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Time to Clean Up: As Operation Car Wash Progresses, Are Medical Device and Pharmaceutical Companies Out of Time with the Brazilian Anti-Corruption Authorities?

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For many business, compliance, and legal insiders within the life sciences sector, there has long been uneasiness around the relative 'quiet' from Brazilian anti-corruption authorities in the life sciences sector. Against that 'quiet,' Brazil continues to suffer from an unprecedented corruption scandal that has destabilized both its political and economic systems. 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.

As Operation Car Wash progressed, there was a sense that prosecutors would turn 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 a few weeks ago 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, 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. The indictment, which was unsealed and published this week, lists 20 distributors and manufacturers who allegedly participated in the cartel.

The question now becomes whether the medical device companies, and their cousins across the pharmaceutical industry, and other pockets of the life sciences sector, are out of time with the Brazilian anti-corruption authorities, who have the wind at their backs following highly-publicized settlements in connection with the multi-jurisdictional prosecutions of petroleum, construction, and infrastructure giants in excess of \$3.1B. Will the relative 'quiet' in the life sciences sector, that many have known and enjoyed for longer than could have reasonably been expected, now turn incredibly noisy for some?



Operation Car Wash

What started as an investigation into a money laundering and currency exchange ring, run out of the Posto de Torre gas station in 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\$6B in bribes to public officials. Aberto Youssef (the central black market money dealer and launderer in Operation Car Wash), one of his key clients Paulo Roberto Costa (the former Petrobras executive in charge of procurement for its refining division), and executives from construction companies have provided detailed testimony that will be used to prosecute the increasing number of public officials involved.

The Brazilian Supreme Court, which retains constitutional jurisdiction to prosecute criminal actions against high-ranking federal officials, recently released what is being referred to as “Fachin’s List” (in reference of Justice Edson Fachin, who is in charge of the case in the Supreme Court) which named 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 includes 201 new cases under investigation that will not be filed with the Supreme Court, but in lower courts of competent jurisdiction.

As Operation Car Wash was initially focused on Petrobras and construction companies, much of the public focus has not surprisingly been on kickbacks and bribes associated with large public energy and infrastructure contracts. However, as judges and investigators begin to probe further into the corrupt payment streams and financial dealings of these public officials, it is more likely than not that they will uncover kickbacks and bribes tied to public health contracts under Brazil’s Unified Health System (“SUS”), the largest public health system in the world. Indeed, medical device and pharmaceutical manufacturers can look no further than some of the distributors and other third parties with whom they do business, and who are in the news for alleged corruption offences, to see what the future may hold.

Operation Mr. Hyde

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

Following the legislative 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 Câmara de Regulação do Mercado de Medicamentos (“CMED”) agency oversees pharmaceutical drug pricing. 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.

Several investigations similar to Operation Mr. Hyde are underway in a handful of states, where suppliers to both private and public hospitals have allegedly required kickbacks ranging from 10% to 20% in so called “marketing fees” to sell at those hospitals. The lead prosecutor from one organized crime unit that oversaw Operation Mr. Hyde publically signaled that this is just the “tip of the iceberg.” Public audits have revealed that many public hospitals and publically 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.

Within the last few months, the fallout from Operation Mr. Hyde has spilled across Brazil’s borders. In December 2016, ABRAMGE, an association of 177 private health insurance companies and medical providers in Brazil, in an unprecedented maneuver, sued several prominent, global medical device manufacturers in U.S. federal court charging that the companies paid millions in kickbacks to Brazilian doctors so they would use their medical products—regardless of the need or cost of the products.

Operation Exposed Invoice

On the heels of Operation Mr. Hyde and the public scrutiny around kickbacks in the medical device industry, in April 2017, the Operation Car Wash Task Force in Rio de Janeiro brought criminal charges against a number of individuals involved in a massive organized crime ring that centered around the former Governor of the State of Rio de Janeiro, Sergio Cabral. The Operation Car Wash Task Force, which is overseeing Operação Fatura Exposta (“Operation Exposed Invoice”), used information gathered in previous investigations Operação Calicute (“Operation Calcutta”) and Operação Eficiência (“Operation Efficiency”) which looked into corruption in the 2007-10 and 2011-14 governments of Mr. Cabral. Those investigations led to his arrest in November 2016 for allegedly receiving more than R\$100M in bribes and illicit payments related to public works and construction contracts.

According to federal prosecutors, Mr. Cabral designed the kickback scheme when he named Sergio Côrtes as Secretary of Health for Rio de Janeiro in 2007. The scheme, which is currently being exposed by Mr. Côrtes’ former Deputy Secretary, César Romero, included 10% kickbacks to Mr. Cabral, Mr. Côrtes, and other public officials in national and international bids for medical devices purchased by the Instituto de Traumatologia-Ortopedia (“INTO”) and the State Secretary of Health. Apparently, Mr. Cabral would retain 5%, Mr. Côrtes would retain 2%, and the remaining 3% would be disbursed amongst the other participants in the form of monthly stipends, international trips, and other in-kind transfers. Investigators estimate that between 2007 and 2017, the scheme reached in excess of R\$300M.



As part of his plea agreement, Mr. Romero provided prosecutors detailed testimony and evidence during his deposition on how the scheme worked and who was involved, portions of which were included in the recently released indictment. The indictment alleges that Mr. Côrtes and other conspirators would prepare technical requirements in public tenders that would favor companies that participated in the scheme. Miguel Iskin, president of medical device distributor Oscar Iskin & CIA Ltda., organized a cartel of 20 foreign companies, referred to as “the international bidding club,” that pre-selected the winners of certain public tenders. Foreign companies were apparently favored because, as part of the importation and customs declaration process for medical devices, the foreign companies were directed to include line item tax charges on invoices, 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 Mr. 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, Mr. Cortes was arrested along with Mr. Iskin, based in part on the evidence and testimony provided by Mr. Romero. There is a possibility that there are more arrests to come.

What Device and Other Life Sciences Manufacturers Can Do to Protect Their Interests in Brazil

Although not their only area of meaningful compliance and enforcement risk, multi-national 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 in this increasingly difficult climate:

- **Monitor Brazilian News Reports:** Companies would be mindful to monitor ongoing Brazilian proceedings and have a high degree of awareness of whether any of their distributors or other third parties are named or implicated in any of the ongoing investigations. This is especially true with respect to Operation Exposed Invoice, as Brazilian news outlets plan to continue exposing the details of Mr. Romero’s testimony in a piecemeal fashion. It may or may not be surprising, but 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.
- **Implement (or Refresh) a Crisis Response Plan:** Companies may further consider creating or refreshing crises 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 a target. Is your company actively monitoring public media reports in Brazil, and is it adequately prepared to respond to negative media or other inquiries? The time to crisis plan is before the crisis actually begins, as the best crisis planning can be done in the context of the ‘quiet,’ rather than in the midst of the storm of enforcement.
- **Diligence, Training, and Certifications:** To the extent a company has not conducted meaningful diligence, required distributor and third-party training, or obtained related certifications, it would certainly be in their best interest to do so. Companies that have done so may consider either refreshing such diligence, training, and certifications or ensuring that



such documentation is sufficiently documented and accessible. Has your company conducted thorough diligence on its Brazilian third parties, and is the documentation complete and readily accessible?

- **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. In the event that such an exercise is outsourced to professional firms, it is advisable that companies solicit the assistance of practitioners that have experience conducting such reviews, and have a solid understanding of both the U.S. regulatory expectations and Brazilian market. Does your company have contractual audit rights with Brazilian third parties, and has it exercised those rights to gain an understanding of how your third parties operate on your behalf? Are you sufficiently familiar with the common bribery and kickback schemes in the Brazilian market?
- **Involvement in Public Tenders:** Companies should consider the level of involvement or oversight that they exert over distributor bids on public tenders associated with their products. There are a number of measures that companies can take to mitigate the risk of distributor misconduct in public bidding. However, such measures and controls will likely depend on their unique sales structure and channels. Does your company have a defined process to manage distributor bids on public tenders for your products? Is there a reasonable level of transparency and does your company have insight into matters like which tenders they are bidding on, which tenders they have won, and what the pricing and payment terms are for the awards?
- **Monitoring and Auditing Distributor Pricing:** Companies with more mature and effective compliance programs understand the value of controls that can prevent and detect unusual price discrepancies. Prior to implementing such enhancements, companies may consider conducting a privileged review and assessment of distributor pricing in anticipation of potential Brazilian or U.S. government scrutiny. Does your company have controls in place to review and approve meaningful price concessions to distributors, such as discount, rebates, commissions, chargebacks, etc.? Without an appropriate assessment, these areas may present the types of compliance gaps that can, and often do, lead to actual compliance breakdowns.

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