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# Global Anti-Corruption Enforcement in the Life Sciences Industry: Trends, Risks & Best Practices in 2021

July 23, 2021

Nick A. Mongelluzzo | W. Warren Hamel

## Overview

The life sciences industry continues to face many unique anti-corruption challenges associated with the reality of doing business in jurisdictions around the world with complex regulations and deep public sector involvement in the provision of health care services. Unlike many multinationals, life sciences companies must contend with government involvement in nearly every aspect of their business: from research and development to approval and production all the way through distribution and the final sale. Anti-corruption enforcement from U.S. agencies and others across the globe is trending upward (in both frequency and the size of financial penalties) and there are strong indications of a continued emphasis on the health care sector over the next several years. Examination of recent settlements in the industry provide insight into some of the unique risks facing life sciences companies, as well as recommended best practices.

## Global Enforcement Trends

Global enforcement of anti-corruption laws has markedly increased since 2010. The United States remains the primary enforcer of bribery and anti-corruption laws world-wide, although the United Kingdom, France, Brazil, South Korea and several others countries have continued to increase enforcement in recent years and are poised to make up an even larger share of total international enforcement activity in the future. Life sciences companies operating internationally can expect increased multilateral cooperation involving multiple enforcement agencies and overlapping laws in the coming years.

## United States

The United States Department of Justice (DOJ) and Securities & Exchange Commission's (SEC) joint enforcement of the Foreign Corrupt Practices Act (FCPA) remains the predominant enforcement mechanism of international anti-corruption law. In the past five years (2016-2020) the U.S. enforcement agencies brought 217 enforcement actions in connection with FCPA violations in nearly every continent, up from 144 actions in the preceding five-year period (2011-2015). The past three years have notably seen expanded use by DOJ of criminal statutes other than the FCPA to combat international corruption, including the money laundering and mail and wire fraud statutes, as well as the Travel Act to charge bribery-related conduct. Such prosecutions were relatively rare prior to 2016 (less than 10 between 2011 and 2015) but increased to over 70 in the most recent five-year period (with 19 in both 2019 and 2020).

Companies involved in health care (including pharmaceuticals and medical devices) continue to be a major target for U.S. enforcement, with over 60 total FCPA-related matters concluded as of 2020. Only the oil and gas industry has been the subject of more FCPA matters. In 2009, a then-DOJ Assistant Attorney General (AAG) stated at the 22nd National Forum on the FCPA that "One area of focus will be overseas sales in the pharmaceutical industry. In some foreign countries . . . nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product may involve a 'foreign official' within the meaning of the FCPA..." In a prior 2009 speech to the Pharmaceutical Regulatory and Compliance Congress, the AAG said "Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in your industry." In 2016, the then-SEC FCPA Unit Chief declared the SEC was "going back to the pharma industry after a

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break for a period of years.” Since 2011, the DOJ and SEC have brought enforcement actions against 23 life sciences companies with over \$1.7 billion in total fines, penalties, and disgorgement.

## International Activity

There has been a marked increase in recent years in the frequency and size of enforcement actions by European agencies. The UK continues to lead Europe in major anti-corruption enforcement matters and has shown that it will cooperate with enforcement agencies in the United States, the EU, Asia and South America. Several European countries, France chief among them, have also increased their involvement in international enforcement actions in recent years. The largest international anti-corruption settlement in history occurred in 2020, a €3.6 billion global settlement between Airbus and enforcement agencies in France, the United Kingdom, and the U.S. European agencies have been involved in many of the major anti-corruption investigations over the last five years: an investigation into a multinational construction company in 2016 (\$3.5 billion resolution with the U.S., Brazil, and Switzerland); Vimpelcom in 2016 (\$795 million resolution with the U.S. and the Netherlands); Telia in 2017 (\$965 million resolution with the U.S., the Netherlands, and Sweden); and Société Générale in 2018 (\$585 million resolution with the U.S. and France). European agencies have also brought numerous actions where the U.S. was not involved or declined to bring an action, for example, Hempel in 2019 (€30 million resolution with authorities in Denmark and Germany).

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**“Good corporate citizens within the pharmaceutical and medical device industries invest heavily in their compliance programs. And they need to do so. Most of you operate in a heavily regulated space, and the risks of non-compliance are high.”**

– Former DOJ Assistant Attorney General Speaking at the 20th Annual Pharmaceutical and Medical Device Compliance Congress, November 6, 2019

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Numerous countries in Asia, Africa and South America have also increased their footprint in the international anti-corruption space. China adopted amendments to its Criminal Law that took effect in March 2021 that allow for increased punishment for corrupt conduct by individuals in the private sector and has continued to vigorously target domestic corruption. In June 2020, Malaysia passed a law establishing corporate criminal liability for corruption offenses in the wake of the 1MDB scandal. South Africa has launched numerous investigations regarding international companies paying bribes domestically, including a renewed prosecution of French defense company Thales in February 2021. Latin American countries, including Brazil, Argentina, and Colombia, and often in partnership with U.S. agencies, have actively enforced their anti-corruption laws, including those rising from the continent-wide fallout of the recent Brazilian corruption investigations into state-controlled energy and international construction companies.

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## U.S. Enforcement Actions in the Life Sciences Industry (2016 – 2020)

The life sciences industry has seen a flurry of FCPA enforcement activity in recent years. In 2020 alone DOJ and SEC brought four actions against U.S. and international pharmaceutical and medical device companies for \$500 million in total fines, penalties, and disgorgement, and imposed future reporting obligations. The underlying conduct involved in the settlements reached in the past five years stretched as far back as 2001 and spanned dozens of countries in every continent except Antarctica. The allegations predominantly involved bribery of doctors, hospital staff and other health care workers in relation to the purchase or prescription of pharmaceuticals or medical devices. Some of the U.S. enforcement actions in the industry in the past five years include the following resolutions.

**SciClone Pharmaceuticals.** 2/4/2016. SciClone resolved an SEC investigation into its operations in China including allegations that the company violated the FCPA's books and records and internal controls provisions by making improper payments to employees of state-run health care institutions. The conduct alleged included the provision of vacations to administrators of important clients, regular dinners for the families of clients' employees, and lavish entertainment at SciClone events in connection with pharmaceutical orders and licensing approvals. SciClone paid \$12.8 million in combined disgorgement, interest, and penalties to resolve the allegations.

**Nordion Inc.** 3/4/2016. Nordion settled an SEC investigation into its operations in Russia including allegations the company violated the books and records and internal controls provisions of the FCPA in connection with a former employee's related bribery of Russian government officials. According to the settlement, the former employee retained a third party agent with the intent of funneling bribes to a government official in connection with the approval of Nordion products, eventually paying over \$200,000 to the agent. Nordion paid a \$375,000 penalty to settle charges that it lacked basic internal controls and accurate books and records required by the FCPA. The employee involved in the conduct separately settled with the SEC.

**AstraZeneca.** 8/30/2016. AstraZeneca settled an SEC investigation involving allegations that its subsidiaries in China and Russia made improper payments in the form of cash, gifts, and other items to foreign health care providers as incentives to purchase or prescribe AstraZeneca pharmaceuticals. The SEC alleged that between 2005 and 2010, AstraZeneca sales staff set up bank accounts in doctors' names and made deposits, used fake tax receipts to secure reimbursements for fictitious expenses, and colluded with a travel agency to generate fake invoices to fund the payments in question. According to the SEC, AstraZeneca China sales staff and their managers maintained written charts and schedules that recorded the amount of forecasted or actual payments of maintenance fees, gifts, entertainment, and other expenses that the company would make per month or year in numerous regions throughout China. AstraZeneca paid \$5.5 million in combined disgorgement, interest, and penalties to resolve the allegations.

**GlaxoSmithKline (GSK).** 9/30/2016. GSK settled an investigation by the SEC involving allegations that between 2010 and 2013 China-based GSK subsidiaries engaged in pay-to-prescribe schemes that involved the provision of gifts, improper travel and entertainment, shopping excursions, family and home visits, and cash to health care professionals in China. According to the SEC, the costs associated with these payments were recorded in GSK's books and records as legitimate expenses, such as medical association sponsorships, employee expenses, conferences, speaker fees, and marketing costs. The payments to these health care professionals allegedly resulted in millions of dollars in increased sales of GSK pharmaceutical products. GSK paid \$20 million in combined disgorgement, interest, and penalties and agreed to provide status reports to the SEC for 2 years.

**Teva Pharmaceutical.** 12/22/2016. Teva settled a joint DOJ-SEC investigation into FCPA violations including allegations it made illicit payments to obtain regulatory formulary approvals and favorable drug purchase and prescription decisions. In

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Russia, Teva contracted with a repackaging company that was owned by an official at the Ministry of Health, who earned roughly \$65 million through the agreement. In Ukraine, Teva hired a government official as a consultant and paid him approximately \$200,000 through monthly fees and travel expenses. In Mexico, Teva paid government-employed doctors to drive prescriptions. The DOJ said Teva's policies were unable to detect or stop the bribery and the managers overseeing compliance were "unable or unwilling" to enforce the company's anti-corruption program. Teva was required to retain an independent corporate monitor for at least three years and paid \$519 million in combined disgorgement, interest, and penalties.

**Orthofix International.** 1/18/2017. Orthofix settled an SEC investigation into violations of the FCPA's books and records and internal controls provisions stemming from allegations that between 2011 and 2013 senior personnel at Orthofix's Brazilian subsidiary made improper payments to doctors at government hospitals to induce them to use Orthofix products. Orthofix provided high discounts to third parties and paid illegitimate invoices for fictitious services to generate the funds for the bribes and inaccurately recorded these costs on its books and records. A repeat FCPA offender, Orthofix was required to retain an independent compliance consultant to review and test its FCPA compliance program and pay over \$6 million in combined disgorgement, interest, and penalties.

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**"Bribery in connection with pharmaceutical sales remains a significant problem despite numerous prior enforcement actions involving the industry and life sciences more generally."**

– Former SEC FCPA Unit Chief, Sanofi Settlement Announcement, September 4, 2018

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**Cardinal Health.** 2/28/2020. Cardinal settled an SEC investigation into a Chinese subsidiary it acquired in 2010 relating to improper payments made to health care workers to drive sales. Cardinal's subsidiary held marketing accounts for a European dermocosmetic company whose products it distributed. The European company directed Cardinal's subsidiary's employees, who used account funds to make illicit payments to government health care professionals and employees of state-owned retail companies who had influence over purchasing decisions. The profit-sharing agreement with the European company provided Cardinal with a percentage of profits from sales. Despite terminating certain marketing contracts and taking other remedial measures upon learning of the conduct, Cardinal did not fully investigate associated accounts and continued making payments into 2016. Cardinal agreed to pay \$8.8 million in combined disgorgement, interest, and penalties to resolve the alleged violations of the FCPA's books and records and internal accounting controls provisions.

**Herbalife Nutrition Ltd.** 8/28/2020. Herbalife resolved a joint DOJ-SEC investigation into books and records violations in connection with its operations in China between 2006 and 2016. According to the resolutions, Herbalife employees paid Chinese authorities with decision making authority in connection with the approval of licenses in 2006 and continued to make payments over a ten year period to encourage the sale of Herbalife products, totaling \$25 million in entertainment and gifts to Chinese officials. Herbalife agreed to pay a total of \$123 million in fines, disgorgement, and interest to resolve the investigations.

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## Corruption Risks in Life Sciences

### Sales

The payment of bribes to drive sales remains the primary corruption risk to life sciences companies. Because of the government's involvement in health care procurement in most of the world, doctors, hospital staff and health care administrators responsible for pharmaceutical procurement and prescription are typically considered "foreign officials" for the purposes of the FCPA. Like the enforcement of the Anti-Kickback Statute and related domestic laws in the U.S., payments made to doctors and health care administrators to induce the purchase or sale of drugs abroad may fall under the FCPA's bribery provisions. Mischaracterizations of honoraria, consulting fees, discounts, partner expenses, or any other payments to these individuals, directly or indirectly, may implicate the FCPA's accounting provisions even where bribery cannot be proven.

*Careful attention to expenditures related to research, marketing, distribution, or sales in high risk jurisdictions is a necessary component of a well-functioning anti-bribery compliance program. Life sciences companies must monitor the purpose and size of such payments as well as the reputations, connections, and credentials of recipients.*

### Price Controls and Regulatory Approvals

Many countries regulate the sale of pharmaceuticals through price controls and virtually all require some level of regulatory approval before domestic sale is permitted. The regulatory bodies that control pharmaceutical sale prices and approvals vary by jurisdiction, but often involve individuals considered foreign officials under the FCPA, UK Bribery Act, and other anti-corruption laws. Interactions with and payments to these individuals, including those done by third party agents, must be scrutinized to avoid potential bribery allegations.

*Public source searches for "politically exposed persons" (PEPs) may not be sufficient to identify individuals with responsibility for price or regulatory determinations. Additional due diligence, including individualized background reviews, consultant, and broker anti-bribery certifications, and analysis of payment amounts compared to end consumer payments and those paid to potentially related parties, may need to be conducted.*

### Research Abroad

Life sciences companies have dramatically increased the number of clinical trials conducted overseas in recent years. While there are myriad reasons for doing so, these trials create both an opportunity for, and avenue to, facilitate bribery. Clinical trials conducted abroad are often supervised and investigated by local medical personnel, who as previously discussed, are often considered foreign officials in many instances for purposes of the FCPA. These individuals, often comparatively underpaid by U.S. standards, may be susceptible to bribery in return for approval of drugs for sale in their country. The clinical trials themselves may also be unnecessary or duplicative efforts with the true intention of marketing the company and its products to foreign officials (while paying them).

*Life sciences companies conducting clinical trials abroad should pay particular attention to the purpose of the trial and the investigators conducting the trial. If the trial is being conducted for the purpose of approval in another jurisdiction in which the clinical results would not be acceptable, the trial itself may be called into question for ulterior motives. A trial with otherwise valid purposes that uses an inordinately large number of local investigators or consultants, or which pays excessive fees to such consultants, may also be called into question.*

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*It is important to note that even non-government employed doctors or health care personnel may pose corruption risks. In addition to local versions of the Anti-Kickback Statute, many international anti-bribery laws criminalize corporate bribery. The FCPA accounting provisions, and other previously noted laws, may pose another source of liability.*

## High-Risk Avenues for Corrupt Payments

The usual suspects for potential bribery risks apply to life sciences companies: excessive payments to consultants, brokers, distributors, or third-party agents; gifts, hospitality, entertainment, and travel expenses to PEPs or related third parties; and contributions or payments to charities or businesses associated with PEPs. Additionally, life sciences companies operating abroad also often require complex distribution channels involving multiple partners, storage, and marketing expenses, as well as bona fide consultants for identifying leads and navigating complicated regulatory processes. Life sciences companies should also be aware of the potential for:

- Speaker fees and honoraria.
- Falsified or over-priced storage contracts.
- Inflated invoices to customers or channel partners.
- Joint ventures with enterprises associated with foreign officials.
- Concealed payments through customs brokers.
- Misused or falsified marketing and promotional expenses.
- Falsified reimbursement requests or cash distributions.
- Excessive margins or discounts for distributors or channel partners.
- Research grants or regulatory investigator costs.

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**“Pharmaceutical representatives have regular contact with doctors, pharmacists, and administrators from public hospitals in foreign countries. Those people often are classified as foreign officials for the purposes of the FCPA, and they often decide what products public hospitals or pharmacies will purchase. This influence over the awarding of contracts is true for virtually every country around the globe.”**

– Former Director, Division of Enforcement, SEC, Pharmaceutical Compliance Congress, March 3, 2015

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## Expectations for 2021 and Beyond

We expect increased resources and attention to anti-corruption efforts both from the United States and abroad in 2021 and for the foreseeable future. Despite the disruption of the COVID-19 pandemic, there were four U.S. enforcement actions against life sciences companies in 2020. President Biden and senior officials in the administration in 2021 have promised an increased focus on both domestic and foreign anti-corruption enforcement. Internationally, many countries are retooling their anti-corruption regimes to allow for more corporate enforcement, including FCPA-sized monetary penalties and deferred prosecution agreement corporate resolutions. Additionally, we expect to see:

- Expanded use of the accounting provisions of the FCPA to penalize companies for suspected corrupt conduct where DOJ cannot bring a bribery charge. *Where a suspected bribery violation cannot be confirmed, DOJ and SEC may still pursue associated books and records, or internal controls violations. Foreign anti-bribery laws with different scopes and jurisdictions (including private or corporate bribery) provide additional avenues for pursuing conduct not covered by the FCPA.*
- Increased use of non-FCPA mechanisms, including the money laundering, mail fraud, and wire fraud statutes to target corrupt conduct outside the scope of the FCPA. *Private sector bribery (including receipt of a private sector bribe) is not covered by the FCPA, but it may run afoul of another tool in the government's arsenal and other foreign bribery laws, such as the UK Bribery Act.*
- Increased enforcement from non-U.S. enforcement agencies, including increased cooperation and information sharing between those agencies. *Expect multiple regulators to become involved where conduct involves activity in multiple countries.*
- Higher regulator expectations of corporate compliance program design and efficacy, and implementation of robust internal remediation measures where misconduct is (or should have been) identified. *Revisions to DOJ's Evaluation of Corporate Compliance Programs indicate that gathering data through compliance monitoring without revising risk assessments and addressing potential misconduct will weigh against a company's argument that it had an effective compliance program in place.*
- Increased whistleblower activity and higher whistleblower awards. SEC revised its whistleblower awards program in September 2020 to promote efficiency and expand protections. *The frequency and size of whistleblower awards have been increasing and we expect these trends will continue.*
- Continued use of investigation methods not typically associated with FCPA enforcement, including use of undercover agents, confidential informants, and wire taps. *Third party due diligence, employee training and active transaction monitoring remain the best defenses against potential bribery misconduct.*

Venable has many attorneys who are well versed in bribery and anti-corruption matters and has advised multinationals from initial design and implementation of compliance programs through internal investigation and, where required, necessary interactions with government authorities. Please reach out to one of our several anti-corruption attorneys with any questions or issues that may arise.