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Lessons learned: Anti-bribery enforcement trends in healthcare

By Robert Clark, JD

Robert Clark (rclark@traceinternational.org) is Manager of Legal Research, TRACE, Annapolis, MD.

Throughout the pandemic, the healthcare and pharmaceutical industries have received outsized attention. From the early scramble by hospitals to secure ventilators and personal protective equipment, to the sprint by drug companies to develop effective treatments and vaccines, this public health crisis has highlighted the pressures and challenges faced by the institutions we rely on for our safety and well-being. Coincidentally, the healthcare and pharmaceutical industries have also received a recent increase in attention from US anti-bribery enforcement agencies, both domestically under the Anti-Kickback Statute and abroad under the Foreign Corrupt Practices Act (FCPA). According to TRACE's publicly available *2020 Global Enforcement Report*, healthcare is the fourth most prosecuted industry under the FCPA.[1]

The cases generally follow a straightforward pattern: A company's employees or agents provide monetary and other incentives for healthcare providers to recommend or prescribe their companies' products to their patients. The incentives are sometimes conveyed in nominally legitimate forms, like hosting product demonstration dinners or sponsoring physicians' participation in professional conferences. But upon closer inspection, the ruse becomes evident.

This kind of manipulation is harmful enough under any circumstances and can become outright catastrophic when it leads, for example, to the overprescription of addictive and life-threatening substances like synthetic opioids. While not every case is that dire, they all raise concerns that should matter to any healthcare or pharmaceutical company, both as a matter of ethics and from the perspective of law enforcement. We can find some of these concerns illustrated in the three major healthcare and pharmaceutical FCPA cases that were settled in 2020.

Cardinal Health: When halfway is not enough

When it acquired its way into the Chinese market in 2010, Cardinal Health—a giant multinational distributor of pharmaceuticals and medical products—knew there was some cleaning up to do.[2] The subsidiaries it had bought from another distributor maintained excess distribution margin accounts for certain suppliers from which they would make marketing payments at the direction of the suppliers. Recognizing the massive compliance risk of carrying another party's marketing expenses on its own books, Cardinal Health promptly terminated most of those accounts—but not all of them.

Specifically, there was one European supplier of over-the-counter dermocosmetic products—cosmetics with dermatologically therapeutic properties—for which Cardinal Health decided there was a minimal likelihood of trouble under the FCPA. The relationship between the companies went beyond accounting: Approximately 2,400 of the supplier's workforce—retail, sales, and marketing personnel—were formally employed by Cardinal Health under a human resources services agreement, though they continued to be actively supervised by the supplier rather than by Cardinal Health. These employees conducted their work using the supplier's computer and email systems, giving Cardinal Health no visibility into their activities.

This was a huge blind spot in Cardinal Health's compliance program, worsened by the company's failure to provide anti-bribery training to the supplier's workforce or to implement documentation controls for payment requests from the supplier's marketing team. In hindsight, the occurrence of corrupt activities comes as little surprise. Of the more than $250 million of approved marketing expenditures, an unhealthy amount found its way into the hands of government-employed healthcare providers and retailers, whether as cash, luxury items, gift cards, or travel expenses.

Even when Cardinal Health knew of the dangers, it failed to adequately address them. It had terminated the marketing accounts of other manufacturers upon learning of alleged improprieties but continued ignoring the most concerning red flags associated with the dermocosmetic company. Though concerns were raised internally, the company's inaction persisted for several years, even after it was fined by Chinese authorities for giving improper in-kind commissions to retail sales personnel. Finally in 2016, Cardinal Health's compliance team conducted a proper audit and reported the evidence to the company's home office. Cardinal Health would go on to voluntarily self-report to the U.S. Securities and Exchange Commission and undertake appropriate remedial measures. But its late awakening was not enough to spare it from a $2.5 million civil fine as well as disgorgement, or return, of $5.4 million in illegal gains, plus interest.

Cardinal Health doesn't seem to have been looking for trouble. It recognized compliance risks in a new market and took steps to mitigate them. But it didn't go far enough.