TRIANGLE BUSINESS JOURNAL

MAY 4, 2012

Focus: Law

Corruption law's importance to Triangle companies

By David Smyth

In the international business community, few law enforcement matters in recent years have attracted as much attention as the Foreign Corrupt Practices Act. FCPA enforcement – conducted by both the U.S. Department of Justice and the Securities and Exchange Commission – has been intense and increasing over the last decade. The total numbers of FCPA actions brought by both agencies have risen from a mere five in 2004 to between 40 and 74 in the last three years. This trend has particular relevance for Triangle companies, including pharmaceutical companies and clinical-research organizations.

Briefly, the FCPA is divided into two sets of provisions: the anti-bribery provisions and the accounting provisions.

On the anti-bribery side, the statute forbids corruptly paying any "thing of value" to a foreign government official to obtain or retain business. Publicly traded companies also have to heed the statute's accounting provisions, which require them to 1) keep books and records that accurately reflect their transactions, including any foreign bribes and 2) maintain accounting controls sufficient to ensure that corrupt payments are not made on their behalf.

Retail giant Wal-Mart currently is amid a full-blown crisis relating to bribery charges in Mexico – forcing the company to create a new global position to oversee compliance with FCPA provisions.

It is easy to fall into the FCPA's clutches, especially when the term "government official" in many countries applies to many more people, including health care professionals, than it would in the United States. Law enforcers have noticed that pharmaceutical companies and CROs do business overseas and that some have real FCPA issues. In fact, an ongoing sweep of the medical industry has already seen tangible results. Last year Johnson & Johnson agreed to pay $70 million to settle FCPA cases involving bribes of public doctors in several European countries, as well as kickbacks in Iraq. Since February, medical-device companies Biomet and Smith & Nephew have settled cases for bribes allegedly paid to public doctors in various foreign countries. The price tags for those matters were about $22 million each, but they tell only part of the story.

The real expenses often lie in internal investigations required to learn the extent of the problem. Avon Products has disclosed that it spent $93 million on its own FCPA investigation in 2011, on top of $95 million in 2010 and $59 million in 2009. What's worse, the Justice Department seeks criminal penalties for egregious violations. Actions against individuals have also become more common, meaning prison time is a real possibility if foreign bribery is detected and prosecuted.

CROs are prime targets for law enforcement in this area. These companies have increasingly taken clinical trials abroad in support of both research and early marketing efforts. Overseas, they find receptive population centers, available expertise, and far lower costs than in the West. But this positive business environment carries significant risk. Equipment and supplies must be imported into the country, permits must be secured to comply with local regulations, and clinical facilities must be built or renovated. At every stage of the process, CROs often encounter government officials who demand to be paid for their efforts. If those payments can be construed as being designed to obtain or retain business, the consequences can be dire.

But CROs and other companies can manage that risk without bringing clinical trials back to the United States. First, a company should adopt a comprehensive corporate anti-corruption policy – separate from a general ethics policy – that addresses the activities of employees and third parties acting on its behalf. Second, it should conduct documented due diligence on those third parties, especially sales agents, to identify any potential FCPA red flags before engaging those third parties. Third, a company should provide regular training to its employees and contractors on applicable compliance policies, and test those staff on their awareness just as regularly. These are just the basics, but they constitute a good start for any company involved in global markets.

Enforcement of the FCPA is not going away any time soon. Indeed, the SEC's and Justice Department's legal theories seem only to be expanding. Laws in other countries, including the recently passed U.K. Bribery Act, are catching up to, and even surpassing, the U.S.'s efforts in this area. In the coming months, the DOJ is planning to issue guidance that may add some clarity to the enforcement landscape. But no silver bullets are on the horizon. Triangle companies in international markets would be wise to consult with competent counsel to assess areas of exposure and prepare for action if suspicious activity arises.

Smyth is a former assistant director in the SEC's Division of Enforcement who is now in private practice in Raleigh with the law firm Brooks, Pierce, McLendon, Humphrey & Leonard, LLP. He authors a blog on securities enforcement issues at www.cady-barthedoor.com.

Reprinted for web use with permission from the ***Triangle Business Journal***. ©2012, all rights reserved. Reprinted by Scoop ReprintSource 1-800-767-3263.