VOL. IX, ISSUE 6/APRIL 16, 2010

RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Bracing for Increased FCPA Enforcement in the Pharmaceutical and Device Industries

By Kirk Ogrosky

The Department of Justice (DOJ) announced the Foreign Corrupt Practices Act (FCPA) pharmaceutical and device industry Initiative (the Initiative) in November of 2009. Almost five months later, the FBI's Washington field office is still in the early stages of its operational plan. In the meantime, DOJ's leadership has been transitioned and its prosecutorial resources increased.

Since the FCPA was enacted, approximately 160 cases have been brought by the Fraud Section at DOJ. In recent years, both the number of active investigations and the size of these settlements have grown exponentially. Unlike other federal crimes where 93 separate U.S. Attorneys' Offices utilize a variety of tactics, FCPA enforcement rests exclusively at Main Justice. One key feature of the initiative is that it couples traditional Anti-Kickback Statute prosecutor resources with FCPA trained agents.

This article updates the status of the Initiative and outlines some key issues for the upcoming year.

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Leveraging Aggregate Spend Initiatives

By Ben Carmel and Natasha Thoren

Manufacturer payments to health care professionals and healthcare organizations (HCP/O) are poised to receive increased scrutiny in 2010. At the federal level, passage of the Physician Payment Sunshine Act provisions has forced pharmaceutical and medical device firms to review their aggregate spend reporting practices.Meanwhile, eight states currently have spend disclosure laws, and several states with high populations of HCPs, such as Connecticut, New York, and New Jersey have introduced legislation in this area.

Given the likelihood of new legislation from additional states stemming from the weak federal preemption clause of the federal statute, pharma is facing the prospect of a turbulent compliance environment for the foreseeable future.

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Bracing for Increased FCPA Enforcement in the Pharmaceutical and Device Industries

Why—Origin of the Initiative

Given ten years of investigations related to promotional activities in the United States, many industry legal counsel are asking why DOJ elected to focus on global sales and marketing efforts of pharmaceutical and device companies. Over the past three years, the FBI received widespread information that internal controls at pharmaceutical and device companies were insufficient to prevent conduct like that seen in prior investigations. Closer examination by DOJ led to the conclusion that the intersection between the pharmaceutical and device industries and foreign government officials provided ripe opportunities for violations.

Within government, the most noteworthy case in this area is Syncor. The matter arose when Cardinal Health discovered during due diligence that Syncor made over $500,000 in cash payments to physicians in Taiwan and Mexico who controlled utilization and referral decisions at state-owned hospitals. In Mexico, Syncor allegedly: 1) inflated invoices to state-owned hospitals then kicked the price difference back to physicians, 2) provided $200,000 to physicians in the form of trips to conferences, charitable donations and computers, and 3) made loans to physicians that were never repaid. Another government investigation established that a device company operating in China made over $1.5 million in payments to physicians who controlled purchasing decisions for state-owned hospitals. The fact patterns in these prior matters is a good place to start to understand the government's approach to the Initiative.

Where—Countries of Focus

The Initiative will focus on business practices in over 30 countries. Investigations in Western Europe appear to be leading the first wave of matters due largely to law enforcement cooperation. As a starting point, companies should focus on high-risk conduct in Germany, Greece, Italy, Poland, Spain, and Turkey.

What—Areas of Enforcement Activity

Law enforcement personnel in the United States are focusing on the following types of conduct:

1) inflated invoices where excess amounts are being paid to physicians;

2) payments to consulting companies with ties to distributors;

3) charitable donations to foundations at the direction of physicians;

4) loans to individuals in positions to control utilization;

5) payments of any type to tender committee members;

6) trips to conferences with little or no educational value; and

7) excessive payments to investigators at state facilities related to post marketing studies.

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For the past few years, FCPA enforcement personnel have made significant strides in understanding foreign health systems and identifying systemic weaknesses where the risk of bribery is high. Federal agents have identified key officials with authority to impact utilization decisions in their target countries.

Based on this backdrop, those with the highest risk include young medical device manufacturers due to a perception that these companies regularly use aggressive promotional practices and lack developed compliance plans. Companies promoting implantable devices and pharmaceuticals that are administered in an in-patient setting are also at higher risk.

How—Ensuring Compliance

While there is no perfect way to avoid investigation, diligence in compliance and identification of systemic weaknesses can be done through basic auditing and testing. For example, when foreign sales divisions seek to retain third-parties as intermediaries, auditing should be able to establish documentation supporting the fact that the third party intermediary:

a) was not a government official;

b) had sufficient expertise to execute the task required;

c) had physical offices;

d) did not have prior convictions; and

e) was not retained at the specific direction of a government official

A warning sign that might mandate a more extensive examination of the purpose of the transaction might be as simple as an inordinately large number of third-party intermediaries in a particular country. Finally, watch for payments made to third-parties, payments to bank accounts in different countries, and payments based on percentage of sales.

With regard to funded travel for conferences, understand who within your organization has authority to approve such travel. For foreign physicians, ask if there is transparency within the foreign organization and if all approvals have been received. Make sure that the type of conference is focused on educational activity, not leisure. Minimize trappings that draw attention to travel such as first-class airfare, expensive hotels, excessive entertainment, and cash per diem. Finally, compliance with the PhRMA Code's guidance on educational programs is a positive first step to ensure that relationships with foreign physicians, who may be deemed foreign officials, are not the subject of investigation.

Who—Leadership Changes

Starting in April of 2010, Acting Deputy Chief Charles Duross will take over supervision of the FCPA group. At the same time, the new Initiative will remain under the supervision of Acting Deputy Chief Hank Walther, who began heading up healthcare fraud enforcement in March. Duross has over ten years of prosecutorial experience having served as an Assistant U.S. Attorney in the Miami office prior to 2007. Walther, one of the first prosecutors to head up a Medicare Fraud Strike Force (MFSF) team in Miami, recently indicted a series of FCPA cases leading to arrests in Las Vegas. Both Duross and Walther became prosecutors after spending several years in private practice. In particular, Walther was recruited by DOJ having handled criminal investigations for pharmaceutical manufacturers. The Criminal Division is expected to make final leadership selections before summer.

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What's Next—UK and SFO

In addition to the U.S. activity, there have been two major developments within the last few weeks in the UK. First, Parliament passed comprehensive bribery legislation that is expected to go into effect in late summer 2010. The Bribery Act brings the UK into compliance with the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. While the new law largely tracks the FCPA, it creates an additional offense for a company's failure to prevent bribery by "a person who performs services" on behalf of the company. However, the scope of enforcement authorities in the UK remains unsettled. Lord Justice Thomas in the Southwark Crown Court recently remarked that the Serious Fraud Office did not have the power to enter into a binding plea agreement with a negotiated monetary penalty on March 26, 2010. Whether the court is bound by penalties negotiated by the SFO complicates the SFO's initiative to establish a U.S. style voluntary disclosure regime. ■

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