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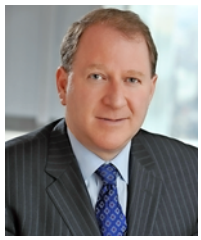
BNA's
Health Care
Fraud Report™

Anti-Bribery Compliance Programs Must Have Teeth



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U.S and foreign governments have dramatically increased scrutiny of the health-care sector for violations of the Foreign Corrupt Practices Act over the past five years.

The FCPA, which covers companies that list their securities in the U.S., prohibits offering or paying bribes to foreign government officials at any level of government. The U.S. Justice Department and the Securities and Exchange Commission jointly enforce the statute.

Health-care companies should ensure their internal FCPA compliance programs are robust and third party vendors are properly vetted, Skadden, Arps, Slate, Meagher & Flom LLP attorneys Warren Feldman in New York and Michael K. Loucks in Boston told Bloomberg BNA's Dana Elfin in a recent interview. [*Editor's note: Loucks is author of the Bloomberg BNA book, Prosecuting and Defending Health Care Fraud Cases*.]

The DOJ and SEC extended FCPA liability to the health-care sector in their case against Syncor International Corp. In the case, Syncor International Corp.'s former CEO and chairman was alleged to have steered bribes to doctors at Taiwanese private and public hospitals. Because Syncor was the first case in which the government charged a company for bribing doctors who were considered to be foreign officials, it paved the way for future prosecutions in the area.

Feldman and Loucks also said:

- FCPA compliance programs must demonstrate a strong commitment from top management;
- Companies may increasingly face enforcement interest from multiple players, including DOJ, SEC and foreign governments; and
- It's too early to tell how FCPA enforcement will play out it in the new Trump administration.

BLOOMBERG BNA: *What changes have you seen in FCPA enforcement in the health-care sector since the Syncor case opened the floodgates in 2002?*

Feldman: FCPA enforcement in general has increased dramatically since 2002, with greater concentration on the health care sector over the past five years. In 2016, the government's focus on the industry seems to have become particularly sharp. The SEC and the DOJ brought a total of eight cases against pharmaceutical and medical device companies, more than they brought over the past three years combined. The SEC has become more active than the DOJ in this space; five of the eight cases in 2016 were independent SEC actions. Another noteworthy development has been the geographical focus on China, Russia and Eastern Europe. Since 2012, all but two of the FCPA cases against health-care companies have involved misconduct in some or all of those areas.

Loucks: The FCPA cases brought against the health-care sector have principally focused on the pharmaceutical industry, and they look a lot like the anti-kickback statute (AKS) enforcement the DOJ has pursued against health care providers and suppliers for conduct in the United States. Indeed, the FCPA and the AKS are probably the only two federal statutes that criminalize behavior aimed at inducing another person to take some action (for example, prescribing a drug).

BLOOMBERG BNA: *There has been a surge of FCPA enforcement in the health care sector since the Syncor case. To what do you attribute the increased level of FCPA enforcement in the health care sector?*

Feldman: There are several driving factors. First, multinational health-care companies looking to achieve growth in key emerging markets find themselves expanding operations in corruption-prone areas such as China, Russia and Eastern Europe. These are huge markets vital to a company's success, but operating there has a greater degree of inherent corruption risk compared to other places. Second, especially in China, al-

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most all health-care professionals (HCPs) are likely to be considered ''government officials'' by U.S. enforcers, which increases a company's exposure to FCPA liability. Finally, FCPA enforcers have identified the health-care space as fertile ground for successful prosecutions and companies tend to be risk-averse and favor settling over litigating. One investigation will often lead to the next, so the increase in health-care cases we are seeing now may be the result of that snowball effect.

Loucks: Warren is 100 percent right. One successful prosecution in an area begets many follow-on cases. Other countries see that a global company has been tagged for FCPA violations in a neighboring country and they commence an investigation. DOJ attorneys expand the investigation into conduct in just one country to other countries. In the United States, when a company settles a whistle-blower suit, that settlement often puts it on what I call the whistle-blower treadmill: Whistle-blowers and their counsel consider the company a mark that will pay and they then file new cases, triggering new investigations. It can be hard for companies to get off that treadmill.

BLOOMBERG BNA: *What FCPA compliance issues should the health-care industry pay particular attention to as compared to other industries (for example, dealing with government employees or government-run hospitals)?*

Feldman: The very high levels of interaction with government officials for health-care companies creates greater exposure to FCPA risk. For example, sales reps are constantly dealing directly with HCPs and hospital employees, many of whom are considered government officials depending on the country. Pharmaceutical companies regularly seek to include their products on national reimbursement lists and/or hospital formularies, which involves important interactions with government officials. Pharmaceuticals and medical devices often need to be imported, sometimes under considerable time pressure, which requires various approvals and permits. These interactions all create opportunities for FCPA exposure. Multinational companies must often engage local third parties to assist in their operations, and these third parties can create significant FCPA risks for the companies.

Loucks: This issue is similar in both the FCPA and AKS contexts. Sales reps in both environments are incentivized to sell, and their companies provide them with tools that can include providing things of value to HCPs, such as speaking engagements. Supervising how those tools are used is critical, and foreign environments may provide greater challenges to U.S.-based companies. Although the sales culture may differ from state to state, all states use the same language, federal political system and federal legal rules. By contrast, the cultures and rules governing behavior, and thus the interactions with HCPs in countries like Nigeria, Serbia and China differ dramatically. Policing the conduct of employees in such diverse environments presents special challenges.

BLOOMBERG BNA: *What are the common missteps that have historically led health care companies into FCPA compliance trouble?*

Loucks: I was involved in the leading edge of U.S.-based enforcement of the AKS in the 1990s. I've seen over the past decade companies recognizing the need to comply with the FCPA, with similar starting points to recognizing the need to comply with the AKS when the DOJ geared up enforcement in the 1990s. Those starting points include: loose, or non-existent compliance systems, a view that because there has been so little enforcement, ''it can't happen to me,'' and a view that because ''everyone else is doing it,'' there is safety in that herd.

Feldman: In the corruption-prone jurisdictions in which the global health-care companies have sought to grow, there is frequently a perception that the domestic companies operate with significant disregard for anti-corruption laws and compliance standards. As a consequence, the global companies may have been lulled into a sense they did not have a significant problem since they did not operate in that manner. Instead, issues often manifested in more complex forms. For example, many problems arose through third parties' activities, including companies' use of travel agents and meeting planners. Additional issues have arisen around speaker programs and charitable contributions. Accordingly, companies have been ramping up their compliance efforts in these areas to avoid future problems.

BLOOMBERG BNA: *What are the most important elements health-care companies should build into their FCPA compliance programs?*

Loucks: Giving the program teeth and employees' recognizing the program has the support of top management. The vast majority of all employees will follow the rules if the organization communicates that doing so is important. Taking swift and decisive action against employees caught cheating is the single most important element of a compliance system and the most effective tool for communicating the views of upper management.

Feldman: I agree with Michael that companies are well advised to rigorously train their sales force on how to deal with HCPs who will be considered government officials by U.S. enforcement authorities. This is especially important where the sales team may be operating in environments where the domestic players might be conditioning the HCPs to expect improper inducements. It is also extremely important that the companies address the compliance risks entailed in working with third parties including travel agents and meeting planners. This should include performing due diligence on third parties, contractual terms including audit rights, termination rights and certifications of compliance and training third parties on the companies' anti-corruption policies. In this way, corruption risk can be meaningfully reduced.

BLOOMBERG BNA: *It seems that recently several major global companies have announced reserves in excess of $400 million for settling FCPA probes by the DOJ. Are such large settlements an anomaly or are they becoming more common?*

Loucks: I think we can expect for a time some significant settlements, but then, as with AKS enforcement in the U.S., we'll see the number of such settlements drop. Before 2003 it was not clear the DOJ was interested in FCPA enforcement, thus signaling to the industry its own lackadaisical view of the importance of those

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rules. But, it is now clear that enforcement is a priority. Companies have responded and built compliance systems with teeth where formerly there were none; these company-led enforcement mechanisms will result in a decrease in illegal conduct and diminish the number of future enforcement actions and sizeable settlements. I think the landscape for enforcement will shift, with the balance of power moving from the DOJ to enforcement authorities in other countries. A recent settlement involving Brazilian conglomerate Odebrecht demonstrates this: Of the $3.6 billion corruption penalty imposed, the U.S. gained just 10 percent, with 80 percent going to the country where the corruption occurred (Brazil). I suspect the more than $2 billion recovered by Brazil in that single corruption case is the largest recovery in that country's history. Prosecutors in that country, and all others similarly situated, will take notice. So, too, should corporations and their attorneys: where a country may have had lax or no enforcement against local corruption by locals, global companies should expect that they will be targeted because they will be a deep pocket. And they should expect that, while the DOJ may be involved and may have even initiated the investigation, the key decision makers will increasingly become prosecutors in foreign jurisdictions looking to earn a substantial financial windfall.

Feldman: In the last year, the DOJ and SEC have continued to extract sizable settlements to resolve FCPA investigations. It is likely there are more in the pipeline. With respect to health-care specifically, the record seems a bit more mixed. There have been a number of resolutions this year that have only involved the SEC and the financial terms have been meaningful but not enormous. At the same time, medical equipment company Olympus paid almost $650 million to settle U.S. domestic as well as FCPA-related issues, and generic drug manufacturer Teva paid $519 million to settle FCPA charges. While health-care companies are making major commitments to FCPA compliance to avoid future problems, there is a lingering danger that companies which confront additional problems, notwithstanding their compliance efforts, may face U.S. enforcers looking to extract ever-larger penalties.

BLOOMBERG BNA: *As the one-year anniversary of the voluntary FCPA self-reporting pilot program nears, what have companies' experiences been like with the program?*

Feldman: Since the program began, the DOJ has declined to prosecute six companies that voluntarily disclosed misconduct, issuing declination letters to Nortek, Akamai, Johnson Controls, HMT and NCH, and entering into a non-prosecution agreement with BK Medical. All these companies were required to disgorge profits either by the DOJ or through an SEC settlement. By making the program guidance and the declinations public, the DOJ has made the effects of self-reporting more transparent. This provides companies with actual data points when they are considering self-reporting and can increase the incentive to report. But the government retains significant discretion regarding the nature of the resolution (for example, plea or deferred prosecution agreement vs. declination), assessment of the cooperation, and remediation credit a self-reporting company will receive. Such discretion still creates uncertainty that may lead companies away from voluntary disclosure.

Loucks: The FCPA pilot program is run only by the DOJ and is largely ad hoc: One component of the DOJ has established its rules and criteria and its assessment is subject to no outside oversight. By contrast, the self-disclosure rule applicable to the AKS is run by the Office of Inspector General for the Department of Health and Human Services, and is subject to a detailed and thorough written regulatory protocol. While OIG will refer matters subject to its program to the DOJ for review, DOJ's follow-on decision-making is necessarily impacted by the differing regulatory interests of the OIG. This assures better overall consistency and uniformity of treatment: while the OIG cannot technically promise no DOJ action, in reality, a company accepted into the OIG program will not face follow-on DOJ enforcement. Assuring no follow-on local country enforcement for a voluntary disclosure to DOJ may be an impossible dream for the DOJ FCPA self-disclosure program.

BLOOMBERG BNA: *With the incoming Trump Administration, what do you think we can expect with regard to future FCPA enforcement? Do you think resources will be redirected away from FCPA enforcement and/or further decreasing penalties for companies that self-report?*

Loucks: I think we can expect to see a flattening of U.S. FCPA enforcement over the next five to 10 years, which was going to happen regardless of the change in administration. Where five years ago, virtually all major corruption cases in the world were by the DOJ, and it reaped the lion's share of the financial rewards, there is now enforcement interest in many countries. The DOJ will be increasingly forced to cede enforcement control and decision-making to the aggrieved country where the bribery took place and may find itself behind numerous other countries who have seized the driver's seat. The same phenomenon has taken place in the U.S. in AKS enforcement. A decade ago, a company's biggest and perhaps only enforcement worry was the DOJ or a single U.S. attorney's office. While state prosecutors had their hand out for a piece of the federal pie once assembled, they rarely led the charge. Today, a company may find itself under active investigation with multiple states who may be well ahead of federal authorities, and there may be multiple federal prosecutors involved. The FCPA financial windfall genie is out of the bottle and a reduction in U.S. FCPA enforcement will not put that genie back in.

Feldman: I think it is too early to tell. To be sure, there has been much made of the fact that President-elect Trump called the FCPA a ''horrible law'' in 2012. President-elect Trump's nominee to head the SEC has also written critically of the FCPA in the past. This would suggest that there is at least a possibility that he will look to have the DOJ and SEC scale back their enforcement efforts in this area. Nevertheless, it is a long leap from these sorts of statement to extrapolate that the president-elect will insist on a scale-back of FCPA enforcement efforts. Presidents rarely get that granular with enforcement of a particular criminal statute. The incoming attorney general and new head of the SEC will have a significant say in the direction of FCPA enforcement. It is simply too early to tell how this will play out.

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