Mitigating FCPA Exposure in International Distribution Relationships

Compliance Tips for Food, Drug, Device and Personal Care Companies

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Mitigating the risk of sanctions under the U.S. Foreign Corrupt Practices Act (FCPA) is a core concern in every international commercial transaction, including cross-border distribution relationships in the FDA-regulated industry sectors. The FCPA contains both anti-bribery and accounting provisions. The anti-bribery provisions prohibit U.S. persons and businesses, U.S. and foreign public companies listed on stock exchanges in the United States or which are required to file periodic reports with the Securities and Exchange Commission, and certain foreign persons and businesses acting while in the territory of the United States from making corrupt payments to foreign officials to obtain or retain business. The accounting provisions require issuers to make and keep accurate books and records and to devise and maintain an adequate system of internal accounting controls. The U.S. Department of Justice and the Securities and Exchange Commission share enforcement authority under the Act. This article will review briefly best practices to mitigate FCPA risk in international distribution relationships.

DOES THE COMPANY “KNOW” OF VIOLATIONS?

The FCPA expressly prohibits corrupt payments made directly to foreign government officials as well as corrupt payments made through third parties or intermediaries. More specifically, the statute prohibits payments made to “any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly,” to a foreign official. The fact that a bribe is paid by a third party does not eliminate the poten¬tial for criminal or civil FCPA liability for the U.S. principal. The key to the statute’s wide jurisdictional reach is in the definition of “knowing”: whether a person’s state of mind is “knowing” with respect to conduct, a circumstance, or a result depends upon whether the person: (i) is aware that he or she is engaging in such conduct, that such circumstance exists, or that such result is substantially certain to occur; or (ii) has a firm belief that such circumstance exists or that such result is substantially certain to occur.

MITIGATING RISK OF LIABILITY FOR DISTRIBUTOR ACTIONS

Initial Review and Ongoing Oversight

The statute’s expansive jurisdiction thus provides that companies and individuals can be found liable for their distributor’s violations of the statute. FDA-regulated companies using distributors outside the United States must conduct risk-based due diligence in order to mitigate their FCPA risk exposure. This diligence includes both an initial review of the potential distributor before any agreement is executed and ongoing oversight once the agreement is in place. Further, the diligence should account for the industry, country, size and nature of the transaction, and historical relationship with the distributor. The Transparency International’s Corruption Perception Index is a great resource for understanding which jurisdiction, and which government sectors within a jurisdiction, present a higher corruption risk. Companies should also catalogue the points at which their business operations interact with non-U.S. government officials—the greater the number of contact points, the more robust the compliance program should be.

Key Provisions of a Company’s Compliance Program

At its most basic level, a compliance program should focus on three principles:

1. understanding the qualifications and associations of a potential distributor, including its business reputation, and relationship, if any, with foreign officials:
2. understanding the business rationale for engaging the potential distributor; and
3. undertaking some form of ongoing monitoring of the distribution relationship.

Effective diligence, even if it fails to detect 100% of a distributor’s corrupt behavior, will be a mitigating factor in determining a company's penalty for FCPA violations by its distributor. An effective FCPA compliance program also requires a mechanism to allow employees and others to report suspected or actual misconduct; importantly, a good compliance program should constantly evolve to reflect a company's operations or changes in relevant law or regulation.

The Initial Distributor Review

The initial review of each potential distributor should seek to answer a number of questions, including: Does the government or any official or instrumentality of the government have any ownership or other financial interest in the distributor (keeping in mind the expanding definition of government instrumentality under the FCPA)? Has the distributor ever been charged with any sort of crime, fraud or bribery? Is the qualified to perform the duties for which it may be engaged? Does the distributor rely heavily on political or government contacts as opposed to knowledgeable staff? If the initial due diligence review reveals any red flags, the U.S. lie sciences company should resolve them before entering into any agreement. If there is an FCPA issue down the road, and if a due diligence investigation revealed red flags that were not resolved, or were ignored prior to entering to an agreement, it will be an aggravating factor in assessing the principal's liability and/or possible penalty.

Distribution Agreement Provisions

U.S. companies should include specific FCPA-compliance language in every distribution agreement. Such language should require the distributor to:

1. acknowledge the FCPA's parameters and restrictions;
2. agree to abide by the FCPA's restrictions and requirements, as well as related local law restrictions and requirements;
3. allow the principal to conduct FCPA compliance-focused audits on a periodic basis;
4. acknowledge, and agree to conform to, the principal's FCPA compliance program;
5. agree to provide semi-annual certifications as to FCPA compliance; and
6. allow the principal to terminate the agreement immediately and without penalty (if possible under local law) in the event of an FCPA breach by the distributor.

In addition, indemnification clauses should require that the distributor reimburse the purchaser not just for any "losses," but specifically for the principal's costs of an FCPA investigation.

Monitoring Distributors and Partners

During the agreement's performance, the U.S. company should monitor its distributors and partners by investigating the following questions: Have any unusual payment patterns or financial arrangements emerged? Have there been any payments in cash or cash equivalent? Any payments to an offshore account? Is the compensation rate paid by a distributor or partner substantially above the going rate for similar work in a particular country?

The U.S. company also should follow up on any reasonable rumors that suggest corrupt activity by the distributor.

Keeping the Company's FCPA Policy Current

One final suggestion: U.S. companies should keep the FCPA compliance policy up-to-date, and train those employees who oversee distributors or otherwise have an 'international' portfolio in FCPA compliance. Keep records of such training and of any monitoring and other activities, review records regularly and be prepared to investigate any unusual activity or trends and to take any necessary action.

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