lanny A. Breuer, Prepared Keynote Address to The Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, (Nov. 12, 2009), available at: <http://www.justice.gov/criminal/pr/speeches-testimony/documents/11-12-09breuer-pharmaspeech.pdf>

[2] Asst. Attorney Gen. Lanny A. Breuer of the Criminal Div. Speaks at the Annual Meeting of the Washington Metro. Area Corp. Counsel Ass'n (Jan. 26, 2011), available at: <http://www.justice.gov/criminal/pr/speeches/2011/crmspeech-110126.html>Lanny. As of January 2011, the Fraud Section had promoted a "new head of the Section's FCPA Unit and two assistant chiefs, and ... increased the number of line prosecutors in the Unit, attracting high caliber attorneys with extensive experience — including Assistant U.S. Attorneys with significant trial and prosecutorial experience and attorneys from private practice with defense-side knowledge and experience." See also, Lanny A. Breuer, Assistant Attorney General Lanny A. Breuer Speaks at the 24th National Conference on the Foreign Corrupt Practices Act, (Nov. 16, 2010), available at: <http://www.justice.gov/criminal/pr/speeches/2010/crmspeech-101116.html>. (hereafter, "Breuer November 2010 Speech") (mentions the collaboration between the FCPA Unit and the Asset Forfeiture and Money Laundering Section).

[3] In remarks delivered at an FCPA/Corruption Update in Washington, D.C. on Oct. 4, 2011, Charles Duross, deputy chief of the Fraud Section's FCPA Unit stated that the Fraud Section had more than a dozen dedicated FCPA prosecutors (up from two in 2003), a dedicated FCPA squad at the FBI's Washington Field Office, and numerous Assistant U.S. Attorneys in the field who now had experience in FCPA investigations and prosecutions.

[4] Lanny A. Breuer, Prepared Address to The 22nd National Forum on the Foreign Corrupt Practices Act, (Nov. 17, 2009), available at: <http://www.justice.gov/criminal/pr/speeches-testimony/documents/11-17-09aagbreuer-remarks-fcpa.pdf>.

[5] One example of innovative investigative efforts includes the "Shot Show" sting investigation, where federal agents raided a Las Vegas trade show on Jan. 19, 2010, arresting 21 individuals in the military products industry for alleged violations of the FCPA. FBI agents posed as representatives of an African country and allegedly solicited promises of bribes in exchange for government contracts. The DOJ stated this was "the first large-scale use of undercover law enforcement techniques to uncover FCPA violations and the largest action ever undertaken by the Justice Department against individuals for FCPA violations." Press Release, U.S. Dep't of Justice, Twenty-Two Executives and Employees of Military and Law Enforcement Products Companies Charged in Foreign Bribery Scheme, (Jan. 19, 2010), available at: <http://www.justice.gov/opa/pr/2010/January/10-crm-048.html>. This article will focus, however, on the "letters of inquiry" proactive investigative methodology.

[6] Johnson & Johnson Deferred Prosecution Agreement, (Jan.14, 2011), available at: [http://lib.law.virginia.edu/Garrett/prosecution\\_agreements/pdf/johnson.pdf](http://lib.law.virginia.edu/Garrett/prosecution_agreements/pdf/johnson.pdf) (last accessed Jan. 25, 2012).

[7] On the same day, J&J reached a settlement with the SEC whereby it agreed to pay \$48.6 million in disgorgement of profits, including prejudgment interest, and DePuy International Limited, a J&J subsidiary, became subject to a Civil Recovery Order of £4.826 million, plus prosecution costs, from the U.K. Serious Fraud Office ("SFO"). Press Release, U.S. Securities and Exchange Commission, Litigation Release No. 21922/Accounting and Auditing Enforcement Release No. 3261, (Apr. 8, 2011), available at: <http://www.sec.gov/litigation/litreleases/2011/lr21922.htm>; Press Release, U.K. Serious Fraud Office, DePuy International Limited ordered to pay 4.829 million pounds in Civil

Recovery Order, (Apr. 8, 2011), available at: <http://www.sfo.gov.uk/press-room/latest-press-releases/press-releases-2011/deputy-international-limited-ordered-to-pay-4829-million-pounds-in-civil-recovery-order.aspx>.

[8] Press Release, U.S. Dep't of Justice, Johnson & Johnson Agrees to Pay \$21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations, (Apr. 8, 2011), available at: <http://www.justice.gov/opa/pr/2011/April/11-crm-446.html>. (hereafter, "DOJ J&J DPA Press Release").

[9] DOJ J&J DPA Press Release. The specific language of the J&J DPA reads as follows: "J&J has cooperated and agreed to continue to cooperate with the Department in the Department's investigation of other companies and individuals." In addition, Smith & Nephew's recent entry into a DPA with DOJ includes similar continued cooperation language:

e. Smith & Nephew agreed to continue to cooperate with the Department in any investigation of the conduct of Smith & Nephew and its directors, officers, employees, agents, consultants, subsidiaries, contractors, and subcontractors relating to violations of the FCPA;

f. Smith & Nephew has cooperated and agreed to continue to cooperate with the SEC and, at the direction of the Department, foreign authorities investigating the conduct of Smith & Nephew and its directors, officers, employees, agents, consultants, subsidiaries, contractors, and subcontractors relating to corrupt payments;

g. Smith & Nephew has cooperated and agreed to continue to cooperate with the Department in the Department's investigations of other companies and individuals in connection with business practices overseas in various markets.

Smith & Nephew Deferred Prosecution Agreement, (Feb. 3, 2012), available at: [http://op.bna.com/hl.nsf/id/bbrk-8r8lyv/\\$File/SmNephdocFeb2012first.pdf](http://op.bna.com/hl.nsf/id/bbrk-8r8lyv/$File/SmNephdocFeb2012first.pdf) (last accessed Feb. 10, 2012) (hereafter, "S&N DPA").

[10] In a statement quoted in a U.K. publication, "[GlaxoSmithKline confirm[ed] that investigations by the US Department of Justice and the Securities and Exchange Commission regarding the sales and marketing of pharmaceutical products outside of the USA have commenced." Alistair Dawber, "UK drug firms put under microscope over 'bribery,'" *The Independent*, (Aug. 14, 2010), available at: <http://www.independent.co.uk/news/business/news/uk-drug-firms-put-under-microscope-over-bribery-2052364.html>.

[11] See Breuer November 2010 Speech, where the Assistant Attorney General described the Panalpina investigation as a significant example of how DOJ is "increasingly able to take an industry-wide approach to our FCPA investigations ... because one way in which corporations obtain credit for their cooperation is by providing [DOJ] with information about their competitors and clients.>").

[12] Stephanie Kirchegeassner, "US probes corruption in big pharma," *Financial Times*, (Aug. 12, 2010), available at <http://www.ft.com/intl/cms/s/0/9a8e8f90-a63e-11df-8767-00144feabdc0.html>.

[13] Andrew Jack, "Pharma groups brace for costly settlements," *Financial Times* (Jan. 22, 2012) available at: <http://www.ft.com/intl/cms/s/0/25a5716c-428c-11e1-97b1-00144feab49a.html>.

[14] See, S&N DPA, *supra* n. 10; Press Release, U.S. Dep't 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>.

[15] DOJ J&J DPA Press Release.

[16] See Breuer November 2010 Speech, where he states that "[p]artnerships like the one [DOJ has] with the [U.K.] Serious Fraud Office are critical to our transnational approach to combating foreign bribery, and we intend increasingly to rely on our foreign partners in future cases."

[17] See, U.S. Dep't of Justice, "Steps taken to implement and enforce the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions," (May 2010), available at: <http://www.justice.gov/criminal/fraud/fcpa/docs/05-28-10oecd-convention.pdf>. See also Breuer November 2010 Speech. ("[T]his year has seen a substantial increase in our cooperation with our foreign counterparts. Our participation in the OECD review process, for example, has helped [DOJ] to foster closer relationships with other members of the Working Group on Bribery. And these partnerships have yielded results.").

[18] Council of the Organization for Economic Co-operation and Development (OECD), "Convention on Combating Bribery of Foreign Public Officials in International Business Transactions," available at: <http://www.oecd.org/dataoecd/4/18/38028044.pdf>.

[19] Designation of Public International Organizations for Purposes of the Securities Exchange Act of 1934 and the Foreign Corrupt Practices Act of 1977," 67 Fed. Reg. 13239, (Mar. 19, 2002), available at: [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002\\_register&docid=fr21mr02-103.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=fr21mr02-103.pdf).

[20] DOJ J&J DPA Press Release.

[21] U.S. Dep't of Justice, Opinion Procedure Regulations, available at: <http://www.justice.gov/criminal/fraud/fcpa/docs/frgncrpt.pdf>; DOJ Opinion Procedure Releases: <http://www.justice.gov/criminal/fraud/fcpa/opinion/>.

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