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China Bribery Scandal Could Provide Fodder For U.S. Foreign Corrupt Practices Act Investigations

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Executive Summary

Companies under scrutiny in China for allegedly bribing doctors could face new enforcement actions in the U.S. Lilly's ability to avoid another FCPA investigation may depend on whether the SEC was aware of whistleblower allegations made in the Chinese press.

The Chinese government's bribery charges against [GlaxoSmithKline PLC](#) have led anonymous whistleblowers to make similar allegations against other pharmaceutical companies. The entire industry is now on edge awaiting future actions in China. But companies could also feel the fallout in the U.S.

The U.S. Securities and Exchange Commission (SEC) and the U.S. Department of Justice began an industry-wide probe of the pharmaceutical industry in 2009 for violations of the Foreign Corrupt Practices Act (FCPA), which makes it illegal for individuals to provide payments to foreign government officials to try to obtain or retain business. The recent activity in China could help bolster ongoing FCPA investigations or lead to new queries.

Bethany Hengsbach, a partner at Sheppard Mullin Richter & Hampton, said the Chinese investigations could provide the U.S. government with information it may or may not already have.

"That local authorities in China are launching their own investigations or enforcement actions is sort of the shoe dropping," Hengsbach said. "We have

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been counseling [clients] for a long time that the FCPA law is not the only anti-corruption law they need to be aware of.”

Lilly May Face New Questions From SEC

One company that may be affected by China’s actions is [Eli Lilly & Co.](#) The drug maker eliminated an FCPA headache eight months ago when it settled an SEC complaint alleging it made improper payments to government officials in China, Brazil, Russia and Poland. However, recent allegations made in the Chinese press by an anonymous former employee could embroil the company in another SEC inquiry.

Lawyers say the U.S. government may open another investigation if the conduct cited by the whistleblower was not previously disclosed to the SEC. One attorney who represents companies in FCPA investigations said Lilly may want to take proactive steps and let the SEC know it is willing to answer questions about what is going on in China.

The allegations against Lilly were reported in the Aug. 22 issue of the 21st Century Business Herald. A former employee said Lilly paid at least RMB 30 million (\$4.9 million) in illegal kickbacks to doctors from 2011 to 2012 to get them to prescribe several diabetes products, including *Humalog* (insulin lispro), *Humulin* (human insulin), the insulin pen *HumaPen* and *Byetta* (exenatide). The paper reported that Lilly sales representatives asked physicians in Shanghai and Anhui province to fill out a form when they prescribed diabetes products to new patients and gave doctors RMB 100-3,000 (\$16-\$490) per form (["Chinese Media Alleges Lilly Spent RMB 30 Million In Kickbacks For Two Insulin Products" — PharmAsia News, Aug. 28, 2013 3:11 AM GMT](#)).

It is unclear whether these allegations were discussed with SEC at the time of its investigation. A company spokesperson said Lilly was “made aware of very similar allegations in 2012” by a former sales manager from the region who was mentioned in the 21st Century Business Herald article.

“At the time of the allegations, we did an exhaustive investigation to search for any evidence of kickbacks. The investigation was very thorough and included employee interviews, e-mail monitoring, and expense report audits,” the spokesperson stated in an email. “Although we have not been able to verify these allegations, we take them seriously, and we are continuing our investigation.”

Sanofi, Novartis Also Targeted By Whistleblowers

Lilly is the latest company to face allegations of bribery in China but GSK is the only one to be accused by the government. Chinese authorities made a news splash on July 15 when officials from the Ministry of Public Security’s economic crimes investigation unit held a press conference in Beijing accusing GSK executives of using travel agencies as a conduit to transfer RMB 3 billion (\$490 million) to government officials and doctors to induce them to prescribe GSK drugs. The payments allegedly began in 2007. The government also arrested several GSK executives (["GSK Vows To Cooperate With China On Bribery Allegations; Pledges Review Of All Transactions Related To Travel Agency Use" — PharmAsia News, Jul. 15, 2013 12:14 PM GMT](#)).

Since the announcement about GSK, anonymous whistleblowers have made

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bribery allegations in the press about other companies. The 21st Century Business Herald provided an account of a former [Novartis AG](#) saleswoman who claimed her supervisor instructed her to give money to doctors in exchange for prescriptions of the cancer therapy *Sandostatin LAR Depot* (octreotide acetate) ("[Novartis Starts Investigation On China Bribery Allegations; SAIC Initiates Crackdown On Illegal Competition](#)" — *PharmAsia News*, Aug. 15, 2013 9:07 AM GMT).

The paper also reported the account of another whistleblower who alleged [Sanofi's](#) employees in China doled out more than \$277,000 in bribes in 2007 to about 500 doctors to encourage them to prescribe the blood pressure drugs *Avapro* (irbesartan) and *Avalide* (irbesartan/hydrochlorothiazide) ("[A Closer Look: China's Pharmaceutical Bribery Scandal Continues To Spread](#)" — *PharmAsia News*, Aug. 9, 2013 5:15 PM GMT).

By comparison, SEC's complaint against Lilly alleged that between 2006 and 2009, employees at the company's subsidiary in China falsified expense reports in order to provide spa treatments, jewelry, and other improper gifts and cash payments to government-employed physicians to encourage them to prescribe Lilly products ("[Quick Take: Lilly's FCPA Settlement Points To Importance Of Internal Controls](#)" — *PharmAsia News*, Dec. 21, 2012 6:15 PM GMT).

Lilly agreed to pay \$29.4 million and without admitting or denying the allegations, consented to a final judgment permanently enjoining the company from violating the FCPA, including provisions about anti-bribery, books and records and internal controls. The company also agreed to retain an independent consultant to review and make recommendations about its foreign corrupt practices and procedures.

FCPA Differs From China's Bribery Laws

While China's scrutiny of pharma companies for violation of the country's bribery laws could spur the U.S. government to open new FCPA queries, the laws of the two countries differ in what they deem to be illegal.

Henry Chen, a partner at McDermott Will & Emery, noted in a post on The FCPA Blog that while the FCPA prohibits payments to foreign officials (e.g., a doctor of a state-owned hospital), it does not prohibit payments to foreign governments (e.g., a state-owned hospital). However, he noted that in China some payments made directly to state-owned hospitals could constitute the crime of giving bribes to a unit.

Chen cited a case in which a drug maker ran afoul of China's law by paying rebates to three local hospitals when they purchased the company's drugs. The rebates were made from 1999 to 2002. "The pharmaceutical company, apparently unaware of the criminal law, did not pay the rebates stealthily by cash under the table," he stated. "Instead it wired the rebates, which totaled about \$330,000." The drug maker was convicted of committing the crime of giving bribes to a unit and punished with a fine while an executive was jailed for two years.

Fierce Competition in China's Diabetes Market

The Chinese market is particularly difficult for pharma companies since most hospitals are run by the government and doctors are deemed to be government employees. Hospitals, which lack sufficient government

funding, and doctors, who receive lower pay than their Western counterparts, have turned to prescription drug sales as a major source of income. Hospital pharmacies have traditionally charged a 15% markup, which encourages overprescribing of more expensive drugs, and distributors and pharmaceutical companies often pay kickbacks to doctors ("[Putting GSK's China Bribery Crisis In Context](#)" — *PharmAsia News*, Jul. 18, 2013 6:24 PM GMT).

Hengsbach said U.S. companies operating in China, and the pharmaceutical industry in particular, have been aware of this scenario and the significant FCPA risk that doing business in China presents. "The fact [that] Chinese authorities launched their own inquiries is unfortunate and very scary for the companies involved but I think it's not entirely surprising," she said. "What is perhaps shocking are the certain tactics, individuals allegedly being detained."

China is an important market for the pharmaceutical industry given the size of the population and the growth in drug expenditure. The diabetes space is particularly competitive and in the insulin market Lilly has been in a turf war with market leader [Novo Nordisk AS](#) and Sanofi. In a recent analysis of the diabetes market in China, Citi Research estimated that the market size for injectable insulin is roughly RMB 7.7 billion (\$1.2 billion). It noted that Novo, which markets *NovoLog* (insulin aspart) and *Novolin* (human insulin), has 63.5% of the market, while Sanofi, which sells *Lantus* (insulin glargine), has 15.3%, and Lilly, which markets Humalog and Humulin, has 13.7% ("[IMS Health's Yan Shangjun On China's Changing Diabetes Market: An Interview With PharmAsia News](#)" — *PharmAsia News*, Jun. 7, 2013 6:53 PM GMT).

Despite the allegations cited in the Chinese press, it is uncertain whether any companies besides GSK are under investigation by the Chinese government. Novo Nordisk CEO Lars Rebien Sorensen said in the company's quarterly call in August that local authorities in Tianjin had contacted Novo on Aug. 1 but did not say that it was part of a formal investigation. Sanofi disclosed that the State Administration for Industry and Commerce (SAIC) visited it in the northeastern city of Shenyang but said the purpose of the visit was unknown. Lilly also reported that it was visited by the SAIC as part of a routine inspection that had nothing to do with China's crackdown on the industry's commercial practices ("[China Says Anti-Bribery Investigations Do Not Target Multinational Companies](#)" — *PharmAsia News*, Aug. 14, 2013 11:12 AM GMT).

The full impact of the government's charges against GSK is thus uncertain and whether the aftershocks extend to the U.S. remains to be seen.

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