

On June 3, 2008 the United States Department of Justice announced the settlement of Foreign Corrupt Practices Act ("FCPA") charges against AGA Medical Corporation ("AGA"). AGA, a privately-held medical device manufacturer, agreed to pay a \$2 million criminal penalty and adopt certain compliance measures, including the appointment of a corporate monitor acceptable to the Department of Justice in exchange for deferred prosecution in connection with corrupt payments to Chinese government officials in violation of the FCPA. Between 1997 and 2005, AGA, a high-ranking officer of AGA and other AGA employees allegedly agreed to make corrupt payments to doctors in China who were employed by government-owned hospitals and caused those payments to be made through AGA's local Chinese distributor. In exchange for these payments, the Chinese doctors allegedly directed the government-owned hospitals to purchase AGA's products rather than those of the company's competitors.

The remarkable aspect of the AGA prosecution is its proportions. Over the past five years, the Department of Justice, along with the Securities and Exchange Commission and the FBI, has stepped up enforcement efforts with respect to the FCPA. Settlements have jumped into the millions of dollars and the frequency of FCPA enforcement actions have increased exponentially. While the AGA settlement comes nowhere near the \$44 million paid by Baker Hughes in its 2007 FCPA settlement with the Department of Justice and the SEC, the fact that AGA's annual revenues were less than \$150 million in 2007 indicates that the enforcing agencies are not so much concerned with the scale of the entity that violates the FCPA but rather, with the frequency of the fraudulent acts the entity perpetrated. Smaller device, pharmaceutical and biotech firms should be just as vigilant about compliance with the FCPA as their larger competitors are.

The FCPA generally prohibits bribery or other corrupt payments to foreign officials that are intended to facilitate obtaining or retaining business. The FCPA antibribery provisions apply to violations by both U.S. and foreign companies and persons (so long as the foreign company or person causes a prohibited act under the FCPA to take place within the territory of the U.S.). Violators of the FCPA may be subject to civil and criminal penalties of fines ranging from the hundreds of thousands to millions of dollars, and individuals who are found guilty of such violations may face up to five years of imprisonment. While the FCPA is applicable to all sectors doing business abroad, it is particularly relevant to the business practices of the pharmaceutical, biotech and durable medical equipment industries, as well as certain research institutions, as these entities often operate multinationally and interface with foreign officials on a regular basis to gain access to markets or permits for studies. "Foreign officials" not only include government bureaucrats, but also doctors, nurses, and any other staff of a state-run hospital or other medical facility, so even an industry-funded trip to a medical conference for a state-employed doctor can implicate the FCPA if it meets certain criteria. While a single instance of a small corrupt payment like an all-expenses paid trip may not trigger a response from the federal government, patterns of smaller bribes (such as the ones paid by AGA to Chinese officials) are often viewed similarly to large payouts.

The FCPA allows for a so-called "grease payment" exception, where facilitating payments to merely accelerate routine government actions (e.g. obtaining permits, licenses or other official documents, expediting lawful customs clearances, etc.) are acceptable under very limited circumstances when permitted under local law. Only such payments for actions that are wholly unconnected to the award of new business or the continuation of prior business would be acceptable under the FCPA.

In order to ensure compliance with the FCPA, any healthcare entity with an international presence should consider taking the following measures:

- Implement a comprehensive policy that addresses what businesses practices are acceptable or unacceptable in foreign markets. The policy should also address the applicability of the “grease payment” exception.
- Incorporate detailed written procedures governing, among other things, gifts and hospitality, meetings, consultant arrangements, charitable contributions, research and other grants with foreign officials. Such procedures should also define who constitutes a foreign official and discuss the implications of local anti-corruption regulations alongside an explanation of the FCPA.
- Institute a periodic audit of internal operations to ensure the entity’s own compliance with the FCPA and implement annual certification requirements for consultants and service providers that ensure that third party contractors are also complying with the FCPA.
- Most importantly, entities should train employees both at the entity’s headquarters and in local jurisdictions in a culturally sensitive fashion so that they fully understand and follow the mandates of the FCPA.

Moses & Singer can help entities to determine whether they are affected by the FCPA, and, if so, how they can best comply with its requirements. We can provide regulatory and compliance advice, drafting of relevant agreements, as well as assistance in the context of FCPA-related investigations and legal proceedings.

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