Vol. 6, No. 11 June 7, 2017 PRINT E-MAIL

BRAZIL

Time to Clean Up: What Life-Sciences Companies Need to Know About Brazil's Operation Car Wash

By Gary Giampetruzzi, Jonathan Stevens, and Thiago Ribeiro
Paul Hastings

In 2014, the Federal Police of Brazil initiated a well-known and now far-reaching investigation referred to as *Operação Lava Jato* (Operation Car Wash). The investigation originally focused on corruption at the state-controlled oil company Petróleo Brasileiro, S.A. (Petrobras) following allegations that top executives accepted kickbacks in return for awarding contracts to a cartel of construction firms at inflated prices. Since pulling on that initial string, Brazilian prosecutors have unraveled an intricate web of corrupt payment streams that reach the highest levels of government and span various sectors and political parties.

Because Operation Car Wash was initially directed at Petrobras and construction companies, much of the public focus has been on kickbacks and bribes associated with large public energy and infrastructure contracts. However, as judges and investigators continue to probe the corrupt payment streams and investigators make use of advanced techniques such as strategic plea bargains, other politicians and sectors are being drawn into the fray.

Many industry observers believed it was only a matter of time before prosecutors turned to some of the medical device and pharmaceutical distributors identified in the probe and focus on graft and kickbacks in the public-health sector. The first real move in that direction occurred recently when authorities arrested the former Secretary of Health for the State of Rio de Janeiro and the owners of a large medical device distributor for alleged fraud, kickbacks, price fixing and bid rigging, as well as active and passive corruption associated with public contracts. The corrupt scheme centered around executives from a well-known medical device distributor, a public trauma and orthopedic institute in Rio de Janeiro, and a cartel of companies that colluded to inflate prices and bribe public officials.

Operation Car Wash Details: New Politicians and Companies Implicated

What started as an investigation into a money-laundering and currency-exchange ring run out of the Posto de Torre gas station in the Federal District of Brasilia has evolved into a country-wide initiative to root out public corruption. The Operation Car Wash Task Force, led by prosecutors from the 13th Federal Court in Curitiba, Paraná (some of whom notably trained in the United States) has successfully used a number of strategic plea bargains to uncover more than R$6 billion (US$1.8 billion) in bribes to public officials.

Uncovering an Off-Shore Slush Fund

Recent testimony and evidence gathered from construction company executives helped Brazilian authorities to decode key communications and spreadsheets detailing a massive off-shore slush fund referred to as *Caixa Dois.* The fund was allegedly used to make unrecorded political contributions to numerous politicians, including to Brazil's last four presidents – Fernando Henrique Cardoso, Luiz Inácio Lula da Silva, Dilma Rousseff, and Michel Temer.

More Than 300 Investigations of Public Officials

Though recent headlines have focused on current and former presidents, Operation Car Wash has permeated every level of government. The Brazilian Supreme Court, which retains constitutional jurisdiction to prosecute criminal actions against high-ranking federal officials, recently released a list of 108 public officials, including nine current ministers in President Michel Temer's Cabinet, 29 senators, 42 representatives, and numerous governors, mayors, and former public officials that will be formally investigated for acts of corruption. A second list details 201 new cases under investigation that will be filed in lower courts of competent jurisdiction.

New Evidence of President Temer's Involvement in Corruption

Brazil fell further into crisis recently when one of the country's largest news outlets shared excerpts from an alleged secret recording of current President Michel Temer. The recording appears to capture Temer approving payoffs to Eduardo Cunha, the incarcerated former speaker of Brazil's lower chamber and the architect of last year's impeachment of former president Dilma Rousseff, in exchange for Cunha's silence in the Operation Car Wash probe.

The tape was reportedly submitted to the Supreme Court by Joesley Batista, an executive from J&F Investimentos S.A., as part of a leniency agreement with the Brazilian Federal Prosecutor's Office. J&F Investimentos S.A. owns JBS S.A., the largest meat-packing consortium in the world, and has major holdings in the commercial banking, pulp and paper, and electricity sectors, among others. According to reports, Joesley Batista, his brother Wesley Batista, and other top executives provided evidence of R$600 million ($187.5 million) in illicit payments to approximately 1,900 politicians in exchange for political favors and access to capital from Brazil's development bank, BNDES. In the largest settlement of its kind, J&F Investimentos S.A. just reached an agreement in principle with the Brazilian Federal Prosecutor's Office to settle the financial penalty aspect of its leniency agreement for R$10.3 billion (US$3.2 billion).

As of now, President Temer has signaled that he will not resign. However, many experts believe that these most recent revelations could lead the country to impeach its second president in less than nine months due to corruption.

Operation Mr. Hyde Uncovers More Corruption in the Life-Sciences Sector

In early 2015, while Operation Car Wash was gaining traction, an investigative journalism piece from one of Brazil's most popular television programs, *Fantástico*, garnered national attention for exposing the widespread practice of providing 10 to 30% commissions or kickbacks to physicians in exchange for the use of certain orthopedic, cardiology, and neurology medical devices. Distributors and manufacturers admitted on hidden cameras to splitting their profits with physicians or, if possible, inflating the price of products to provide funds for the commission or kickback. Likewise, it was discovered that physicians were falsifying records and performing unnecessary procedures for personal gain.

Legislative Hearings

The *Fantástico* exposé resulted in legislative hearings, numerous indictments and criminal charges, and the imprisonment of close to 30 individuals as part of an operation referred to as *Operação Mr. Hyde* (Operation Mr. Hyde). The legislative hearings focused on several distributor practices, including:

- the practice of selling products to federal, state and municipal governments through "emergency contracts" that are not subject to statutorily required public bidding or other competition;
- the practice of selling the same product to customers in different areas at significantly different prices; and
- the provision of continuing medical education and travel to HCPs.

Proposed Legislation

Following the hearings, the Brazilian Senate drafted Federal Act Proposal 17/2015 (Act). The proposed Act, among other things, seeks to regulate pricing in the orthopedic, prosthetic and implantable medical device market in the same way that the Câmera de Regulaçao do Mercardo de Medicamentos (CMED) agency oversees pharmaceutical drug pricing. Under such a regime, the government would set a maximum sales price for medical devices in both the private and public sectors. The Act further sets forth specific penalties and fines for companies, distributors, hospitals and doctors that engage in illicit commissions and kickbacks, ranging from three times to 15 times the value of the payment.

The "Tip of the Iceberg"

The lead prosecutor from one organized crime unit that oversaw Operation Mr. Hyde publicly signaled that this is just the "tip of the iceberg." Public audits have revealed that many public hospitals and publicly reimbursed health plans were paying significantly more than market price for various products and the prosecutor referred to current efforts as "the initial phase" of uncovering a much larger scheme.

Several investigations similar to Operation Mr. Hyde are underway in a handful of states. Those investigations have uncovered schemes where suppliers to both private and public hospitals have allegedly required companies to provide kickbacks ranging from 10 to 20% of the underlying contracts in order to sell to the hospitals. To disguise their true nature, the kickbacks were described as "marketing fees."

Within the last few months, the fallout from Operation Mr. Hyde has spilled across Brazil's borders. In an unprecedented maneuver, in December 2016, ABRAMGE, an association of 177 private health insurance companies and medical providers in Brazil, sued several prominent, global medical device manufacturers in U.S. federal court. ABRAMGE alleged that the companies paid millions in kickbacks to Brazilian doctors to entice the doctors to use the companies' medical products, regardless of the need for or cost of the products. Many of these companies have moved to dismiss the claims brought by Abramge, arguing that they are without legal merit.

Operation Exposed Invoice Uncovers Corruption at Medical-Device Distributor

In April 2017, on the heels of Operation Mr. Hyde, another investigation conducted by the Operation Car Wash Task Force, *Operação Fatura Exposta* (Operation Exposed Invoice), centered around the former Governor of the State of Rio de Janeiro, Sergio Cabral, who was arrested in November 2016 for allegedly receiving more than R$100 million (US$31.2 million) in bribes and illicit payments related to public works and construction contracts. Information leading to his arrest was gathered in two earlier investigations, *Operação Calicute* (Operation Calcutta) and *Operação Eficiência* (Operation Efficiency), which uncovered corruption during Cabral's 2007 to 2010 and 2011 to 2014 terms.

According to federal prosecutors, Cabral designed the kickback scheme at the time he named Sergio Côrtes as Secretary of Health for Rio de Janeiro in 2007. Allegedly, Cabral, Côrtes and other public officials required kickbacks of 10% to be paid in connection with national and international bids for medical devices purchased by the *Instituto de Traumato-Ortopedia* (INTO) and the State Secretary of Health. Apparently, Cabral would retain 5%, Côrtes would retain 2%, and the remaining 3% would be disbursed amongst the other scheme participants in the form of monthly stipends, international trips and other in-kind transfers. Investigators estimate that between 2007 and 2017, the fraud resulted in over R$300 million (US$93.7 million) in misappropriated funds.

The illegal behavior was initially exposed by Côrtes' former Deputy Secretary, César Romero. As part of his plea agreement, Romero provided prosecutors with detailed testimony and evidence on how the scheme worked and who was involved. Romero's full deposition has not been made publicly available, but portions were included in the recently released indictment.

The indictment alleges that Côrtes and other conspirators would prepare technical requirements in public tenders that would favor companies that participated in the scheme. It also contains allegations about distributor Oscar Iskin & CIA Ltda. (Oscar Iskin) and an "international bidding club" that favored foreign companies that paid kickbacks to win public tenders.

The kickbacks were funded by having the foreign companies include line-item tax charges on invoices as part of the importation and customs declaration process for medical devices, despite the fact that the public entities purchasing the products, INTO and the State Health Secretary, are exempt from paying such taxes. The public entities would approve and pay the invoices with the inflated amounts that included taxes, and the cartel would use the excess funds to execute the kickbacks.

The indictment named the following entities (some of which were controlled by Oscar Iskin's president, Miguel Iskin) as participants in the cartel: Rizzi, M.D. Internacional, AKA Trade, INDUMED, Per Prima, Comercial Médica, DBS3 Comercial Científica, Drager, Helo Med, Maquet, New Service, Ultra Imagem, M&M Lopes, Stryker, Macromed, Multimedic, and Siemens.

In April 2017, Côrtes was arrested along with Miguel Iskin, based in part on the evidence and testimony provided by Romero. There are likely more arrests to come.

How Device and Other Life-Sciences Manufacturers Can Protect Their Interests in Brazil

In this increasingly difficult climate, multinational medical device and pharmaceutical companies that sell products indirectly through Brazilian distributors can do a number of things to protect themselves from third-party risks.

Monitor Brazilian News Reports

Companies should monitor ongoing Brazilian proceedings and be aware of whether any of their distributors or other third parties are named or implicated in any ongoing investigations. This is especially true with respect to Operation Exposed Invoice. Brazilian news outlets plan to continue exposing the details of some of the key testimony in that investigation in a piecemeal fashion. The reality is that many medical device and other global manufacturers are unwittingly employing and using the very distributors that are in the news and in the crosshairs of the Brazilian prosecutors.

As an example, a representative from Oscar Iskin was captured on undercover recordings offering HCPs 20% kickbacks in the *Fantástico* piece in January 2015. Further, Miguel Iskin was subpoenaed to testify in the legislative hearings around October 2015 following the exposé, but did not end up testifying after being granted several extensions by none other than Eduardo Cunha, the incarcerated former speaker of Brazil's lower chamber. Companies that actively monitor Brazilian news reports would be aware of this type of information and use it to inform decisions about particular distributors or other third parties moving forward.

Implement (or Refresh) a Crisis Response Plan

Companies should consider creating or refreshing crisis response plans that, among other things, allow them to quickly gather information and fashion uniform and consistent messaging in the event the company, or one of its distributors or third parties, is named as an investigation target. The time to crisis plan is before the crisis actually begins; the best crisis planning can be done in the "quiet," rather than in the midst of the storm of enforcement.

Due Diligence, Training and Certifications

Effective third-party due diligence is critical in Brazil where corporate relationships are intertwined and complicated.

Diligence efforts should focus specifically on whether the company's third parties own or operate affiliate companies. However, conducting diligence is not enough. Companies should have documentation of these efforts complete and readily accessible. The diligence file should demonstrate that there were reasonable efforts made to verify the nature of each third party's affiliated companies, including certifications from each distributor or third party that it doesn't own affiliated companies.

To the extent a company has not conducted meaningful diligence, it is in a company's best interest to require distributor and third-party training and obtain related certifications of understanding and compliance with anti-corruption laws and policies. It is also advisable to update due diligence, training, and certifications on a regular basis.

See "In-House Perspectives on Third-Party Due Diligence: Right-Sizing and Risk Ranking (Part One of Three)" (May 24, 2017); Part Two (June 7, 2017)."

Enforce Contractual Audit Rights

Companies with contractual audit rights may consider exercising those rights and conducting a privileged, on-site review and assessment of their distributors or other third parties in anticipation of potential Brazilian or U.S. government scrutiny. The breadth and scope of such audits would obviously depend on the nature of the relationship and should correspond to an appropriately tailored risk assessment.

If such an exercise is outsourced to professional firms, companies should solicit the assistance of practitioners that have experience conducting such reviews and have a solid understanding of both the U.S. regulatory expectations and the Brazilian market. Similarly, if a company uses internal resources to staff the audit, the team must be sufficiently familiar with U.S. regulation and the common bribery and kickback schemes in the Brazilian market. Companies with records, reports and remediation plans from properly executed distributor audits are well-positioned with U.S. regulators in the event of distributor misconduct.

See "When and How Should Companies Include Audit Rights in Third-Party Contracts? (Part One of Three)" (July 23, 2014); Part Two (Aug. 6, 2014); and Part Three (Aug. 20, 2014).

Oversight of Public Tenders

Companies should consider the amount of control they exert over distributor bids on public tenders associated with their products. There are several measures that companies can take to mitigate the risk of distributor misconduct in public bidding. Such measures and controls will likely depend on their unique sales structure and channels. A company should consider whether it has a defined process to manage distributor bids on public tenders for its products. It should ensure that there is a reasonable level of transparency in its distributor relationships. It is also advisable to have insight into matters like which tenders the distributors are bidding on, which tenders they have won and what the pricing and payment terms are for the awards.

See "Detecting and Mitigating Corruption Risk When Participating in Public Procurements: Understanding the Procurement Process (Part One of Three)" (May 13, 2015); Part Two (May 27, 2015); and Part Three

(June 10, 2015).

Monitor Distributor Pricing

Companies with more mature and effective compliance programs understand the value of controls that can prevent and detect unusual price discrepancies. In Brazil, improper distributor and third-party payments in the medical device space are most likely generated by excess funds created by discounts, rebates and other price concessions. Unlike the pharmaceutical industry, which has statutorily prescribed price ceilings, medical device prices can vary significantly and manufacturers often do not know the end user price or their distributor's margins.

Prior to implementing pricing-oversight enhancements, companies should consider conducting a privileged review and assessment of distributor pricing in anticipation of potential Brazilian or U.S. government scrutiny. A company should have controls in place to review and approve meaningful price concessions to distributors, such as discounts, rebates, commissions and chargebacks. Without an appropriate assessment, these areas may present the types of compliance gaps that can, and often do, lead to actual compliance breakdowns.

Gary Giampetruzzi is global vice chair of the investigations and white collar and life sciences departments and a partner in the litigation department at Paul Hastings in New York. Prior to joining Paul Hastings, Mr. Giampetruzzi most recently served as vice president, assistant general counsel and head of government investigations at Pfizer Inc, with responsibility for government investigations across the company's multiple business units and operations globally, and associated government litigation with U.S. and international prosecutor offices.

Jonathan Stevens is an associate in the litigation department at Paul Hastings in Washington, D.C., and former in-house counsel at Exactech, Inc., a multinational orthopedic device company.

Thiago Ribeiro is a foreign associate at Paul Hastings in Washington, D.C., and former in-house counsel at Odebrecht S.A., a global construction conglomerate based in Brazil.