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FOCUS ON GLOBAL HEALTH CARE COMPLIANCE

August 2, 2018

Implications of Distributor Misconduct for Global Health Care and Life Sciences Companies

Health care and life sciences companies with operations in the United States and abroad face increased liability arising from their common reliance on third-party distributors in international markets. Third-party distributors are often responsible for the direct marketing and selling of a company's products outside of the U.S. and provide value to multinational companies based upon their presence in local markets, including experience with local regulatory authorities, relationships with local businesses, and established on-the-ground infrastructures and resources. The U.S. Foreign Corrupt Practices Act ("FCPA") and other nations' anti-corruption laws specifically hold companies accountable for the actions of third parties, which may give rise to unanticipated material liabilities if companies do not adequately oversee third-party agents. Although all companies operating abroad should generally be aware of potential liability under the FCPA, health care and life sciences companies may be at even greater risk given the nature of their products, which often need regulatory approval, are paid for by government payors, and may involve risk to patient health and safety.

Much like the domestic approach to addressing corruption in ex-U.S. operations through the FCPA, many nations have developed anti-corruption regimes that hold multinational companies accountable for third-party activity. For instance, the U.K. Bribery Act (2010) prohibits the promise or giving of financial or other advantage to induce or reward the improper performance of a relevant function or activity through a third party.[1] Similarly, Brazil's Clean Company Act (2013) prohibits the direct or indirect offer of an undue advantage to a public official or a third person related to the official.[2] The Clean Company Act also generally prohibits a company's use of an intermediary to conceal the company's true interests or the identity of the beneficiaries of actions performed to the detriment of domestic or foreign public assets.[3] Although China's Anti-Unfair Competition Law traditionally did not address third-party liability expressly, a 2017 amendment to the law prohibits a business entity from providing or promising economic benefits to induce a third party to seek trading opportunities or competitive advantages on behalf of the business entity.[4] These legal and enforcement changes showcase third-party misconduct as an area of increasing regulatory scrutiny. In 2017, corporate resolutions between health care and life sciences companies and the U.S. Department of Justice ("DOJ") and Securities and Exchange Commission ("SEC") constituted 27.3% of all FCPA-related corporate resolutions, and global trends suggest that foreign authorities have increasingly been cooperating with U.S. authorities in FCPA enforcement efforts over the past five years.[5] If the increase in U.S. anti-corruption enforcement against health care and life sciences companies operating abroad is any indication, companies should prepare for increased anti-corruption activity internationally. To avoid costly anti-corruption enforcement, health care and life sciences companies should vet and monitor their third-party distributors closely and revisit their internal

[1] Bribery Act 2010, c. 23, § 1(2) (Eng.).
[2] Lei No. 12.846, de 1 de Agosto de 2013, DIARIO OFICIAL DA UNIAO [D.O.U] de 2.8.2013, Capitulo II, art. 5, sec. III (Braz.).
[3] *Id.* at Capitulo II, art. 5, sec. II.
[4] Zhonghua Renmin Gonghegue Fan Bu Zhengdang Jingzheng Fa (Xiudìng) (中华人民共和国反不正当竞争法 (修订)) [Anti-Unfair Competition Law of the People's Republic of China] (promulgated by the Standing Comm. Nat'l People's Cong., Nov. 4, 2017, effective Jan. 1, 2018) (China).
[5] Mark F. Mendelsohn et al., *FCPA Enforcement and Anti-Corruption Year in Review*, HARV. L. SCH. F. CORP. GOVERNANCE AND FIN. REG. (Feb. 11, 2018), https://corpgov.law.harvard.edu/2018/02/11/fcpa-enforcement-and-anti-corruption-year-in-review/.

controls and compliance programs regularly to safeguard against liability under the FCPA and the evolving constellation of local anti-corruption laws.

I. Enforcement: Anti-Corruption Laws and Improper Third-Party Actions

The DOJ and SEC have imposed direct liability upon companies based on improper activities of third-party distributors acting on the behalf of the companies. Exposure to risk is created by activities such as failing to adequately oversee third-party distributors or disregarding these distributors' corrupt activities and relationships to further business goals. A number of recent enforcement matters illustrate the behaviors of and interactions between companies and their distributors that the DOJ and SEC deemed problematic under the FCPA.

In June 2016, Analogic Corporation ("Analogic"), a Massachusetts-based medical device company, and its wholly owned subsidiary in Denmark, BK Medical ApS ("BK Medical"), agreed to pay more than $14M under a non-prosecution agreement and settlement agreement with the DOJ and SEC, respectively. The company entered into these agreements to resolve FCPA charges for allegedly allowing BK Medical to be used as a "slush fund for its [third-party] distributors."[6] BK Medical's distributors routinely requested that BK Medical create "special invoices" to exaggerate the sales price of BK Medical's ultrasound equipment. After BK Medical received the inflated payments from distributors, it wired the excess funds to various third parties, as requested by the distributors, without determining whether there was an appropriate business reason for the payments. Altogether, BK Medical paid approximately $20 million over the span of nine years to third parties with whom it did not have established business relationships.[7] The SEC asserted that BK Medical violated the FCPA's books and records provisions when the company falsified its books (which rolled up into Analogic's books), causing Analogic to document BK Medical's doctored financials in Analogic's books and records. These improper payments, the unjustified basis for the payments by distributors, and Analogic's failure to devise and maintain an adequate system of internal controls exposed Analogic to significant FCPA risk.[8] In addition to risk exposure at the entity level, this enforcement action also included imposition of individual liability upon executives who recklessly disregarded the corrupt actions of their corporations' third-party distributors. BK Medical's former Chief Financial Officer ("CFO") paid a civil monetary penalty of $20,000 to the SEC to resolve charges that he knowingly disregarded the company's internal controls and falsified its books and records.[9] Prior to and during his tenure as BK Medical's CFO, the executive personally authorized more than 140 suspicious payments to third parties at distributors' requests, with knowledge

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[6] Press Release, U.S. Sec. Exch. Comm'n, SEC Charges Medical Device Manufacturer with FCPA Violations (June 21, 2016), https://www.sec.gov/news/pressrelease/2016-126.html; *see also* Press Release, U.S. Dep't of Justice, Analogic Subsidiary Agrees to Pay More than $14 Million to Resolve Foreign Bribery Charges (June 21, 2016), https://www.justice.gov/opa/pr/analogic-subsidiary-agrees-pay-more-14-million-resolve-foreign-bribery-charges.

[7] *See generally* Cease and Desist Order, In re Analogic Corp., Exchange Act Release No. 78,113, 114 SEC Docket 8 (June 21, 2016), https://www.sec.gov/litigation/admin/2016/34-78113.pdf. *See also* Press Release, U.S. Sec. Exch. Comm'n, SEC Charges Medical Device Manufacturer with FCPA Violations (June 21, 2016), https://www.sec.gov/news/pressrelease/2016-126.html.

[8] Press Release, U.S. Dep't of Justice, Analogic Subsidiary Agrees to Pay More than $14 Million to Resolve Foreign Bribery Charges (June 21, 2016), https://www.justice.gov/opa/pr/analogic-subsidiary-agrees-pay-more-14-million-resolve-foreign-bribery-charges. *See also* Press Release, U.S. Sec. Exch. Comm'n, SEC Charges Medical Device Manufacturer with FCPA Violations (June 21, 2016), https://www.sec.gov/news/pressrelease/2016-126.html. The FCPA includes a "books and records" provision, which requires companies to maintain their internal records in a manner that accurately reflects their transactions, including the transactions of third parties working on a company's behalf. Foreign Corrupt Practices Act of 1977, Pub. L. 95-213, 91 Stat. 1494 (1977), 15 U.S.C. §§ 78m(b)(2)(A)).

[9] Press Release, U.S. Sec. Exch. Comm'n, SEC Charges Medical Device Manufacturer with FCPA Violations (June 21, 2016), https://www.sec.gov/news/pressrelease/2016-126.html.

that these actions violated the company's internal accounting controls.[10] As the Chief of the SEC Enforcement Division's FCPA Unit noted in connection with this enforcement, "Issuers and their subsidiaries cannot turn a blind eye to suspicious payments, even if they believe they are simply 'helping out' a business partner."[11]

The DOJ and SEC have also targeted distribution arrangements in which life science companies and their subsidiaries used distributors to exert improper influence over government decisions. In December 2016, Teva Pharmaceutical Industries Ltd. ("Teva") and its Russian subsidiary ("Teva Russia") agreed to pay approximately $520 million to the SEC in penalties for bribing government officials in Russia, Ukraine, and Mexico through illegal payments and improper discounts. One of the schemes involved Teva Russia allegedly issuing payments through the high profit margins that a Russian company earned as a third-party distributor. The distribution company was operated and partly owned by a government official, while the company's controlling shares were held in name by the official's wife. Teva Russia intended these payments to influence the official's use of his authority to obtain approval in federal program tenders, faster drug registrations, and increased market access.[12] Unlike BK Medical, which turned a blind eye to improper arrangements, Teva Russia offered discounts and unusually high profit margins to the distribution company, with the expectation that the government official exert his political influence on the Russian Ministry of Health for Teva's benefit.[13]

Recent examples of anti-corruption enforcement by foreign governments against companies operating outside of the health care and life sciences sectors are also instructive. For example, the United Kingdom's Serious Fraud Office entered into a Deferred Prosecution Agreement ("DPA") in January 2017 with Rolls-Royce, a multinational manufacturer, for failing to prevent bribery committed by one of the company's third-party distributors. Rolls-Royce entered into a distribution agreement with a Nigerian company to distribute gas compression engines to an oil and gas exploration company. This agreement permitted the distributor to charge a mark-up on Rolls-Royce products, the proceeds of which the distributor used to make improper payments to Nigerian officials in one of the country's public entities that supervised the government's investment in the oil and gas sector.[14] Notably, Rolls-Royce was not blameless in this arrangement, as evidence indicates the company hired the third-party distributor intending to offer bribes to government officials to secure bids and gain unfair competitive advantages. The company hoped to receive confidential information on technical project details and competitor pricing, and even requested the distributor to stop certain competitor proposals from being accepted.[15] However, the Crown Court in its judgment against Rolls-Royce noted that the actions of the third-party distributor were alone sufficient to impose liability on Rolls-Royce for failing to prevent bribery under section 7 of the U.K. Bribery Act.[16] The Court treated Rolls-Royce's bad-faith actions and willful disregard as "aggravating factors" in determining the company's ultimate fine and whether a DPA (rather than immediate prosecution) was an appropriate remedy.[17] While the judgment does not state what Rolls-

[10] *See generally* Cease and Desist Order, In re Analogic Corp., Exchange Act Release No. 78,113, 114 SEC Docket 8 (June 21, 2016), https://www.sec.gov/litigation/admin/2016/34-78113.pdf.
[11] *See* Press Release, U.S. Sec. Exch. Comm'n, SEC Charges Medical Device Manufacturer with FCPA Violations (June 21, 2016), https://www.sec.gov/news/pressrelease/2016-126.html.
[12] *SEC v. Teva Pharm. Indus.*, No. 1:16-cv-25298, 10 (S.D. Fla. Dec. 22, 2016), https://www.sec.gov/litigation/complaints/2016/comp-pr2016-277.pdf.
[13] *Id.* at 14–15 (S.D. Fla. Dec. 22, 2016), https://www.sec.gov/litigation/complaints/2016/comp-pr2016-277.pdf. *See also* Press Release, U.S. Dep't of Justice, Teva Pharmaceutical Industries Ltd. Agrees to Pay More than $283 Million to Resolve Foreign Corrupt Practice Act Charges (Dec. 22, 2016), https://www.justice.gov/opa/pr/teva-pharmaceutical-industries-ltd-agrees-pay-more-283-million-resolve-foreign-corrupt.
[14] Statement of Facts, *Serious Fraud Office v. Rolls-Royce PLC [2017]*, EWCC (QB) 36, [217].
[15] *Id.* at [224].
[16] *Serious Fraud Office v. Rolls-Royce PLC [2017]*, EWCC (QB) 36, [34].
[17] *Id.* at [104].

Royce's exposure to liability might have been had it not demonstrated bad faith, companies should take note that the U.K. Bribery Act considers adequate procedures to prevent corrupt activities to be a defense, and the willful hiring of the corrupt distributor by Rolls-Royce could be interpreted as a breakdown of the compliance process.[18]

In light of these enforcement risks, health care and life sciences companies engaging third-party distributors abroad should examine their compliance policies and internal controls using guidance from these agencies and industry best practices. The following sections outline some key considerations and safeguards that companies should take into account when implementing meaningful compliance controls over third parties.

II. DOJ and SEC's Guidance on Identifying the Warning Signs for Improper Third-Party Conduct and the Development of Effective Global Compliance Programs

In 2012, the DOJ and SEC published a resource guide on the FCPA that highlights warning signs of improper third-party activity. These signs include, but are not limited to:

- "excessive commissions to third-party agents or consultants;
- unreasonably large discounts to third-party distributors;
- third-party 'consulting agreements' that include only vaguely described services;
- the third-party consultant is in a different line of business than that for which it has been engaged;
- the third party is related to or closely associated with the foreign official;
- the third party became part of the transaction at the express request or insistence of the foreign official;
- the third party is merely a shell company incorporated in an offshore jurisdiction; and
- third party requests payment to offshore bank accounts."[19]

The DOJ offered additional guidance in 2017 to assist multinational companies in developing effective global compliance programs. The guidance highlights elements and controls that multinational companies should consider to strengthen their compliance programs, such as establishing a business rationale for using third parties; developing mechanisms to guarantee that the contract terms with third parties clearly specify the services in which the third parties will be engaged; educating "relationship managers" about compliance risks with third parties; incentivizing compliance for third parties; developing a risk management process; strengthening due diligence protocols; and continuously auditing and improving anti-corruption policies and procedures.[20] While it is important for companies to account for such guidance in structuring their compliance efforts, the SEC and DOJ have made clear that a checklist approach to implementing oversight of third-party agents is not sufficient for the establishment of an effective compliance program. Rather, a company subject to U.S. laws that operates abroad should tailor its safeguards against foreign corrupt practices to the specific risks that it encounters in its respective business.

[18] Bribery Act of 2010, c. 23, § 7(2) (Eng.).
[19] U.S. DEP'T OF JUSTICE AND U.S. SEC. EXCH. COMM'N, A RESOURCE GUIDE TO THE U.S. FOREIGN CORRUPT PRACTICES ACT 22, 23 (Nov. 12, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf.
[20] U.S. DEP'T OF JUSTICE, EVALUATION OF CORPORATE COMPLIANCE PROGRAMS (Feb. 2017), https://www.justice.gov/criminal-fraud/page/file/937501/download.

III. Guidance for Health Care and Life Sciences Companies' Compliance Programs

Health care and life sciences companies in particular should be aware of the ways corruption may manifest through third parties, such as inflation of drug or device prices or costs to create a slush fund via a distributor; assertion of improper influence via distributors; and failure to properly oversee a distributor engaging in non-compliant activities. In particular, companies should closely monitor their relationships with third-party distributors and foster a culture of compliance. Key aspects of effective compliance programs include:

A. **Monitoring:** Companies and their subsidiaries should know their third-party distributors well, understand the business rationale for the third-party distributors' decisions, and establish monitoring mechanisms to detect red flags and other activities prohibited by the various anti-corruption laws. For example, companies may audit distributor margins[21] and conduct trend analysis and comparisons to identify suspicious trends in distributor payments. Companies may also monitor distributors' interactions with health care professionals who may be considered government officials in some situations and subject to local anti-corruption laws. Further, companies should adopt measures that ensure sufficient oversight of third-party distributors and implement processes in which no single department, particularly sales departments that are more likely to be motivated by achieving sales targets, is unilaterally responsible for making final decisions. Finally, the integrity of these processes can further be protected using tools, such as decision matrices, that require approvals from multiple gatekeepers. Without these measures, unlawful payments to third parties can remain undetected for years.

B. **Due diligence:** Given the SEC and DOJ's emphasis on conducting adequate due diligence, companies should be especially vigilant in conducting diligence of third-party distributors prior to starting business relationships. Some helpful tools to conduct more effective diligence include performing public reputation checks and checks to determine if the distributors are connected to politically exposed persons; requiring third-party distributors to complete and attest to a due diligence questionnaire containing questions about whether the company has an accounting system that can detect fraud and other controls that can prevent misconduct; for health care and life sciences products, conducting debarment checks against government payer databases; and requesting certifications from third parties that state that they understand and will adhere to the company's anti-corruption policies and procedures as well as applicable laws and regulations. Further, while it is essential to conduct diligence at the start of a distributor relationship, it is also necessary to update such diligence periodically. The scope and depth of an appropriate diligence plan will depend on several factors, such as the industries and countries in which a company operates. Nevertheless, companies should engage in risk-based due diligence to adjust the degree of scrutiny as problematic activities are detected.

C. **Training:** Companies should train employees, particularly those who interact with third-party distributors on a regular basis, to identify potential red flags relevant for the areas where they operate. Useful topics include guidance on when health care professionals could be considered government officials and whether supplying gifts or entertainment to health care professionals could be considered improper payments under applicable local laws or trade association ethical standards. Employees should be retrained periodically, ideally at least annually. When possible, companies would conduct these trainings live and in the local language, to provide employees an opportunity to ask questions and fully comprehend the material. One effective approach involves the presentation of case studies, through which trainees can actively participate in analyzing common risk areas they

[21] While a margin audit is an example of a tool that companies can use to identify suspicious trends in distributor payments, companies should not conduct or utilize margin analysis as a means of collusion or concerted effort to fix prices, in contravention of applicable antitrust laws.

might encounter in their day-to-day activities. Such training is particularly important for companies that operate internationally and may find it difficult to monitor the daily activities of third-party distributors centrally. Companies could provide similar trainings to third-party distributors directly, through summits and other distributor events, to create an opportunity for senior management to retrain their distributors and communicate to them the importance of avoiding corrupt behavior. It is important to stress that companies must ensure that trainings of employees and third parties are not a check-the-box exercise. Analogic's case exemplifies an ineffective training program. In 2008, a Senior Vice President at Analogic believed that BK Medical posed significant FCPA risk for the corporation, so Analogic implemented an FCPA training program for the sales and finance staff of BK Medical. The program addressed business ethics and FCPA compliance. However, despite the training, the subsidiary failed to take any steps to determine whether its distributors were behaving in an unlawful manner, despite various red flags.[22] While this is perhaps indicative of other issues such as a general lack of awareness towards compliance, the Analogic case also highlights authorities' emphasis on the effectiveness of a compliance program. Companies should customize trainings to address the specific needs and situations of each jurisdiction, the unique risks that a company might encounter when conducting business internationally, and should include guidance on specific steps employees at all levels of the corporation may take when improper behavior is detected. In particular, passive distribution of knowledge on corruption-related issues is insufficient; rather, the company will need to have demonstrated that its employees have internalized the trainings and policies, and that the company has taken on an active role in monitoring and preventing third-party misconduct.

D. **Culture of compliance:** Companies should establish institutional commitment at the outset and foster a top-down culture of compliance to demonstrate their commitment to avoiding corrupt practices. They should widely distribute, and periodically redistribute, their policies and procedures that prohibit bribery to employees at all levels of the company. In addition to implementing training programs for employees, companies should raise awareness at the executive/leadership level of the importance of complying with the FCPA and other anti-corruption laws, and of establishing open lines of communication with employees regarding suspected non-compliance with these laws. Senior management should take particular care to foster an environment in which employees feel the company encourages reporting of concerns. As non-management employees are often responsible for maintaining third-party relationships and serve as gatekeepers, they may be the first to know if corrupt practices are occurring. Thus, companies should ensure that these employees are aware of the available channels of communication to report red flags, which can include anonymous hotlines, in addition to open-door policies with senior managers involved with compliance matters and the compliance department.

Both domestically and abroad, health care and life sciences companies must maintain strong compliance systems to safeguard against corrupt practices. However, the path to global compliance can be challenging, particularly when third parties are involved. Companies' inability to exercise adequate oversight and control over third-party distributors creates risk, in particular when operating in environments of which they have little knowledge and jurisdictions that are associated with a high risk of corruption. In spite of these and other hurdles, health care and life sciences companies have an obligation to implement safeguards against prohibited activities using what resources they do have.

[22] Cease and Desist Order, In re Analogic Corp., Exchange Act Release No. 78,113, 114 SEC Docket 8 (June 21, 2016), https://www.sec.gov/litigation/admin/2016/34-78113.pdf.