

Lessons Learned from Pfizer's Settlement of FCPA Claims

BY THE GLOBAL COMPLIANCE & DISPUTES PRACTICE GROUP

On August 7, Pfizer H.C.P., an indirect wholly-owned subsidiary of Pfizer, Inc., entered into a two-year deferred prosecution agreement ("DPA") with the Department of Justice ("DOJ"), resolving FCPA violations in Bulgaria, Croatia, Kazakhstan, and Russia. In a related matter, Pfizer Inc. and Wyeth LLC, which Pfizer Inc. acquired in 2009, reached settlements with the Securities and Exchange Commission ("SEC"), resolving concerns in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia.

In its announcement of the settlement, the DOJ recognized "the significant efforts the company made to eliminate such improper practices, not only by implementing compliance reforms, but also by assisting U.S. authorities in our ongoing FCPA investigations of other companies and individuals." The DPA emphasized Pfizer's timely voluntary disclosure; its thorough and wide-reaching self-investigation of the underlying and related conduct; the "extraordinary" cooperation provided by the company to the DOJ and the SEC; its early and extensive remedial efforts; and the substantial and continuing improvements Pfizer has made to its global anti-corruption compliance procedures.

This Alert outlines some of the unique components of Pfizer's settlements and how they differ from other recent settlements, such as the requirements tailored to Pfizer's existing compliance program, the emphasis on Pfizer's internal investigation and remediation and the evolution in the U.S. Government's view of due diligence.

Pfizer's Compliance Commitments

Settlements with the U.S. Government typically include an appendix that outlines the standard, "best practices" compliance commitments to be undertaken by the company. While those compliance standards generally are included in Pfizer's settlements, the addenda to Pfizer's settlements largely reflect the Government's approval of Pfizer's extensive compliance program. Attachment C.1, for example, describes recognized best practices for compliance programs identical to those in last year's Johnson & Johnson ("J&J") DPA (that settlement was discussed in the Firm's April 2011 Stay Current).

As with the J&J DPA and other recent DPAs, Attachment C.1 acknowledges that Pfizer already had many standard best practices in place; a second addendum sets out enhanced compliance obligations largely tailored to Pfizer's existing compliance program. Indeed, the majority of the requirements in Attachment C.2 note Pfizer's strong compliance program and mandate that Pfizer maintain or continue its current practices, such as:

- having a sufficiently experienced Chief Compliance Officer and leaders of compliance within business units;

- existing gifts, hospitality and travel policies that form a part of its “enhanced anti-corruption policies and procedures”;
- the commitment of “enhanced resources” for the international functions of the Compliance Division;
- mechanisms for making and handling compliance reports and complaints;
- its program of annual proactive anti-corruption reviews of high risk markets;
- its FCPA trend analysis, tracking and reviewing certain categories of interactions with government officials and due diligence performed on agents and business partners;
- its process of risk-based due diligence on acquisition targets;
- its anti-corruption contract provisions for third party agreements;
- its training program; and
- its system of annual certifications confirming implementation of anti-corruption policies, procedures and controls.

By tailoring the company’s obligations to its existing procedures, the DPA recognizes Pfizer’s past improvements to its global anti-corruption compliance program and institutionalizes the program going forward.

Investigate and Remediate

Pfizer’s settlements post-date the J&J settlements even though Pfizer made an earlier initial voluntary disclosure in October 2004 and cooperated with investigators since that time. Given the length of the investigation, it is not surprising that the SEC and DOJ both commented on Pfizer’s ongoing remediation and program enhancements over the past eight years. These continued efforts are a reminder that, even during an investigation, companies can and should continue to improve their compliance systems and internal controls.

In referring to Pfizer’s extensive remedial actions, the SEC noted that Pfizer undertook a comprehensive worldwide review of its compliance program. The DPA also examined the various ways in which Pfizer conducts global reviews of its operations. These processes include a review of allegations identified by Pfizer’s internal investigations and a system of proactive FCPA reviews and enhanced audits. The DPA’s requirements for the FCPA proactive reviews (which the SEC describes as “innovative”) mirror the requirements in the J&J DPA for “FCPA Audits.” These reviews are to occur in five high-risk operating companies annually for J&J; Pfizer performs these reviews in approximately 10 markets annually. One of the key differences from the J&J DPA is that Pfizer’s proactive FCPA reviews are to be conducted by Compliance and Legal Division personnel, with participation by auditors where appropriate, while J&J’s reviews are to be conducted by audit personnel with participation by compliance and legal functions where appropriate. The Government has not indicated a preference for any particular approach, and we note that many of our clients differ in the approach to an internal investigation and/or FCPA review; the critical issue is to ensure that the department with the right balance of resources, understanding of the business, and knowledge of the applicable legal standards – including data privacy and labor law issues when collecting personal data – conduct the inquiry.

Pfizer also conducts enhanced audits in addition to these proactive FCPA reviews. Pfizer’s DPA sets forth the same non-exhaustive list of factors previously used in the J&J DPA to identify high risk

markets that should receive these reviews: (1) a high degree of interaction with foreign government officials; (2) the existence of internal reports of potential corruption risk; (3) a high corruption risk based on certain corruption indexes; and (4) financial audit results. Moreover, the DPA's list of steps that these proactive reviews should include is identical to those required of J&J's FCPA Audits.

Although the internal department or function leading FCPA reviews can vary by program, the DOJ's other requirements remain consistent, including a risk-based approach to conducting reviews and the overarching obligation that companies regularly evaluate their compliance programs through proactive reviews, investigation of internal reports and financial audits. Companies should take note of the government's view of factors that help identify high-risk markets and the steps recommended for proactive review of business operations in such markets.

Diligence Requirements for Third Parties and Acquisitions

The DPA reflects ongoing changes in due diligence requirements for third parties and acquired entities. For example, where J&J's settlement required it to ensure that new business entities are only acquired after "thorough FCPA and anticorruption" due diligence, if practicable prior to the acquisition, Pfizer's settlement adds that risk-based diligence is required "when practicable and appropriate on the basis of a FCPA risk assessment." Similarly, the description of diligence required for third parties indicates that Pfizer should conduct its risk-based diligence when appropriate on the basis of a FCPA risk assessment.

The difference in this requirement between the J&J and Pfizer DPAs in part reflects Pfizer's practice of performing risk assessments and tailoring due diligence to the results of such assessments, as the SEC recognized in noting that Pfizer undertook a risk-based FCPA due diligence review of Wyeth's global operations after its acquisition of Wyeth in 2009 and voluntarily reported its findings. Pfizer followed this 18-month due diligence review, which was conducted in consultation with the DOJ, by diligently and promptly integrating Wyeth's legacy operations into Pfizer's compliance program and cooperating fully with SEC investigators where deviations from best practices were found.

The change in the DPA requirements also demonstrates the Government's recognition of the challenges in conducting due diligence prior to every acquisition, the importance of a risk-based due diligence approach, and the reality that extensive due diligence might not be appropriate after a FCPA risk assessment. This view is much more in line with the global reality that, while a risk analysis is always needed, the extent of anti-corruption diligence performed by legal, accounting and compliance personnel will vary with the acquisition target. Given the current economic climate and the challenges companies face in allocating limited resources, companies should consider incorporating a risk-based approach to due diligence if not already in place.

Self-Monitoring and Reporting

The past several years have seen a trend whereby settlements permit companies to forgo independent monitors if they agree to self-monitor and report during established time intervals. The DOJ has allowed companies committed to improving their compliance programs to self-report on their improvements, pursuant to schedules and criteria set forth in the DPA. This practice has reduced the requirement for independent monitors. In the Pfizer settlements, the Government did not require a monitor, but required that Pfizer report the status of its remediation and implementation of compliance measures described in Attachments C.1 and C.2 at no more than nine-month intervals. This requirement is similar to past DPAs, although at longer intervals.

Conclusion

The Pfizer settlements join a recent trend highlighting the risks and challenges that global healthcare companies face. In most countries, healthcare companies regularly interact with healthcare

professionals who are considered government officials for purposes of the FCPA. Those interactions are not limited to traditional sales transactions but include investigator roles on clinical trials, speaking engagements and educational sponsorships, and consulting services related to new products. The addition of third parties in these relationships greatly heightens the corruption risks and requires adequate approval and further oversight.

The settlements are also a reminder of the Government's continued focus on this industry and the risks companies in this industry face given the multiple types of interactions with government regulators and other officials in the conduct of business. Despite these risks and ongoing Government investigations in this industry, Pfizer's DPA emphasizes the impact of a strong compliance program, regular reviews and oversight, ongoing enhancements to procedures and controls, and remediation. The DPA also indicates that in the face of a comprehensive compliance program, the Government's requirements will reflect business realities and may be tailored to the company's compliance practices and operating environment. Accordingly, businesses in this industry and others should take note and ensure they understand the risks in their industry, implement a strong internal compliance program, and take steps to enhance their compliance policies and procedures on an ongoing basis.

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