

DISCUSSING THE TRENDS

Q&A with Douglas N. Greenburg

Life Sciences Industry Grapples With Increasing FCPA Enforcement Activity

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Doug Greenburg is a partner at Latham & Watkins and a Vice Chair of the global Litigation Department. His practice focuses on internal corporate investigations, white collar criminal defense, and US Securities and Exchange Commission (SEC) enforcement proceedings. He has extensive experience representing clients in connection with alleged violations of the Foreign Corrupt Practices Act (FCPA), economic sanction and export control violations, money laundering, securities fraud and complex regulatory matters.

Greenburg regularly advises life sciences companies on FCPA compliance and represents them in government investigations. "You have to keep working at compliance — analyzing whether there are things your organization can be doing better," he said. "You have to devote sufficient resources to it — you cannot shortchange the resources for compliance. And you have to evaluate whether particular markets make sense at the entry level. When you assess entry into a particular market, companies should anticipate compliance expenditures commensurate with the risk in that market."

In this lw.com interview, Greenburg discusses how companies are changing their operating models to reduce risk and prepare against the rise in anti-corruption enforcement activity from non-US governments.

Why are life sciences companies at greater risk of FCPA violation allegations compared to other industries?

Greenburg: Around the world, most doctors and people who are buying life sciences products are working for organizations that are ultimately owned and controlled by governments. Because of that governmental ownership or control, most of the customer representatives that life sciences companies are dealing with will be considered by US enforcement authorities to be "foreign officials" under the FCPA. This means that multiple employees of life sciences companies could be interacting with "foreign officials" on a daily basis in the sales and promotional context thereby presenting increased opportunities for compliance and potential FCPA violations.

Another reason is that life sciences companies often have very large numbers of relatively small sales, which become harder to police from an anti-corruption standpoint. And in many places around the world, life sciences companies typically need to work through distributors and other sales intermediaries who present additional anti-corruption risks. The US government aggressively goes after companies on essentially a "willful blindness" theory. In other words, if the company ignores facts that make it substantially likely its distributor is making corrupt payments (or even, in the government's view, fails to adequately investigate its suspicions), the company could have violated the FCPA even if it doesn't actually know with certainty that the corrupt payments are being made.

Another factor that is present in many industries but certainly in life sciences is the need for a large amount of regulatory and other interaction with government officials in ways other than the sales context. Even though the FCPA as written targets corrupt payments to obtain or retain business or to get any other improper advantage in obtaining or retaining business, it has been broadly interpreted to encompass any corrupt payments that could have the effect of helping a business. So companies have to be very careful about interaction with regulatory officials in any context, such as regulatory approvals, customs or tax.

What do life sciences companies need to do when considering entrance into a new market?

Greenburg: You have to evaluate whether particular markets make sense at the entry level. When you do that, you have to anticipate an expenditure on compliance appropriate to the risk profile for that market. If you do not figure that into your business model, you may be investing in places where you cannot do business effectively. If you think that you can low budget it and rely exclusively on third parties you may not be in a position to effectively monitor, you could

put yourself into a world of problems. Investigations in this area can be enormously expensive — setting aside enforcement costs. You could easily find yourself in a situation where a business that looked profitable is not. So you really have to evaluate what makes sense.

I think we are seeing companies reduce the number of third-party channels they are using to a smaller — perhaps more reliable — group and even eliminating certain categories of customers where the compliance risk is too high. But I think the real challenge is for the smaller companies and newer entrants into international markets who really don't have the infrastructure that some of the larger companies do.

What role can a whistleblower play in an FCPA allegation?

Greenburg: One trend that we've seen for a while and that continues is whistleblowers. The SEC has a new whistleblower rewards program and I think people are raising issues — both legitimate and illegitimate. When whistleblower issues arise, companies really need to triage what needs to be investigated and by whom, and then conduct an appropriate investigation. That sometimes can be done by internal or local resources, but sometimes you really need people who have conducted very sophisticated and complex investigations — often that means outside counsel.

There are a range of ways to investigate these matters; there is no one size fits all approach. But I think it's critical that you do appropriately investigate so that you can figure out what's going on before the local authorities or the US authorities are investigating and ahead of you. From our perspective, there are a number of ways we collaborate with clients in the investigative context to figure out what the needs are and to tailor a response to the particular situation.

The one thing you cannot do is ignore evidence of real issues because that's a recipe to have much bigger issues down the road. And when concerns do arise and you've determined that there actually are issues, you really need to have an effective remediation plan. Remediation plans often have to go beyond looking at fixing the immediate problem. You often have to ask, "Why did the problem occur and is there a risk that this problem is occurring in other parts of the same country or in other parts of the company outside this country?"

Are non-US governments stepping up their anti-corruption enforcement activity?

Greenburg: Yes — we are seeing much greater enforcement activity from non-US governments. And I'm not so much talking about other countries enforcing their own equivalents of the FCPA; the real issue is countries that prosecute their own domestic anti-bribery laws. So for example, in China it is unlawful to pay bribes to officials. What we are seeing now in China is a much more aggressive effort by Chinese authorities to investigate and prosecute large western companies for paying bribes in China.

I think we are going to keep seeing more of that around the world. Everyone has to be sensitive to local law enforcement and aware of the fact that they are going to be more active. And there are a host of things that local law enforcement can in many places do that US authorities cannot, such as come in, arrest anyone they want and compel them to submit to interrogation. Countries around the world can and do raid offices, but often without the procedural protections that exist in the United States.

If a company is subject to an anti-corruption investigation in a non-US jurisdiction, that company — if it is subject to US jurisdiction — needs to think about the risks associated with the FCPA, what type of internal investigation needs to be conducted and what type of disclosure, if any, the company might want to make to US authorities before they find out about the anti-corruption investigation by some other means.

Are there particular issues that public companies need to consider?

Greenburg: US publicly listed companies are subject to the FCPA's internal controls and books and records requirements and need to remember that the SEC will enforce these requirements aggressively. They can come into play even in circumstances where it is not clear at all if a particular amount of money went to foreign officials. If you have a situation where you are paying a bunch of third parties under murky circumstances where you can't really document what services these third parties were rendering, you certainly could have an internal controls issue, you can have a books and records issue all irrespective of whether you have an anti-bribery issue.

So, it is important to create and maintain good records of your use of third parties. For example, if you have a consultant who is doing a study in conjunction with the approval of a certain drug in a particular country, you certainly want to document what that person was doing and keep that documentation. The last thing you want to have is a

record that you paid a substantial amount of money to a consultant but you can't actually show what the consultant was doing. Similarly, you want to do and maintain due diligence on who your third parties are, why they are legitimate and reputable parties. So, there is a whole compliance infrastructure that companies need to have in order to reduce their risks and also to properly defend themselves when these allegations are made.

For More Information

Download and read "[Three Practical Steps to Managing FCPA & Anti-Corruption Risks](#)."

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