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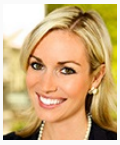
Channing Landreth (channing.landreth@labcorp.com, linkedin.com/in/channing-landreth-b3797511/) is Associate Vice President, Managing Counsel, at Labcorp, Burlington, NC.



Lindsey Fetzer (lfetzer@bassberry.com, linkedin.com/in/lindseyfetzer/) is Partner at Bass Berry & Sims, Washington, DC.

Thad McBride (tmcbride@bassberry.com, linkedin.com/in/thad-mcbride-8407b445/) is Partner at Bass Berry & Sims, Washington, DC.

Update on the Foreign Corrupt Practices Act: Considerations for healthcare companies

by Channing Landreth, Lindsey Fetzer, and Thad McBride

The United States government continues to aggressively enforce the Foreign Corrupt Practices Act (FCPA), the principal US law for combating corruption and improper business dealings abroad. Enforcement efforts especially target heavily regulated companies, which means regular interaction with government officials.

Given its regulatory burden, the healthcare industry—including pharmaceutical, medical device, and biotechnology companies—is particularly vulnerable to FCPA issues.

This article summarizes both the FCPA itself and specific challenges for healthcare companies. It also outlines enforcement actions involving healthcare companies. The article concludes with lessons learned from those enforcement actions—and the specific challenges healthcare companies face—along with some suggested compliance best practices.

Background

At base, the FCPA is quite simple: it prohibits bribes, whether actually made or simply offered or promised, to officials and other employees of non-US governments. In addition, the law includes internal controls and books and records requirements that apply to companies that are publicly traded in the US.

The law is administered by the Department of Justice (DOJ) and, in the case of publicly traded companies in the US, the Securities and Exchange Commission (SEC).

The FCPA was first enacted in 1977 but was not consistently enforced until the early 2000s.[1] In fact, one of the earlier FCPA enforcement resolutions was a 2003 settlement between the SEC and pharmaceutical company Schering-Plough Corporation (now part of Merck & Co.).[2] The matter involved Schering-Plough purportedly making donations to a Polish charity whose director was also a Polish government health procurement official. According to the SEC, although the donations were not to the government official directly, they were for his

benefit and were intended to improperly influence his procurement decisions.

In the last decade, DOJ and SEC have brought enforcement actions against more than 20 healthcare companies resulting in nearly $2 billion in disgorged profits or fines.[3]

Permissible domestic practices could run counter to the FCPA

An array of US statutes, such as the federal Anti-Kickback Statute (AKS), regulate the domestic behavior of healthcare companies and their employees.[4] The AKS prohibits life sciences and healthcare companies from "knowingly and willfully" offering or paying "remuneration," directly or indirectly, to induce patient referrals, reward a referral source, or generate business involving any item or service "for which payment may be made in whole or in part under a Federal health care program." This prohibition—on a payment to obtain a business advantage—mirrors the language of the FCPA.

Yet, the AKS also includes important safe harbors for payments that facilitate interactions between healthcare companies and healthcare professionals. For example, the AKS recognizes that healthcare companies often engage medical professionals to serve as advisers, speakers, and consultants. Such arrangements are permitted under the AKS so long as certain conditions are met.

The FCPA lacks this same sort of safe harbor. In fact, DOJ and SEC appear to be generally skeptical of such engagements in the international context and have brought several enforcement actions related to payments to foreign healthcare professionals as consultants, speakers, or for clinical trial fees.